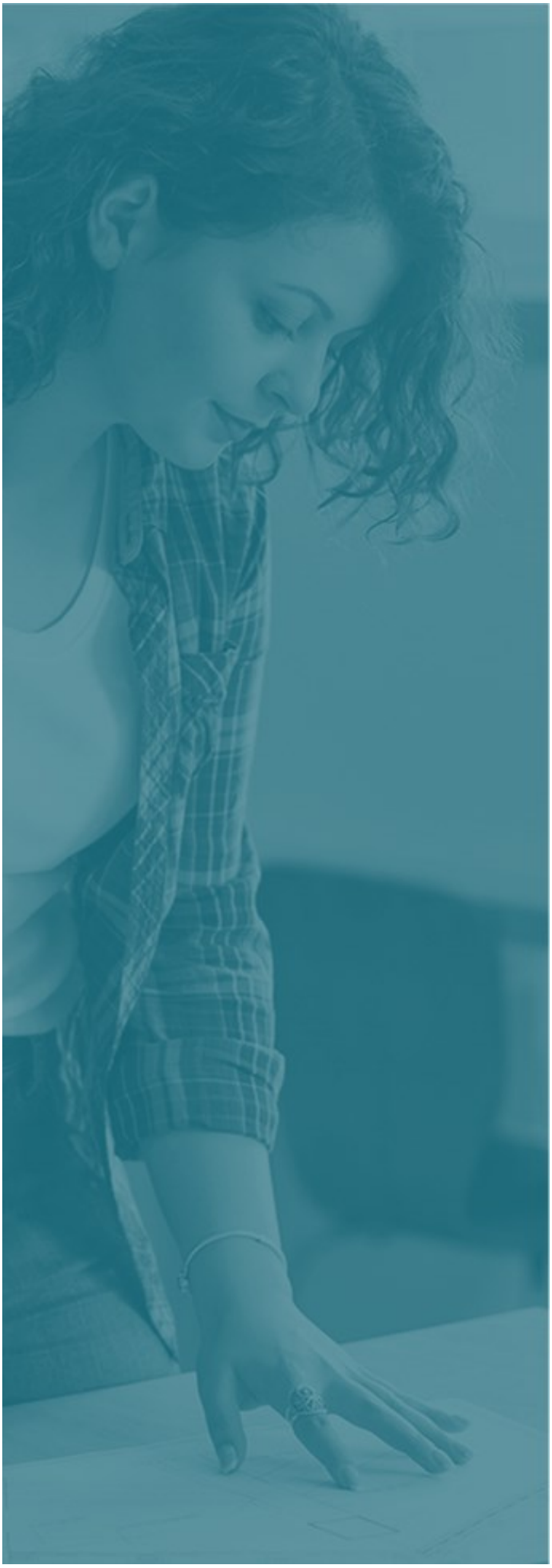
PRODUCT LIFECYCLE MANAGEMENT STRATEGY MANUAL

Realizado durante la pasantía empresarial para la etapa 1 y 2 del proyecto de maestría
ESTRATEGIA DE GESTIÓN DEL CICLO DE VIDA DEL PRODUCTO ORIENTADO A LA DEFINICIÓN DEL PROCESO DE DISEÑO PARA LA MANUFACTURA ADITIVA:
Caso estudio Dispositivos médicos PSI.

Universidad Industrial de Santander



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INTRODUCTION

The company is a company that specialized in the research, design, development, production, and sale of bone fixation systems, including non-active implantable and short-term m invasive medical devices. Since its inception in 2018, the company has been consolidating by manufacturing products of excellent quality and competitive prices. We produce bone fixation systems, patient-specific reconstruction by 3D printed surgical guides, and anatomical models. These products are manufactured with biocompatible materials certified to international standards and traceability is maintained wherever necessary. TDS commercialized the first product through this quality management system in late March 2021.

- **Historical Background:** Is a spin-off from its sister company Industrias Médicas Sampedro S.A.S from Colombia. TDS was established in 2018 with a manufacturing lab and an office space at the Embry-Riddle Aeronautical University's research park 'MICAPLEX' in Daytona Beach, Florida.

- **Purpose:** We aim to provide every surgical patient, with pathologies in the osteomuscular system, access to the best personalized surgical care using technology to augment the capacities of the surgical teams.

- **Structure of company's integrated management system:** The company designs, develops, research, manufactures, and commercializes medical-surgical solutions for the musculoskeletal system and the treatment of high complexity pathologies in a personalized way, or specifically adapted to any pattern of medical practice. Additionally, we focus on achieving a high level of customer satisfaction and environmental care. Likewise, we recognize the importance of human talent. Therefore, the top management and the process owners are committed to providing technical, human, and economic resources to develop a healthy and safe workplace with the continual improvement of labor conditions, identifying, and managing the risks, preventing accidents and occupational illnesses, raising protection to their partners, contractors, and visitors in all the processes of the company. We promote and maintain partners' physical and social welfare and other stakeholders by providing safe and adequate work sites. To comply with the company's purpose, we are committed to implementing and maintaining the efficacy of the Quality Management System by fostering its continual improvement.

In this management manual, we are going to identify the organizational and operational structure of the company from start to finish during the entire process of design and development of medical devices to have greater control of the operation of the company.

0. DIAGNOSIS OF THE PRODUCT LIFECYCLE MANAGEMENT

We find a map of the organized structure whose objective is to demonstrate the degree of responsibilities and levels of command of the staff, this map shows that the highest level of responsibility of the company remains in the CEO and the coordinator.
The operation of the company depends on the hierarchical level structured under the domain of the CEO, who oversees directing six roles to maintain balance. However, it has been shown that the project design engineer, project engineer, and regulatory analyst, together with the growth coordinator, carry out their activities independently, which could demonstrate a high workload.

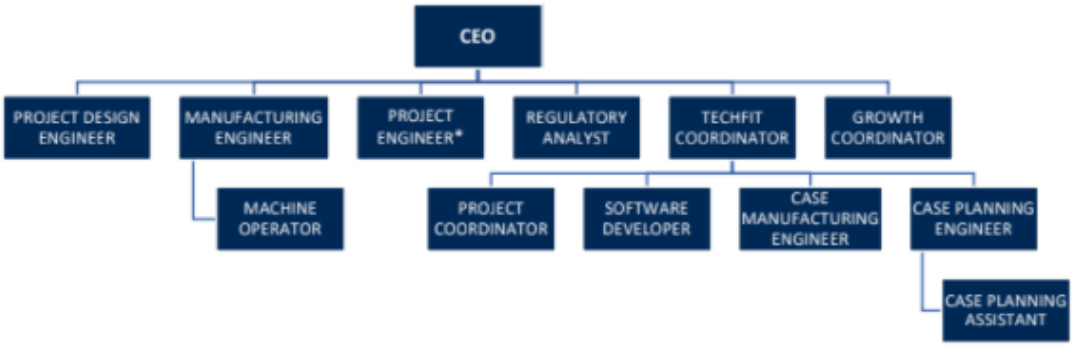

Figure 1. Organized structure by Company DS

The current results of the relationship between roles were evaluated from the Network Analysis, this analysis establishes the relationships within a visualization network and its exchange mechanisms through intervals. For this, the ONODO tool created by the Civio Foundation in collaboration with Eurecat was used. It establishes a series of metrics to determine the importance of each role in the network. (Onodo).

• **Cluster:** Assigns the nodes in the blocks or clusters by the number of relationships they have, establishing the number of groups with which a role is related.

• **Betweenness:** Calculates how many times a node is on the shortest path between two nodes.

• **Degree:** Calculates the number of relationships of each node, that is, the number of roles with which it is related.

• **Cloness:** Calculates the proximity of a node from the rest or how many steps it takes to reach the rest of the nodes.

• **Relevance:** Calculates the relevance of each node based on the number of connections and the relevance of the nodes to which it is contextualized.

• **Coreness:** Measures in which layer of the network a node is. The layer with the highest K is the core of the network. Layer K forms nodes with at least k connections each between them.

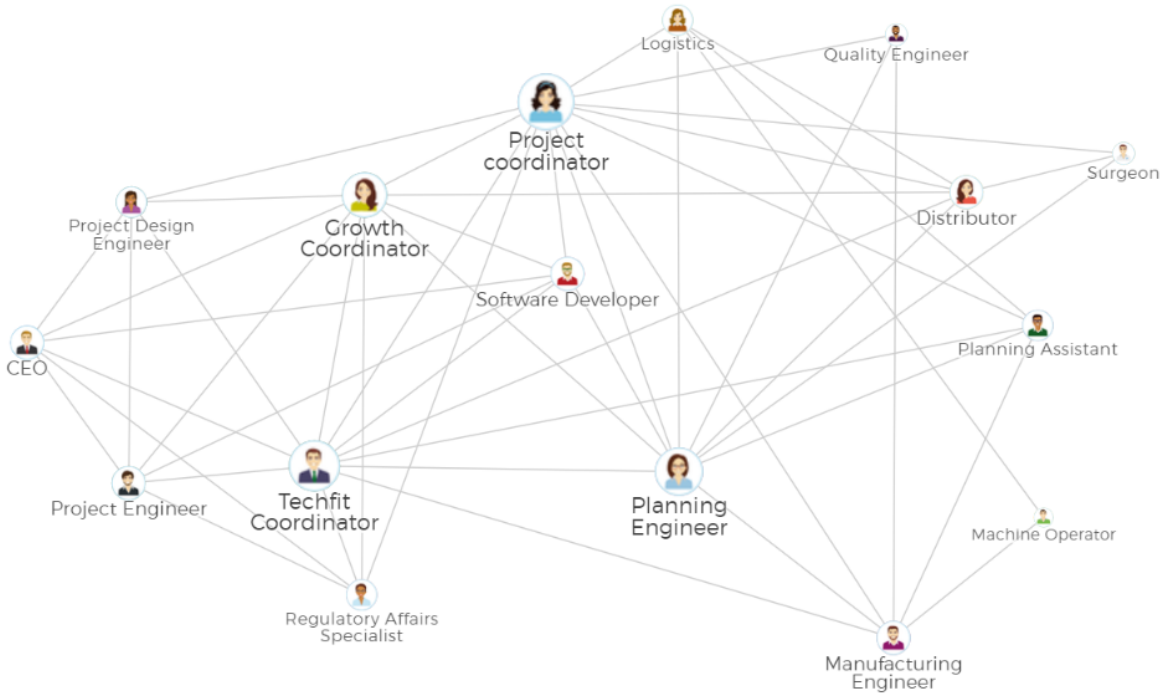

Figure 2 Actual Network Analysis

Table 1. Actual network analysis results.

NODE	TYPE	Cluster	Degree	Relevance	Betweenness	Clones	Corenes
Company coordinator	Manager	1.00	11.00	1.00	17.19	0.79	5.00
Project coordinator	Designers	2.00	12.00	0.99	24.59	0.83	5.00
Growth coordinator	Manager	1.00	9.00	0.87	5.84	0.68	5.00
Planning engineer	Designers	2.00	10.00	0.86	12.11	0.75	4.00
Software developer	Designers	1.00	6.00	0.67	2.27	0.60	5.00
Distributor	Customer	2.00	6.00	0.61	2.71	0.63	4.00
CEO	Manager	1.00	6.00	0.58	0.60	0.54	5.00
Project engineer	Manager	1.00	6.00	0.58	0.60	0.54	5.00
Project design engineer	Manager	1.00	5.00	0.55	1.00	0.58	5.00
Regulatory affairs specialist	Designers	1.00	5.00	0.55	1.00	0.58	5.00
Manufacturing engineer	Designers	2.00	6.00	0.52	9.22	0.63	4.00

Planning assistant	Designers	2.00	5.00	0.52	0.68	0.60	4.00
Logistics	Key role	2.00	5.00	0.43	4,92	0.56	4.00
Quality engineer	Key role	2.00	3.00	0.34	0.00	0.50	3.00
Surgeon	Customer	2.00	3.00	0.33	0.00	0.52	3.00
Machine operator	Key role	2.00	2.00	0.13	0.25	0.43	2.00

In the network analysis, we observed an overload on the Company coordinator, project coordinator, growth coordinator, and planning engineer roles where their relevance (1 to 0.86), and a degree from (12 to 9), while the role of the software developer has 6 degrees. Also, the roles of project coordinator, Company coordinator, and planning engineer present a higher value of betweenness with the other roles.

The growth coordinator, Company coordinator, project coordinator, and planning engineers are four important pillar roles to keep the balance of the company as significant as, without a doubt, Company is. Therefore, the fact that shortcomings of work overload are occurring in the roles only leads us to the option of looking for an alternative; find a solution.

This is a problem that requires an immediate response. Having a history with personnel who have decided to leave is a sign of the above. For this reason, a new distribution in the Hierarchy of roles is proposed, whose purpose is to improve the comfort of the staff and the work environment.

Diagnosis PLM

Before starting to design the strategy, it was necessary to diagnose the current state of PLM management within the company. To do this, we use the Turin Polytechnic maturity self-diagnosis instrument carried out by DIGEP (Department of engineering management and production, 2011), designed for companies dedicated to the design and production of products, analyzing strategic variables of business management, management of the product, project management and integration collaboration (J. Martinez, 2011).

Each variable included questions related to information management in a process area, each question had 4 levels or response options: A, B, C, and D, with A (1 point) being the lowest level of information management. information, and D (4 points) the highest. In the end, all the points obtained from a total of 19 questions were added up. According to the results obtained, a total of 57 points was reached, which places the company at a high management level with some opportunities for improvement. Below is a summary of the results, each ring from the center out is equal to 1, 2, 3, and 4 points.

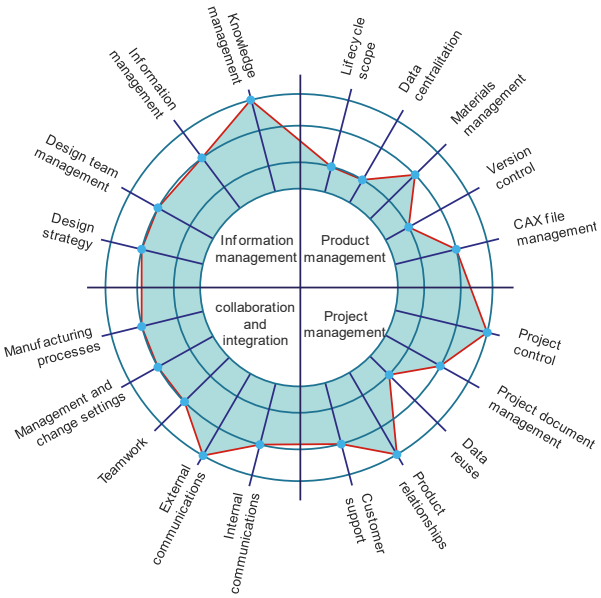

Figure 3 Diagnosis PLM in company.

1. PLM STAGES

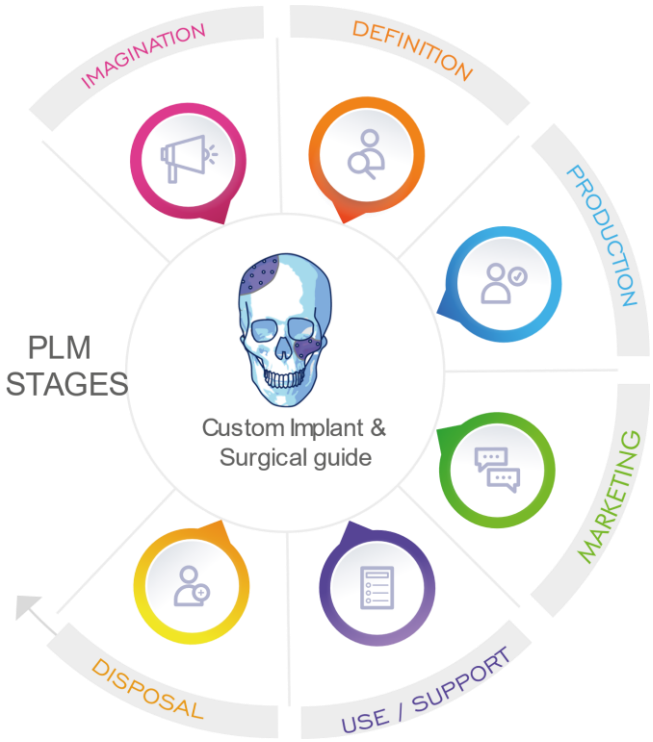

Figure 4 PLM stages.

Description of PLM stages

Imagination: It begins with the service request and pre-planning for the formal development of the design proposal. The imagination process includes the validation of the files to start the surgical planning process and the generation of a preliminary cost proposal.

Definition: The service proposal is conceptualized from a design idea, the personalized design of the proposal, and the detailed review for manufacturing approval.

Production: The pieces and parts are manufactured and machined to create the product in its final form to be used by the specialist or implanted in the patient.

Marketing: It refers to the process of selling, marketing, and distributing the product.

Use / Support: It involves data support for the product after being used in surgery, post-surgical follow-up of implantable parts, and feedback on the use of surgical devices.

Disposal: The final disposal of the part is controlled. It specifies the disposal method or if it is going to be recycled.

2. PROCESS AREAS

It refers to the set of sequential activities that are related during the PLM stages. The company has an organizational grouping that allows the product life cycle to be followed sequentially, those areas may or may not be interrupted during the life cycle (see Figure 2). Those general process areas were specified in the Quality Manual document and brought for identification below:

Table 2. Objectives for process area.

PROCESS	OBJECTIVE
Strategic direction	Plan, organize, address, and control the different activities that improve the processes and allow for the systematic achievement of the company's objectives. Assure compliance with Company's strategic plan through the administration of the Quality Management System, process surveillance, and resource allocation. Deliver high-quality products, comply with applicable standards, generate customer satisfaction, and continuously improve the quality management system.
Human resource	Assure the availability of competent staff required by the company to achieve long and short-term objectives, and provide employees with training, motivation, and adhesion to company values.
Logistics	Plan and manage the resources and supplies that are necessary for the products that are manufactured in Company. Maintain internal and external customers and suppliers. Ensure the appropriate inventory is maintained and the product is delivered to the customer promptly.
Production	Ensure that the company is delivering products to the customer with proper quality, on time, and at the proper cost.
Research & development	Enable company growth by developing process needs into feasible products. Generate and provide a complete Medical Device File to create quality patient-specific devices complying with the applicable regulatory requirements. Responsible for evidence of product performance (Premarket analysis, the medical device developed according to intended use).
Finance	Have required cash to operate projects and ensure that the financial reports are up to date and available to the stakeholders. Plan for future needs and create budgets that reflect those needs.
Growth	Design, implement and verify marketing strategies that assure the brand and the company positioning as well as the profitable increase of sales by ensuring service and customer satisfaction. Develop and maintain a sales plan to achieve tangible results and comply with the service promise.

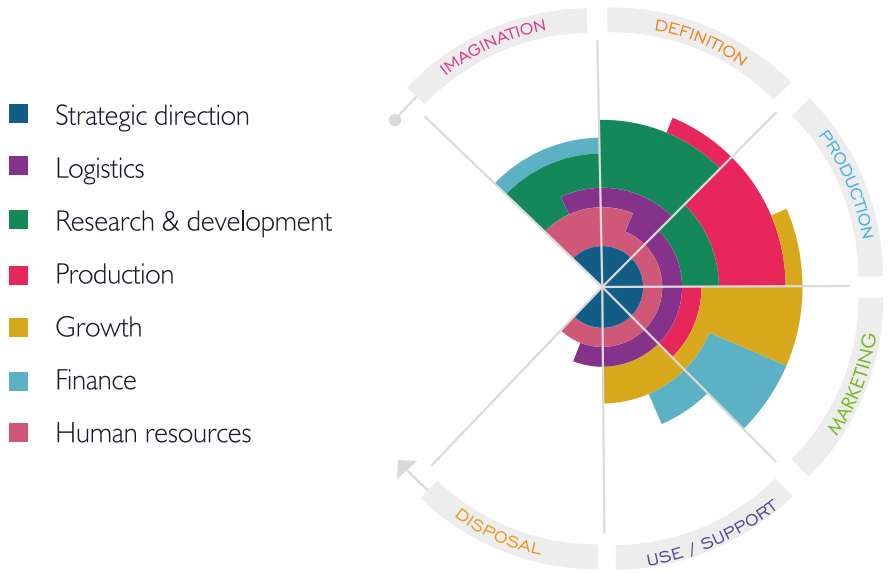

Figure 5 Visualization diagram of the process areas.

Sub-process areas

Each process area has different responsibilities, it influences the specific functioning in Company processes, those are identified according to the responsibility and importance it has regarding each stage of the process through the life cycle from beginning to the end.

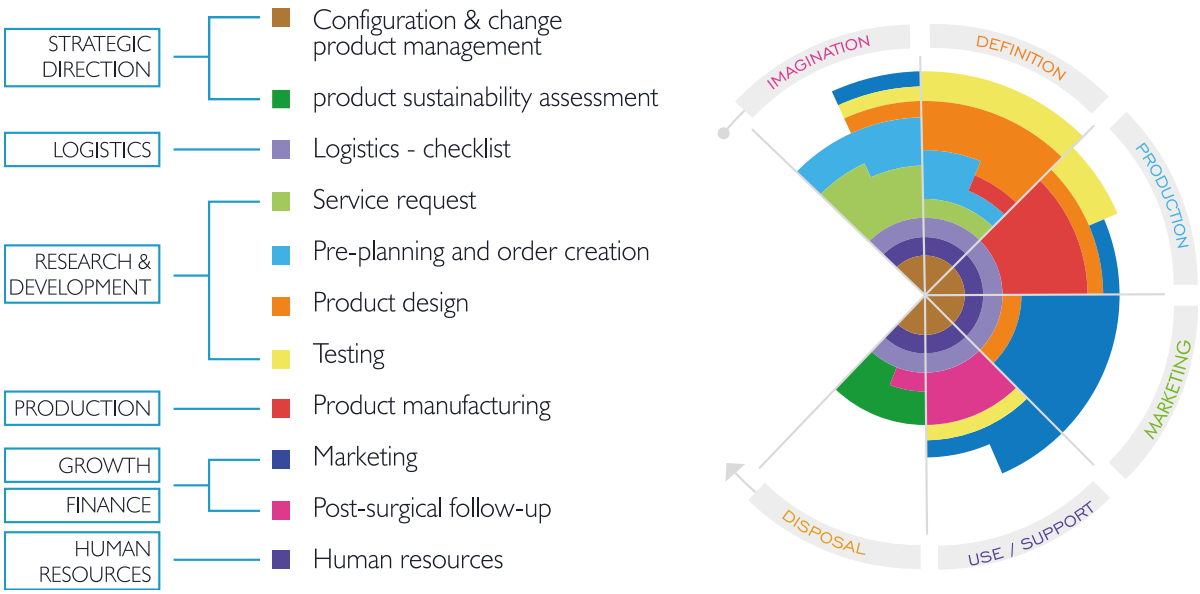

Figure 6 Visualization diagram of the subprocess areas.

The seven process areas concentrate eleven sub-processes, they are involved as shown in figure 3 and described in table 2.

Table 3. Objectives for subprocess areas.

PROCESS	SUB-PROCESS	OBJECTIVE
Strategic direction	Configuration & change production management	It is the heart of PLM. Identifies product configuration items, controls and audits their change, and maintains their integrity by ensuring they are not conflicted by previous updates, limited notifications, or multiple versions.
	Product sustainability assessment	Evaluate the associated environmental impact in all stages of the product life cycle, supplies, consumption, and final disposal of the product.
Human resources	Human resources	Manages all personnel planning throughout the product life cycle, assigning roles to the processes per case, staffing, technical supplies, labor, internal complaints, and claims.
Logistics	Logistics - Checklist	Manages products focusing on risk management, process planning, tracking, progress monitoring, product checking, shipping, and delivery.
Production	Product manufacturing	It is the production of the medical device, using labor, machines, tools, and processing of the raw material in implantable devices or for use during surgical procedures according to the needs of the client.
Research & development	Service request	It stipulates the initial requirements for the approval of a service request, reviews and translates the client's needs to define them as variables, also it is responsible to identifies possible inconsistencies in the request.
	Preplanning and order creation	performs the initial preparation of anatomical structures and image transformation processes through reverse engineering methods, organization, the orientation of cases, and creation of service orders
	Product design	Transform the requirements and design restrictions into a product that obeys the expectations of the end-user. Detailed definition, components, materials, assembly, manufacturing process, and the final presentation.
	Testing	Ensures that the products satisfy the requirements, product evaluation, and quality analysis for the approval and give continuity of the process.
Growth / Finance	Marketing	It is responsible for the organization, communication, commercial management, and delivery of the final product to the client. It manages commercial relations, financial growth, and the creation of the business model and product value.
	Post-surgical follow-up	It is responsible for the final follow-up of each case once the Company solution has been used by the client. The final evaluation of the product is carried out immediately and after the time stipulated by the company to know the state of evolution and acceptance of the medical devices used.

3. ROLES

Important roles that are part of Company are involved in the medical device development process. To identify these roles, it was necessary to follow up the entire global process from start to finish, then these roles were classified into five groups: Leaders (CEO), Managers (directors and coordinators), Consultants (Leaders of projects and process), Key roles (engineers, distributors, assistants, and operators) Customer (Surgeons).

Organizational structure

It should be noted that two new roles are suggested that collaborate with the general process of the company. The Account executive would be responsible for direct communications with the distributors, and the Clinical leader is responsible for the technical contribution, and the follow-up to the designers. Below we describe the map of the proposed organizational structure.

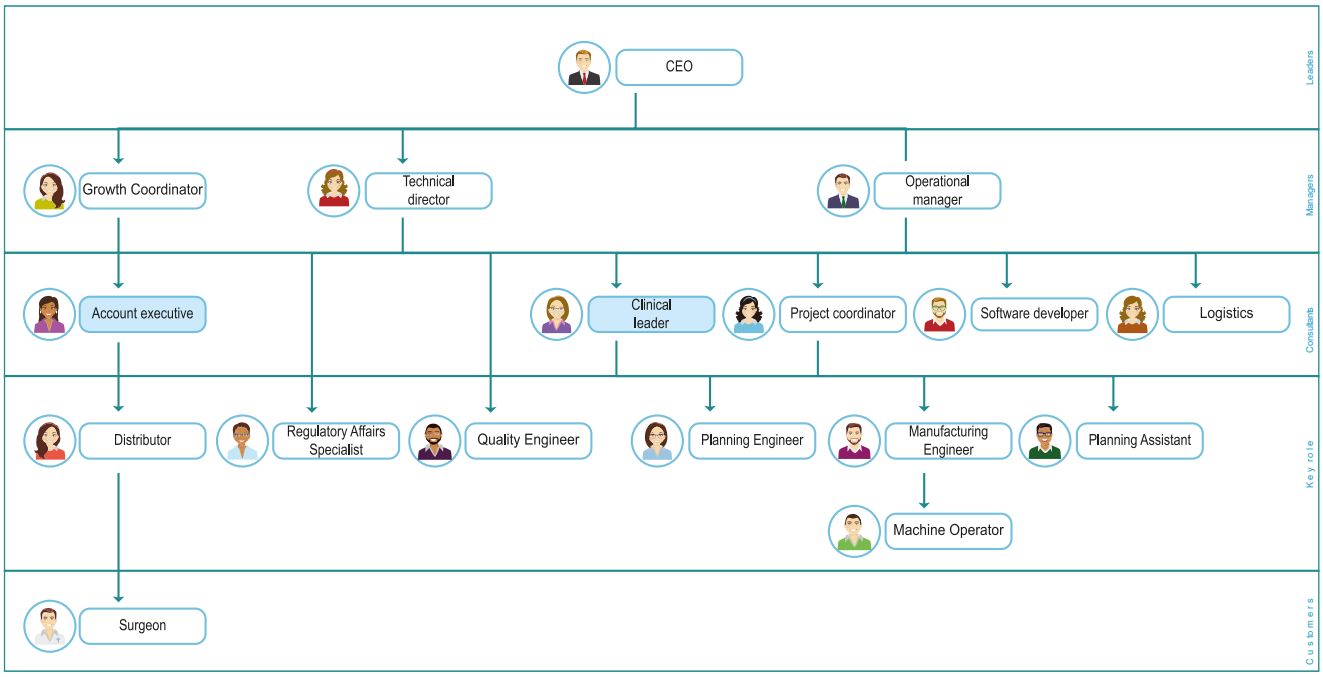

Figure 7 Proposed role hierarchy

The CEO is the leader of the company, he assigns responsibilities and goals to the growth coordinator, technical director, and operational manager who distribute these goals in activities. From left to right, the growth coordinator is responsible for the growth of the company. He will direct the account executive, who will have direct contact with the distributors, and the latter is the one who receives the information from the surgeons.

At the center is the Technical Director, responsible for auditing and monitoring compliance with the FDA and ISO standards required by the company. He directs the regulatory affairs specialist who must be up to date on the standards and their control and the quality engineer who audits that the final product complies with the manufacturing dimensions and reviews the raw material.

On the right is the operational manager who distributes the different activities and goals to the clinical leader and project coordinator for the development of cases. These two roles are responsible for identifying the requirements of the case and assigning them to the planning engineer available or who has the skills of said case. The manufacturing engineer builds the manufacturing code and sends it to the machine operator for the manufacturing of the implantable part. The planning assistant collaborates in the alternate activities of the development of the cases. However, the software developer is also responsible for designing and building the software algorithms that optimize the times of the entire design process. Finally, logistics is responsible for the distribution of the product to the end-user and is also responsible for the purchase of raw materials and their storage.

Connection map

An organization of relationships is proposed to improve the work environment and workload, this proposal reduces the number of connections from 12 to 8 at most, and redistribution the relevance of the roles.

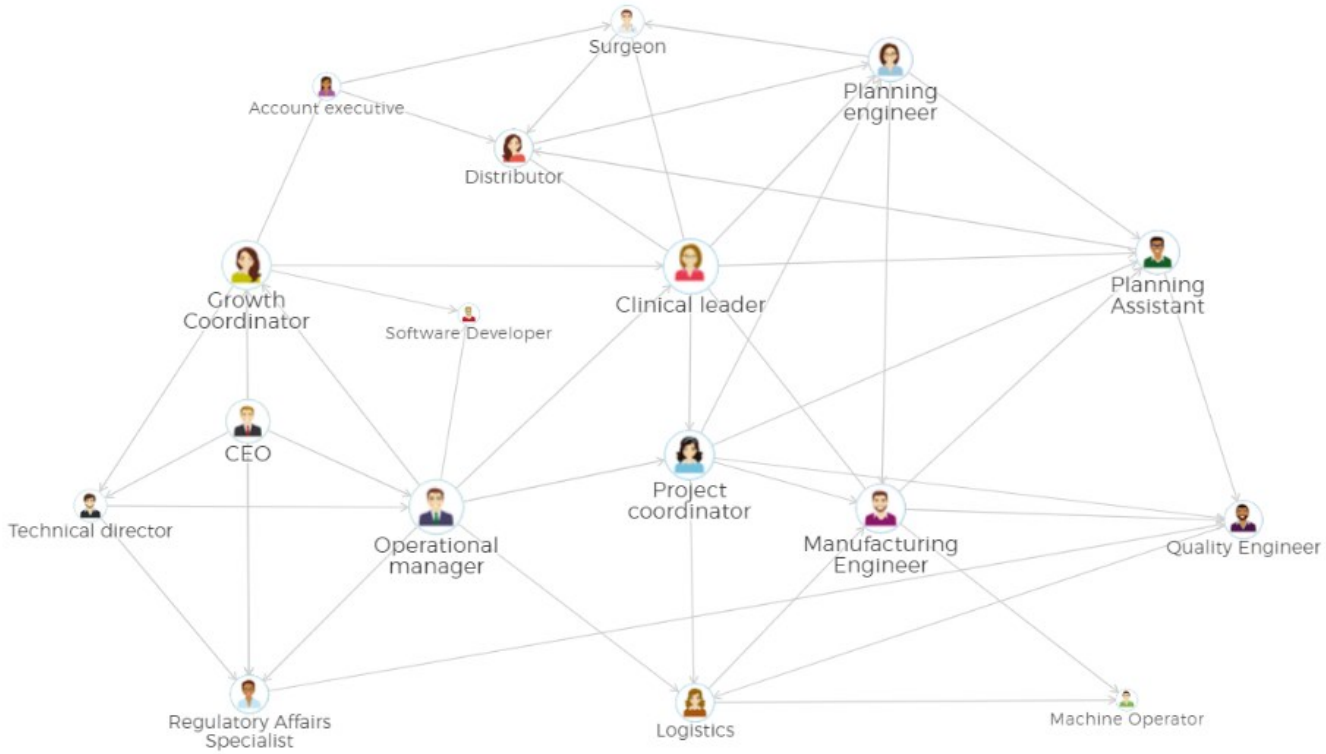

Figure 8 New relationships map proposed

Once we have completed the relationship map, the results are analyzed to find out the level of relevance and the number of connections between them. For this, the ONODO tool was used, described in section 0. This result you can see below.

Table 4. New network analysis results.

NODE	TYPE	Cluster	Degree	Relevance	Betweenness	Clones	Corenes
Clinical leader	Consultants	2.00	8.00	1.00	24.39	0.67	4.00
Project coordinator	Consultants	3.00	7.00	0.94	7.63	0.62	4.00
Manufacturing engineer	Key role	3.00	7.00	0.85	10.75	0.55	4.00
Operational manager	Managers	1.00	8.00	0.83	27.06	0.67	4.00
Planning assistant	Key role	2.00	6.00	0.81	4.84	0.55	4.00
Planning engineer	Key role	2.00	6.00	0.79	4.82	0.53	4.00
Growth coordinator	Managers	1.00	7.00	0.65	19.44	0.62	4.00
Quality engineer	Key role	3.00	5.00	0.63	5.78	0.53	4.00
Logistics	Consultants	3.00	5.00	0.59	7.88	0.53	4.00
Distributor	Key role	2.00	5.00	0.57	4.17	0.48	3.00
Regulatory affairs specialist	Key role	1.00	5.00	0.51	5.23	0.52	4.00
CEO	Leader	1.00	4.00	0.49	0.00	0.47	4.00
Surgeon	Customer	1.00	4.00	0.45	1.74	0.46	3.00
Technical director	Manager	1.00	4.00	0.42	0.00	0.47	4.00
Account executive	Consultants	2.00	3.00	0.28	3.58	0.46	3.00
Software developer	Consultants	1.00	2.00	0.25	0.00	0.43	2.00
Machine operator	Key role	3.00	2.00	0.25	0.00	0.41	2.00

The results of this new iteration of relationships between the roles allowed us to see the relevant need between them during the general process of the company. Therefore, a reduction of the previous 12 to 8 connections between roles was evidenced with this proposal.

The roles that present greater importance due to their connections and relationships, from greater to lesser, are the clinical leader, project coordinator, manufacturing engineer, and operational manager. Those have the greatest responsibility in terms of control and stability in the development processes of medical devices.

4. ROLE DESCRIPTION AND WORKFLOW

ROLE DESCRIPTION

The following graphs will present the different roles accompanied by their activities and documents. In addition, to achieve a clearer concept and understand each of these roles on a large scale, the tables will explain in detail all their activities and the steps that each of the roles develops.

First, we will find the role of a surgeon with its 5 activities, second will be the distributor role with its respective activities, then the planning assistant with 4 activities. The role of planning engineer is divided into levels due to their experience and skills acquired between Junior, with 7 activities, staff with an additional activity, and senior planning engineer with 2 additional activities.

Following them, we will find the manufacturing engineer role with 4 activities, the machine operator with 3 activities the project coordinator role with 6 activities, and the clinical leader with 7 activities. Ninth will be the software developer with 7 activities, then the logistics role with 5 activities, next to the quality engineer with 5 activities, and the regulatory affairs specialist role with 4 activities.

Next to them, is the technical director with 6 activities, the account executive with 5 activities, then the growth coordinator role with 5 activities, then there is the operational manager role with 5 activities, and finally the CEO role with 3 activities.

WORKFLOW

To read the workflows we must take into account the following specifications:

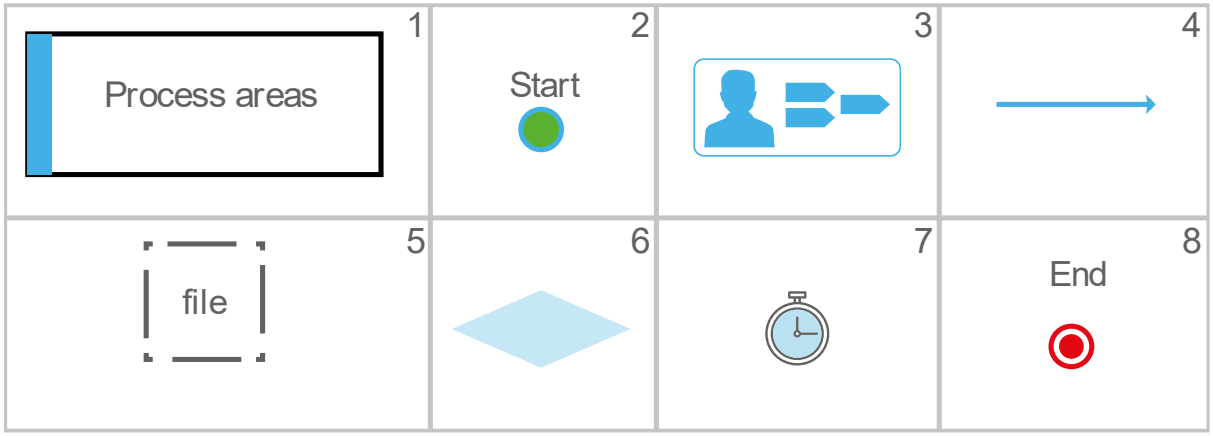

Figure 9 Workflow icons

1. The right bar shows the process areas that involve each role with their respective activities.
2. The green circle means the beginning of its activities.

3. The rectangle with the image of the role corresponds to the activities.
4. Must be read in order of flow arrows.
5. The boxes with dotted lines refer to the documents that are required to carry out the activity in question, if you do not have these documents that activity cannot be carried out.
6. The diamonds are yes or no decision questions.
7. Clocks correspond to waits that can be long and depend on other roles.
8. The red circle means the end of your activities.

Each workflow corresponds to each role showing its activities within the process areas in a linear sequence. The roles are described starting first with the surgeon, second the distributor, then the planning assistant, fourth the Designer based on 3D printing and then based on subtractive manufacturing, fifth the manufacturing engineer, followed by the machine operator, and the project coordinator, eighth the clinical leader, ninth the software developer, followed by the logistics, eleventh the Quality engineer, then the regulatory affairs specialist, a thirteenth the Technical director, continuing with the account executive, fifteenth the growth coordinator, then the operational manager and finally the CEO.

1. Surgery
2. Distributor
3. Planning assistant
4. Planning engineer
5. Manufacturing engineer
6. Machine operator
7. Project coordinator
8. Clinical leader
9. Software developer
10. Logistics
11. Quality engineer
12. Regulatory affairs
13. Technical director
14. Account executive
15. Growth coordinator
16. Operational manager
17. CEO

4.1. Surgeon role

Table 5. The role description surgeon's role

The role description surgeon's role

is responsible for the preoperative diagnosis of the patient, for operating, and for providing the patient with postoperative surgical care and treatment.
The surgeon is also looked upon as the leader of the surgical team. During an operation, the surgeon must make important decisions about the patient's health, safety, and welfare. Furthermore, the surgeon must work to ensure cooperation among the other surgical team members, which typically includes another surgeon or qualified person who acts as the surgeon's assistant, the anesthesiologist, and the operating room nurse.

Does not apply.

Does not apply.

Does not apply.

Does not apply.

Tools:

- Medical Imaging Software.
- DISRP.
- Microsoft office suite.

Methods:

- Image QC diagnosis.
- Medicine practices.
- Diagnosis of patients.
- Surgical practices.

Skills:

You must know about the surgical correction of any process that requires the repair or replacement of structures that affect the shape and function of the body. You must know in-depth about: Criteria and parameters of proportionality, Body harmony, Soft and bone tissues, Surgical and treatment skills, Cognitive skills, and the ability to solve congenital, tumor, acquired, or involutional problems.

Contact me for:

- DICOM image
- Design approval for manufacturing
- Cases requirement
- Diagnosis of patients
- Dental plasters

Decomposition diagram of surgeon role

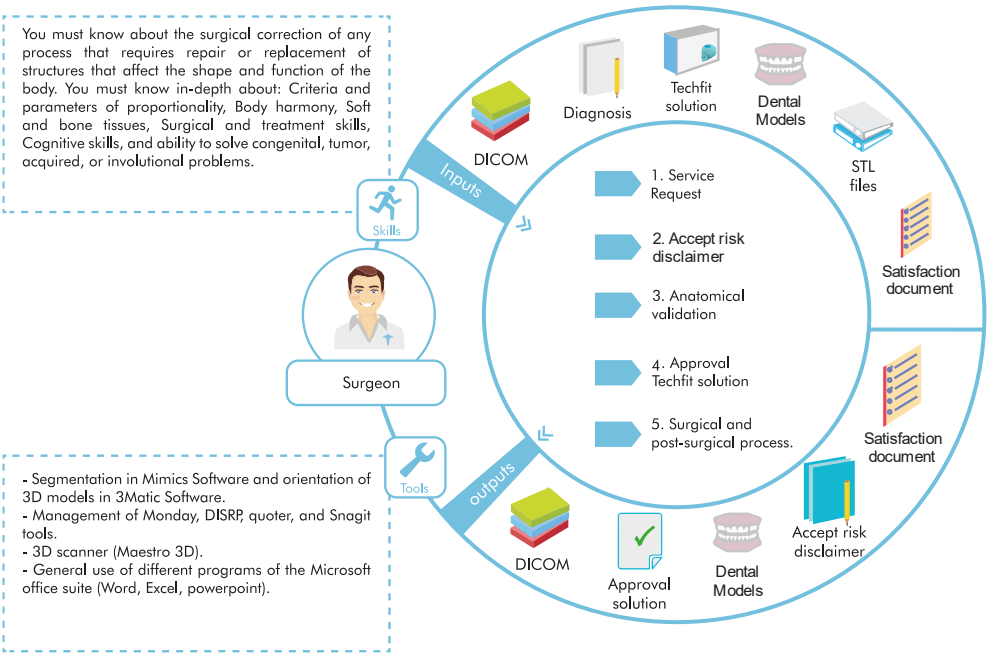

Figure 10 Surgeon role

Table 6. Activity 1 for the surgeon's role

ACTIVITY 1: SURGEON Service request	
This activity aims to carry out the initial process of the case, the identification of the potential case, request for the proposal, and agreement with the distributor to establish the specifications of the case.	
Steps	**S1. Create the request:** Identifies the potential case from the diagnosis generated to the patient and makes the service request to the Company team on the DISRP platform. **S2. Meeting with the distributor:** Case types and possible design requirements are discussed with the distributor. **S3. Select the type of service:** Choose the package of products desired for the intervention and treatment of the patient. **S4. Upload dates:** Depending on the type of service, specific data is required provided by the surgeon, among these are CT images, dental plasters, etc.
Items	**INPUTS** ✓ DICOM images (1) ✓ Diagnosis (2) ✓ Dental models (3) **OUTPUT** ✓ DICOM images (1) ✓ Dental models (3)

Table 7. Activity 2 for the surgeon's role

ACTIVITY 2: SURGEON Accept risk disclaimer	
This activity aims to review for approval or disapproval of the DICOM images used by Company.	
Steps	**S1. Review the concept by Company:** Review the concept by Company about the protocol satisfy in DISRP **S2. Accept Risk disclaimer:** If the DICOM images are not available, you must decide to accept or not the risk disclaimer to continue the process. The result is your responsibility.
	INPUTS / **OUTPUT**
Items	✓ Accept risk disclaimer (4)

Table 8. Activity 3 for the surgeon's role

ACTIVITY 3: SURGEON Anatomical validation	
The purpose of this activity is to carry out all the validations of the Company solution, this process can be done virtually, in person, or on the DISRP platform, this activity is done in the company of the distributor and the planning engineer assigned to the case.	
Steps	**S1. Meeting with the Planning engineer:** The meeting with the Planning engineer to carry out the surgical pre-planning of the case, the anatomical movements, and formal estimation of the medical device. **S2. Meeting for validation:** Once the planning engineer designs the 3D model of the Company solution proposal, a meeting or digital agreement to validate the proposal.
	INPUTS / **OUTPUT**
Items	✓ STL files (5)

Table 9. Activity 4 for the surgeon's role

ACTIVITY 4: SURGEON Approval Company solution	
This activity aims to carry out the approval or disapproval of the design proposals to give continuity to the manufacturing and delivery process. This Company solution cannot continue its lifecycle without the doctor's authorization.	
Steps	**S1. Review the Company solution:** Enter the Platform DISRP to review the Company solution. **S2. Approval or disapproval:** Approval of the Company solution or disapproval of the Company solution
	INPUTS / **OUTPUT**
Items	✓ STL files (5) / ✓ Approval Company solution (6)

Table 10. Activity 5 for the surgeon's role

ACTIVITY 5: SURGEON Surgical and post-surgical process	
This activity aims to use the medical devices made by Company during the surgery and subsequently fill out the satisfaction surveys.	
Steps	**S1. Surgical process:** Perform the surgical procedure using Company solutions. **S2. Fill out the immediate survey:** Once the surgical procedure is finished, the immediate satisfaction survey must be filled out and delivered to the distributor to know the perception of the Company solution. **S3. Fill out the post-surgical survey:** 4 weeks after the surgical procedure, the distributor will facilitate the satisfaction survey to know the clinical evolution of the patient according to the medical devices used and/or implanted
	INPUTS / **OUTPUT**
Items	✓ Company solution (99) ✓ Document satisfaction (99) / ✓ Document Satisfaction (7)

Workflow Surgeon role

To start, the surgeon must request service with the required documents; DICOM, diagnosis, and dental models. Now, if the CT scan satisfies the Company protocol, the next step will be to wait for the design process. However, if he does not comply with said protocol, he must take the CT again or fill out the required risk acceptance to continue with the process. Then, you will have an anatomical validation and the approval of the request given by the company to proceed to be manufactured.

Then you will be able to claim the product that contains the following documents: Company solution and satisfy document. Finally, the surgeon with the complete documentation will be able to carry out the surgical process and fill out the satisfaction document during the post-surgical process.

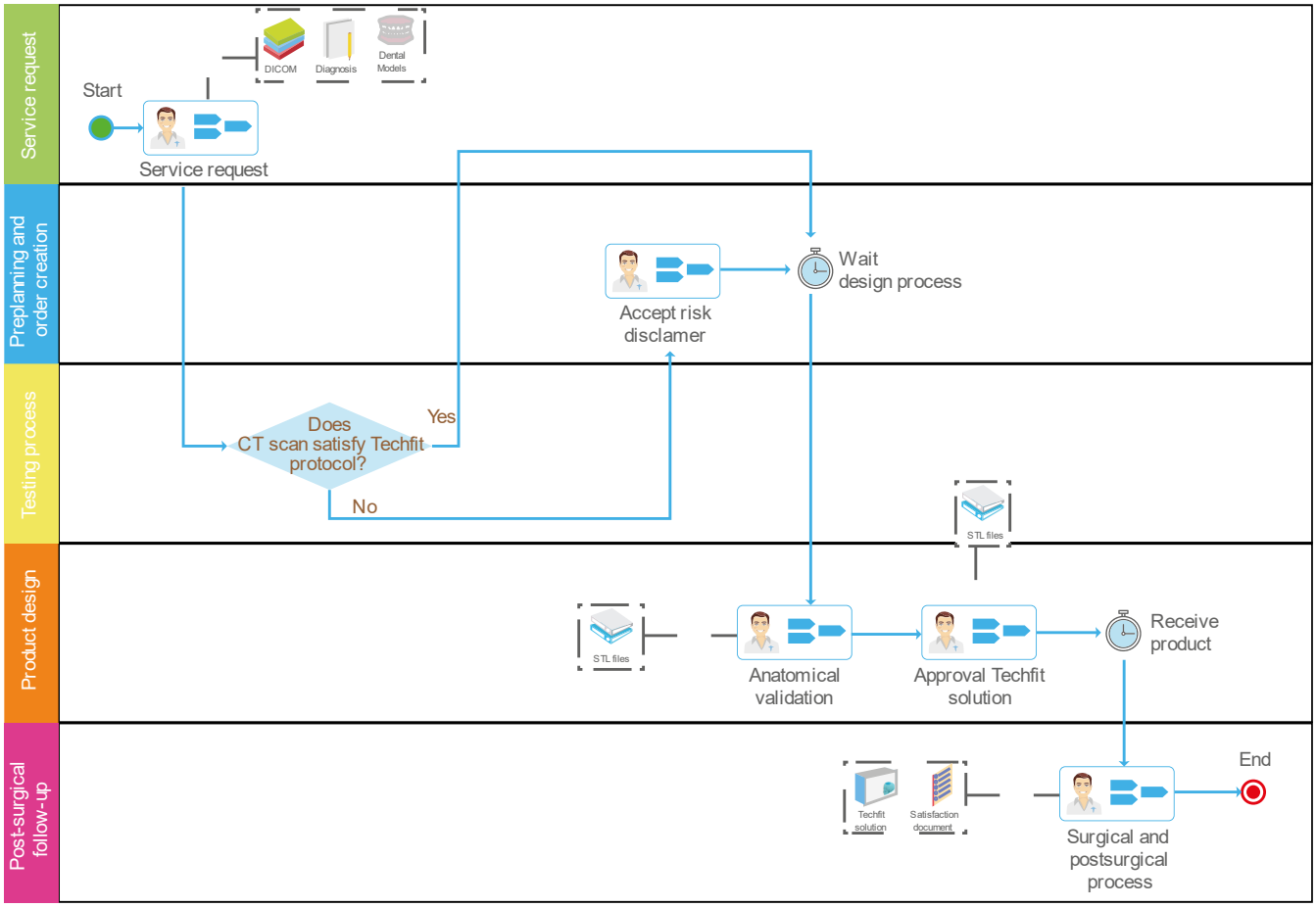

Figure 11 Workflow surgeon role

4.2. Distributor role

The role description of a distributor role

Are responsible for being the intermediary between the company and the customer, preparing the orders, the final invoice for the customer, and discussing the promotions with the growth coordinator. You are the direct voice with the client for the commercialization of the product, you must worry that the Company solution arrives on time for surgery.
Participates in the surgical procedure by supporting and guiding the use of Company solutions, supporting the product concerning the client, and receiving the PCC or QPR.

Does not apply.

Does not apply.

Does not apply.

Does not apply.

Tools:

- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Surgical instrumentation.
- Sales strategies.
- Translate requirements.
- Design troubleshooting techniques.

Skills:

Must know about communication and social skills, skills in support of surgical instrumentation, and maintain direct customer contact. Business decision-making. You are proactive, have good communication, and have adequate time management to develop different assigned activities.

Contact me for:

- Invoices
- Sales order
- Customers contact
- DICOM image
- Planning minute
- Dental plasters

Table 11. The role description of a distributor role

Decomposition diagram of a distributor role

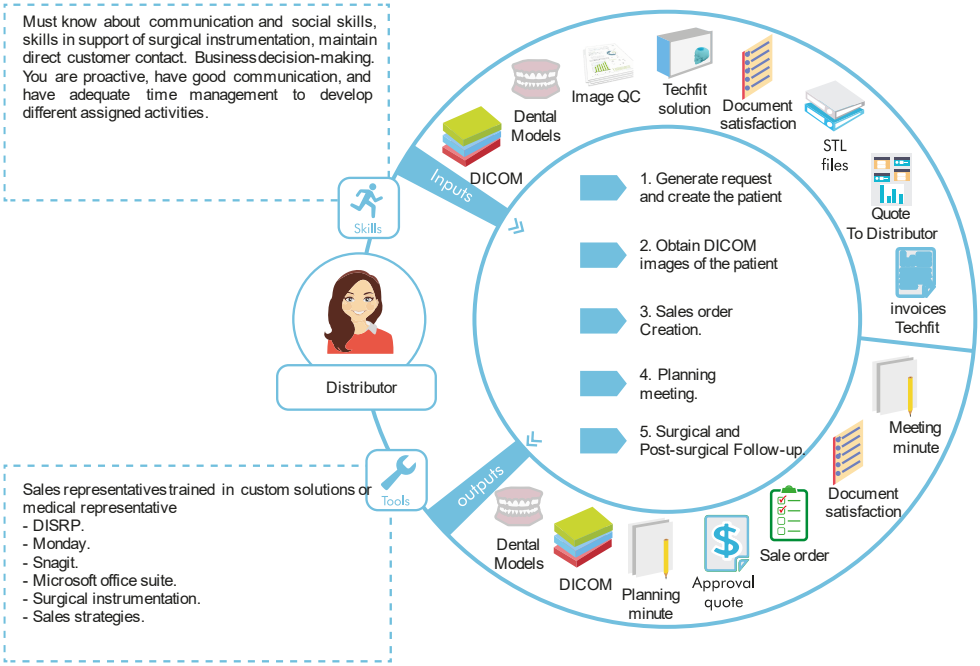

Figure 12 Distributor role

Table 12. Activity 1 for the distributor's role

ACTIVITY 1: Distributor Generate request

The purpose of this activity is to create the service request according to the specifications of the surgeon's requirements, with these requirements the Company staff can evaluate the feasibility of using files and generate the service proposal. Finally, to create the patient in DISRP, compile the DICOM images with the dental models.

Steps

S1. Meeting with the surgeon: A meeting with the surgeon is scheduled to identify potential cases that require a Company solution and the available service packages are shown.

S2. Fill out details of the solution: Fill out the planning minute to create the request.

S3. Generate request: Validate the information and upload the request to DISRP to start the Company process. once it is uploaded to the system, it remains a draft.

	INPUTS	OUTPUT
Items	✓ DICOM images (1) ✓ Dental models (3)	✓ DICOM images (1) ✓ Dental models (3) ✓ Planning minute (7)

Table 13 Activity 2 for the distributor's role

ACTIVITY 2: Distributor
Obtain DICOM images of the patient

This activity aims to obtain the CT or MRI scan of the patient and send it to Company to start the pre-planning and planning process.

Steps

S1. Review the DICOM images: Check that DICOM images exist to upload them to the DISRP server.

S2. Obtain the DICOM images: If there are no DICOM images, it is important to request these taken with the protocol established by Company.

S3. Fill out details of the solution: Fill out the planning minute to create the request.

S4. Send the DICOM images: Upload the DICOM images in DISRP with the planning minute.

	INPUTS	OUTPUT
Items	✓ DICOM images (1)	✓ DICOM images (1) ✓ Dental models (3) ✓ Planning minute (7)

Table 14 Activity 3 for the distributor's role

ACTIVITY 3: Distributor
Sales order creation

This activity aims to create the cost for the sale of medical devices that will be performed by Company staff.

S1. Analyze the quote to the distributor: When the quote to the distributor document is received, it is analyzed and from it, then the quote for the surgeon is created.

Steps	**S2. Send quote and potentially negotiate:** Upload the quote to the surgeon document in DISRP and wait for it to be accepted by the customer, once the quote is accepted the service can be passed on to the prospectus.

	INPUTS	OUTPUT
Items	✓ Image QC (8) ✓ Quote to the distributor (9) ✓ Invoices Company (99)	✓ Sale order (10)

Table 15 Activity 4 for the distributor's role

ACTIVITY 4: Distributor Planning meeting

The purpose of this activity is to monitor all the meetings held for the pre-planning and design planning of the cases, each meeting must have a support called meeting minute that is filled out by the distributor and delivered to the planning engineer.

Steps	**S1. Support meeting of pre-planning process:** The meeting is organized with the planning engineer to carry out the surgical pre-planning, the anatomical movements, and formal estimation of the medical device. **S2. Support meeting of anatomical models:** Once the 3D model of the Company solution proposal is designed, the meeting is organized with the planning engineer to validate the proposal. **S3. Upload meeting minutes:** Once the meetings are over, the meeting minute document must be uploaded to the DISRP platform as supports the information.

	INPUTS	OUTPUT
Items	✓ STL files (6)	✓ Meeting minute

Table 16 Activity 5 for the distributor's role

ACTIVITY 5: Distributor Surgical and post-surgical follow-up

This activity aims to follow up on the cases during the surgical and post-surgical procedures to provide the final feedback.

S1. Support surgical process: You must accompany the procedure and advise the use of medical devices during surgery.

Steps	**S2. Immediate survey:** fill out the immediate satisfaction survey with the surgeon to consider in the post-surgical follow-up. **S3. Fill out the post-surgical survey:** 4 weeks after the surgical procedure, the distributor will facilitate the satisfaction survey to know the patient's clinical evolution according to the medical devices used and/or implanted.

	INPUTS	OUTPUT
Items	✓ Company solution (99) ✓ Document satisfaction by the surgeon (7)	✓ Document satisfaction- final (12)

Workflow distributor role

Once the surgeon requests the service, the distributor generates the request and creates the patient in DISRP, for this, the DICOM must be uploaded. If CT scans or MRIs are not available, you will need to get them from your surgeon and upload them to DISRP to assess if the CT satisfies company protocol. If they do not comply with the Company protocol, they must wait for risk acceptance or request new CT scans, but if the result is positive, they make the sale offer taking into account the quote given by Company, if this offer is approved by the surgeon, they will continue to wait for the design process, but if it is not approved, the case is dismissed and finished.

Finally, the distributor will accompany the planning meetings and once the product is received, he will participate in the surgical procedure and will provide post-surgical follow-up.

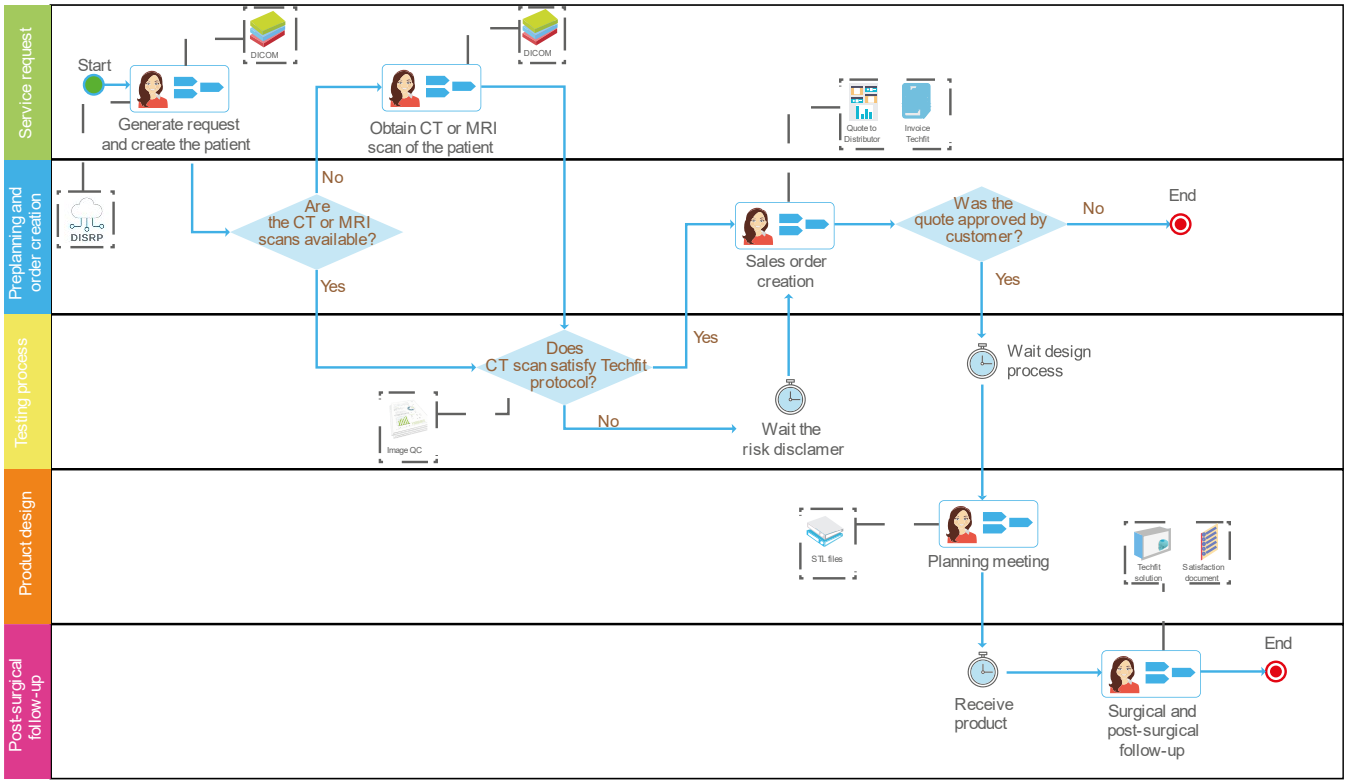

Figure 13 Workflow distributor role

4.3. Planning assistant role

Table 17. The role description of the planning assistant role

Decomposition diagram of planning assistant role

The role description of the planning assistant role

Provides operational support to the Company Coordinator and Planning Engineer, and support to the manufacturing process and release of cases, follow-up, and monitoring in 3D manufacturing and cases developed in Company.
Performs office and administrative assistance functions aimed at facilitating the development and execution of activities in the performance area during the design and manufacturing processes.

Last Name, Name

Medellín, Colombia

@Company.com.co

+57 (300 000 0000)

Tools:

- Mimics Software.
- 3-Matic Software.
- Maestro 3D.
- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Image QC diagnosis.
- 3D segmentation (Reverse Engineer).
- Mesh analysis.
- 3D orientation.

Skills:

You have extensive knowledge in DICOM image segmentation and 3D mesh reconstruction. You are proactive, have good communication, and have adequate time management to develop different assigned activities.

Contact me for:

- Image QC.
- Mimics file.
- Bio model STL.
- Quote preliminary.
- Manufacturing requirements.

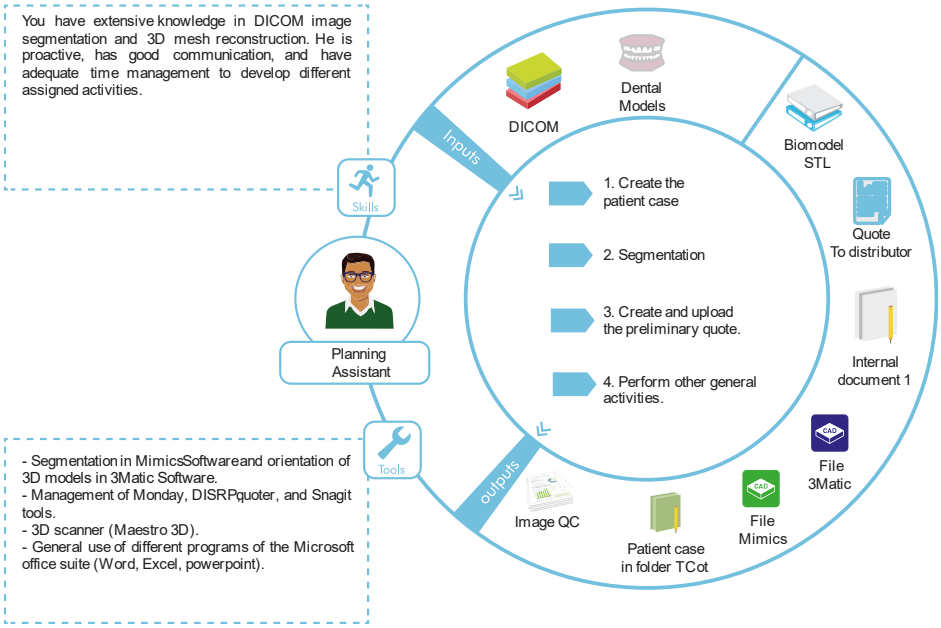

Figure 14 Planning assistant role

Table 18 Activity 1 for the planning assistant role

ACTIVITY 1: Planning assistant Download and segmentation

This activity aims to download the DICOM images from DISRP and perform the segmentation process to start the design process of the case.

Steps	**S1: Download DICOM images:** Download DICOM images from DISRP to the segmentation. **S2: 3D Scan Dental Models:** For cases that require good quality dental models for subsequent activities, the dental models sent by the surgeon should be scanned and saved in the case folder (Follow WI 3D Scan Dental Models). **S3: Segmentation:** Perform segmentation of DICOM files in Mimics software, export STL bone, soft tissue, and dental models, and orient them in 3Matic software (Follow WI Image QC and segmentation).

	INPUTS	OUTPUT
Items	✓ DICOM images ✓ Dental models	✓ Mimics file ✓ Bio models STL

Table 19 Activity 2 for the planning assistant role

ACTIVITY 2: Planning assistant
Orientation and create the patient case in folder TCot

This activity aims to perform the orientation and the case dossier folder on the server.

Steps	**S1: Orientation:** Perform orientation of DICOM files in 3Matic software and compile the DICOM images with the dental models (Follow WI Pre-planning). **S2: Create the Patient case dossier folder:** When the DICOMs are satisfactory, they must be saved inside the case folder created in the Design/Biomodels/Tcot address and named with the Company code + the patient's initials (TDS-0000+ABCD).

	INPUTS	OUTPUT
Items	✓ Mimics file ✓ Bio models STL	✓ Patient case in folder TCot ✓ 3Matic file

Table 20 Activity 3 for the planning assistant role

ACTIVITY 3: Planning assistant
Check the CT scan satisfy the Company protocol

This activity aims to check the DICOM images to approve or disapprove the DICOM to continue the Company process.

Steps	**S1: DICOM satisfies Company Protocol:** Evaluate if the DICOM files satisfy the requirements described in the Company protocol and give their part of approval or disapproval to continue with the process (Follow WI Image QC and segmentation). **S2: Request new DICOM images:** If the DICOM images are not approved according to the protocol, new DICOM images must be requested to continue the Company process.

	INPUTS	OUTPUT
Items	✓ DICOM images	✓ Image QC

Table 21 Activity 4 for the planning assistant role

ACTIVITY 4: Planning assistant
Create and upload the preliminary quote

The purpose of this activity is to generate a preliminary quote of the case according to the Company quoter for the sale price to distributors.

Steps

S1: Create the Preliminary Quote: Open the Company quoter and fill in the items according to the type of case. Materials to be used, place of manufacture, and trade agreements (Follow User Manual V3 - Quoter).

S2: Upload the Preliminary Quote: Upload the value of the quote to DISRP and wait for the approval response from the distributor or surgeon (Follow User Manual V3 - Quoter).

	INPUTS	OUTPUT
Items	✓ Image QC ✓ Bio models STL	✓ Quote to distributor

Table 22 Activity 5 for the planning assistant role

ACTIVITY 5: Planning assistant
Perform other general activities

Within the activities of Company, it is important to accompany some activities during the processes of manufacturing and 3D printing of documents that are generated by the other roles of the company.

Steps

S1: Accompany the 3D Printing Process: The 3D printing machines must always be available to be used, therefore their completion is monitored, and the printed parts are taken to the tank for the removal of the support material.

S2: Assigned Activities by Company Coordinator: Additional activities may be assigned to perform depending on the volume of activities.

S3: Create Other Required Documentation: Sometimes the assistant must prepare the documents to send the manufactured parts for quality review (Fill in DE-IDI-153).

S4: Fill checklist: Complete the follow-up checklist for each case (internal document - part 1 checklist).

	INPUTS	OUTPUT
Items	✓ Bio model STL ✓ STL Manufacture	✓ Internal document – part 1

Workflow of planning assistant role

Through the DISRP software, the planning assistant downloads and segments the DICOM images. Then, it verifies that the tomography satisfies the Company protocol and performs the orientation of the tissues and the creation of the patient's case in the TCot folder. If the TCs comply with the protocol, you can upload and create the preliminary quote.

However, if it does not comply with the protocol, you must wait for risk acceptance. After this, you can create the preliminary quota and upload it to DISRP. Now, if the quote is approved by the client, it will wait for other general activities and finally carry them out, otherwise, it will no longer end with its contribution to the process.

The planning assistant may carry out other general activities if they are given by a superior. In such a case, I would move immediately to expect such activities and carry them out.

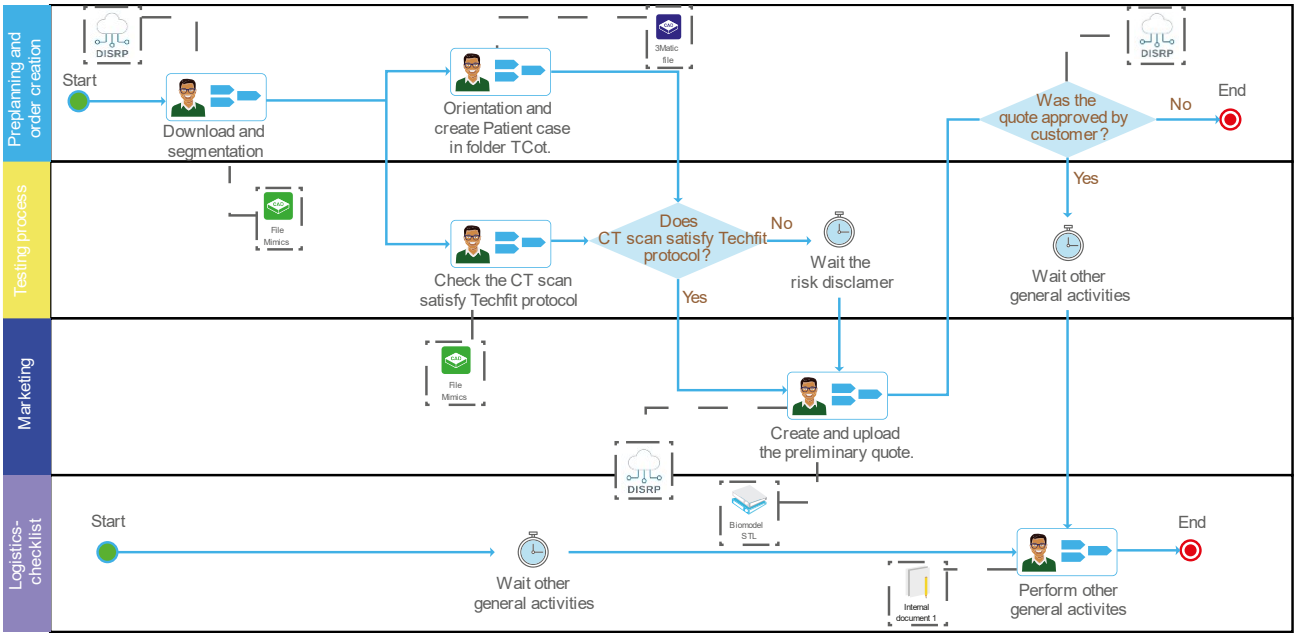

Figure 15 Workflow of planning assistant role

4.4. Planning engineer role

Table 23. The role description of the planning engineer role

The role description of the planning engineer role

Find out and plan the best and most efficient way to complete a project design from start to finish. Determine what materials and equipment will be needed for the conceptualization of the Company solution and estimate the amount of raw material required for its production.
Perform 3D modeling according to the requirements delivered by the specialist to generate the Company solution. Analyze data from prototype tests and prepare progress reports along with the final presentation of the solution.

Last Name, Name

Medellín, Colombia

@Company.com.co

+57 (300 000 0000)

Tools:

- Mimics Software.
- 3-Matic Software.
- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Design methods.
- Product design.
- Translate requirements.
- Design troubleshooting techniques.
- Emulation and simulation of 3D Models.

Skills:

You must have extensive biomedical knowledge, and creativity in medical device design. Computational, organizational, and 3D construction skills with strict attention to detail. Knowledge of manufacturing, teamwork, time management, and good communication with clients.

Contact me for:

- 3-Matic file.
- STL for manufacture.
- 3D printing models.
- STL models.
- DE-IDI-92.
- Final presentation of the case.
- State of 3D manufacturing.

Decomposition diagram of planning engineer junior role.

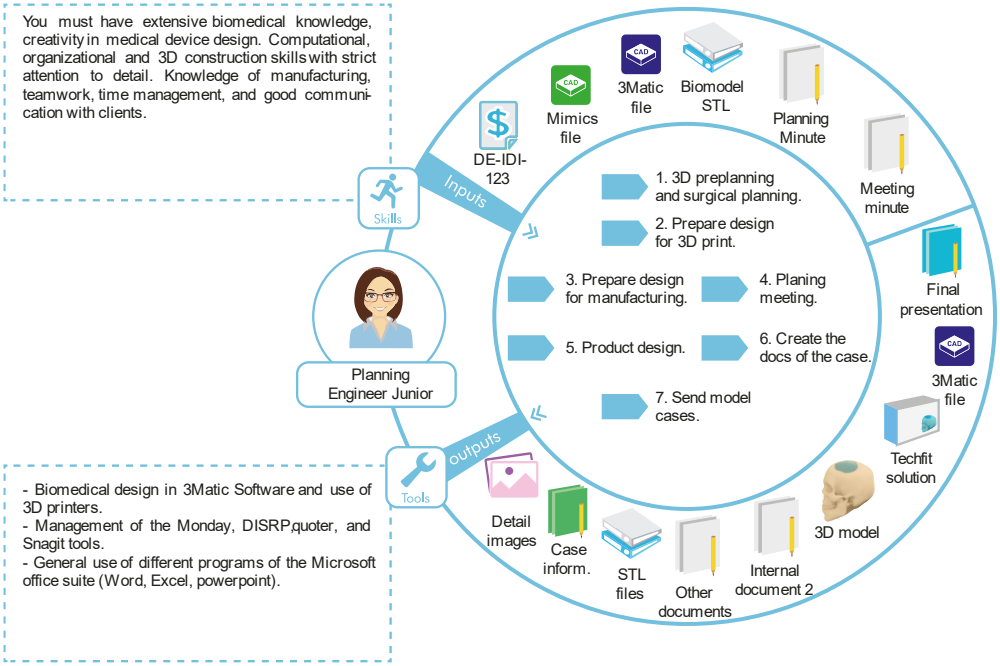

Figure 16 Planning engineer junior role

Table 24 Activity 1 for the planning engineer role

ACTIVITY 1: Planning engineer junior
3D preplanning and surgical planning

The purpose of this activity is the creation of the Company design proposal considering the requirements of the case. For this activity, you must start with the 3D planning and culminate with the detailed design of the Company proposal.

Steps

S1: 3D Planning: The bone cuts must be made; the reflection of the healthy part and the necessary measures must be taken according to the type of case for the planning meeting with the surgeon (follow WI preplanning to the cranium and maxillary cases).

S2: Detail segmentation: if the case needs a more detailed segmentation to decide the surgical plan during the planning meeting and remove noise

	INPUTS	OUTPUT
Items	✓ 3Matic file ✓ Mimics file ✓ Bio models STL ✓ Planning minute ✓ Internal document – part 1 ✓ Service request (DE-IDI-123)	✓ STL file ✓ 3Matic file ✓ Mimics file

Table 25 Activity 2 for the planning engineer role

ACTIVITY 2: Planning engineer junior
Preparing design for 3D print

The purpose of this activity is to generate the STL files according to the configuration and manufacturing location of the parts through 3D printing.

Steps	**S1: Preparing Design for 3Dprinting:** The marking of parts should be checked and there are no edges. For maxillary it is done by automatic orientation. In cutting guides, it is necessary to orient according to grooves so that there is no support material inside them, the cranioplasties must be inclined at 45° to preserve attachment, and part marking with the case code. Check the position of glossing on the object. *(RND-SD-13 3D printing work instruction).* **S2: Support the 3D printing process:** Verify that the parts have finished the 3D printing process and the machine is available. *(RND-SD-13 3D printing work instruction).*

	INPUTS	OUTPUT
Items	✓ STL files ✓ Bio models STL ✓ 3Matic file	✓ STL files ✓ 3D print model

Table 26 Activity 3 for the planning engineer role

ACTIVITY 3: Planning engineer junior
Preparing design for manufacturing

The purpose of this activity is to generate the STL files according to the configuration and manufacturing location of the parts through machining.

Steps	**S1: Preparing Design for manufacture:** Set up parts for the machining process considering part orientation, mesh revision, clamping points, drill guides, and contour revision. **S2: Fill out the case information document:** Fill out the case information document and sending to the manufacturing engineer. *(Case information for manufacturing).*

	INPUTS	OUTPUT
Items	✓ STL files ✓ Bio models STL ✓ Service request (DE-IDI-123)	✓ STL file. ✓ Case information for manufacturing. ✓ Detail images. ✓ Service request (DE-IDI-123)

Table 27 Activity 4 for the planning engineer role

ACTIVITY 4: Planning engineer junior
Planning meeting

The purpose of this activity is the planning meeting with the surgeon where you must coordinate all the design specifications and requirements with the surgeon.

Steps

S1: Coordinate the meeting with the distributor: You must receive the date from the distributor and organize the necessary documents for the meeting.

S2: Digital Surgery Planning: This step is done together with the specialist, the bone movements and/or the outline of the implant and measurements required for the 3D reconstruction are made, taking into account the surgical approach (Follow Planning Minute).

S3: Request the planning act from the distributor: Once the meeting is over, you must ask the distributor for the meeting minutes where you must find all the design specifications and consensus reached during the meeting.

	INPUTS	OUTPUT
Items	✓ STL files ✓ Bio models STL	✓ STL file

Table 28 Activity 5 for the planning engineer role

ACTIVITY 5: Planning engineer junior
Product design

The purpose of this activity is the creation of the Company design proposal considering the requirements of the case. For this activity, you must start with the 3D planning and culminate with the detailed design of the Company proposal.

Steps

S1: Design requirements analysis: The planning act and the bone movements that must be made are taken into account, and the medical devices for the Company solution are created. (Follow WI 3D Design).

S2: 3D Design Solutions Tailored: Carry out the design solution for parts that are used during surgery or implanted so that it can be validated by the check-up designer and the specialist (Follow WI 3D Design).

S3: Detailed Design: Once the Company proposal has been validated and approved by the specialist, the manufacturing specifications are designed, such as undercut review, part marking with the case code, and mesh error review (Follow WI 3D Design).

INPUTS	OUTPUT

Items	✓ 3Matic file ✓ Mimics file ✓ Bio models STL ✓ Planning minute ✓ Internal document – part 1	✓ STL file ✓ 3Matic file

Table 29 Activity 6 for the planning engineer role

ACTIVITY 6: Planning engineer junior
Create the documentation of the case

The purpose of this activity is the realization of the digital and physical documents that are part of the case. These documents are in the minute's folder

Steps

S1: Create the Final Presentation: Make the final presentation, this must include the Initial state, soft tissues, identification of the bone defect, existing plates removed, cutting guides, final resection, bone movements performed, relevant measurements, splints, Company proposal, initial vs. final state comparison, soft tissue simulation (Follow user manual presentation).

S2: Create the Implant Card: It is important to create the implant card for implantable parts, for this you must print 3 copies for Company=1, Distributor=2 (Fill the DE-IDI-92).

S3: Check sterilization document: Fill in before sending implantable parts (Fill in DE-IDI-150).

S4: Release document: You must print 3 copies to the quality engineer, the institution where the case arrives. 3 copies of the documents must be made (Fill out DE-IDI-153).

	INPUTS	OUTPUT
Items	✓ STL files ✓ Bio models STL ✓ 3Matic file	✓ Final presentation ✓ Implant card (DE-IDI-92) ✓ Sterilization doc (DE-IDI-150) ✓ Internal document – part 2 ✓ Release document (DE-IDI-153)

Table 30 Activity 7 for the planning engineer role

ACTIVITY 7: Planning engineer junior
Send model cases

The purpose of this activity is to send the model cases to the responsibility to deliver the Company solutions.

S1: Send the patient's initial state: For this process is necessary to deliver a logistics engineer.

Steps

S2: Send the case to Quality: Once all documentation and the 3D printing process are finished, you must send the case to check by the quality engineer. This is the final process for each case performed by the planning engineer.

S3: Follow the case evolution: Deliver to the quality area to be released for the logistics area, the evolution of the document located in Design/Biomodels/Soft Company management (Fill DE-IDI-153; Follow Company - BI - CX).

	INPUTS	OUTPUT
Items	✓ 3D print model ✓ Final presentation ✓ Implant card (DE-IDI-92) ✓ Sterilization doc (DE-IDI-150) ✓ Internal document – part 2 ✓ Release document (DE-IDI-153)	✓ Sterilization doc (DE-IDI-150) ✓ Company solution ✓ Release document (DE-IDI-153)

Decomposition diagram of planning engineer staff role.

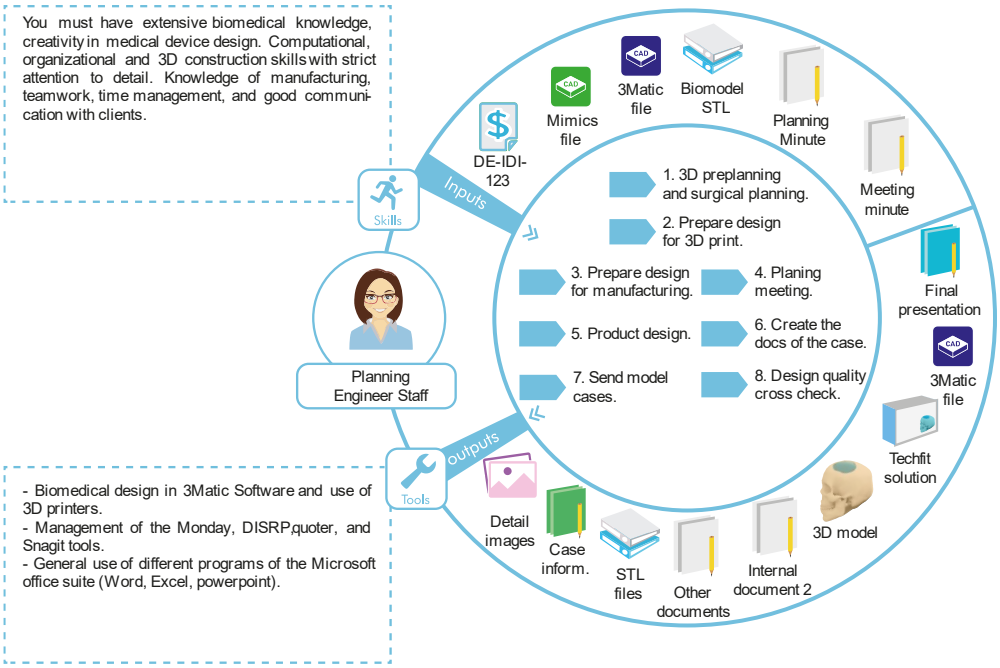

Figure 17. Planning engineer staff role

Table 31. Activity 8 of the planning engineer staff role

ACTIVITY 8: Planning engineer staff
Design quality cross-check

The purpose of this activity is to check the medical devices created by the other designers

Steps	**S1: Check product design:** You must check the medical devices created by the other designers to validate that the design obeys all specifications and is complete to send to manufacturing. **S2: Fill out the internal document:** to send to quality, offices, and an institution where the case arrives (Checklist start to finish).

	INPUTS	OUTPUT
Items	✓ STL files ✓ Bio models STL ✓ 3Matic file	✓ Internal document – part 2

Decomposition diagram of Planning engineer senior role.

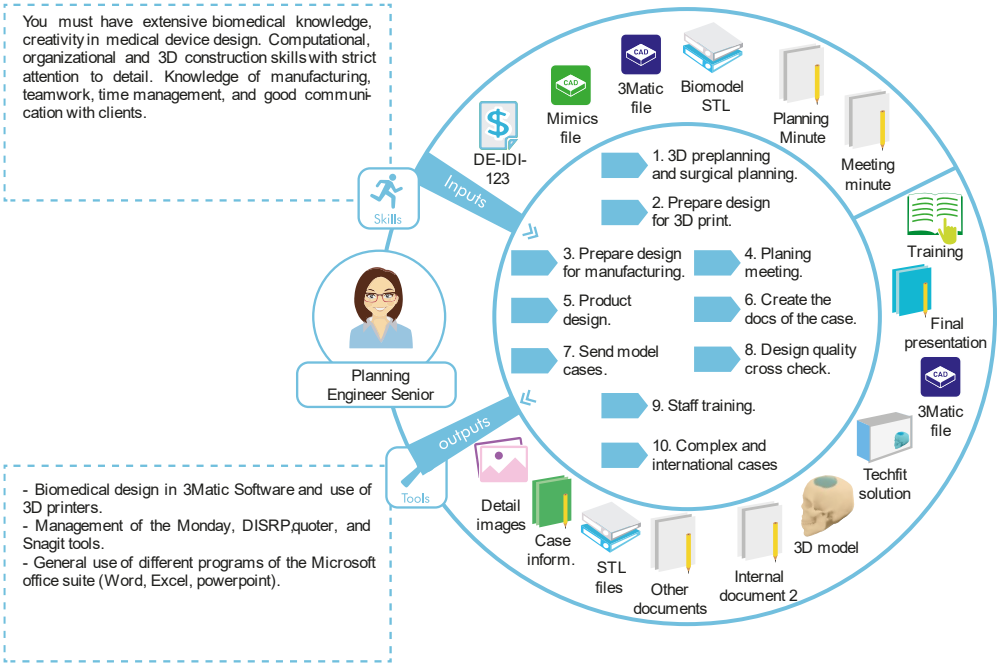

Figure 18. Planning engineer senior role

Table 32. Activity 9 for the planning engineer senior role

ACTIVITY 9: Planning engineer staff

Staff training

The purpose of this activity is the training designers to improve processes that can provide benefits to the company.

Steps

S1: Training ID: Being in constant search and updating of new processes that can improve the design process, complex cases executed to train junior designers.

S2: Create the training document: Create the presentation document that explains the executed process, design details and processes, technical explanation, and type of solution created (Guide document must be created).

S3: Training Meeting: Expose the training to the interested parties to improve the skills of the designers.

S4: Training Evaluation: Complete the document with the conclusions and feedback from the training. (Should there be a document)

	INPUTS	OUTPUT
Items	✓ STL files ✓ Bio models STL ✓ 3Matic file	✓ Training presentation ✓ Improvement proposal ✓ Training evaluation

Table 33. Activity 10 for the planning engineer senior role

ACTIVITY 6: Planning engineer senior Complex and international cases

The purpose of this activity is to carry out those cases that are complex and require greater skill and experience.

Steps

S1: Planning Meeting: Make the bone cuts and, together with the specialist, make the bone movements and/or sketch of the implant and measurements required for the 3D reconstruction, considering the surgical approach (Follow Planning Minute).

S2: 3D Design Solutions Tailored: Carry out the complete design solution for parts that are implantable and/or used during surgery (Follow WI 3D Design).

S3: Create the Documentation of the Case: preparation of all the digital and physical documents that are part of the case. These documents are in the minute's folder (Follow the presentation user manual).

S4: Send Model cases: release the case and finalize the design and manufacturing process (Fill DE-IDI-153; Follow Company - BI - CX).

INPUTS	OUTPUT

Items

- ✓ 3Matic file
- ✓ Mimics file
- ✓ Bio models STL
- ✓ Planning minute
- ✓ Internal document – part 1
- ✓ Final presentation
- ✓ Implant card (DE-IDI-92)
- ✓ Sterilization doc (DE-IDI-150)
- ✓ Internal document – part 2
- ✓ Release document (DE-IDI-153)

Workflow of planning engineer role

The planning engineer can have two workflows according to the type of solution. The first are solutions through medical devices based on 3D printing and the second, are solutions through designs based on subtractive manufacturing. However, that does not mean that a case does not require both alternatives.

For 3D printing.

Once the planning engineer has the service documents located in DISRP, the oriented tissues in the mimics file, and the planning act, he can start with 3D pre-planning and surgical planning. Now, according to the planning act, if the surgeon requested the 3D printing of the initial state, he would prepare the STL of the biomodel for 3D printing and then the biomodel will be sent to the surgeon. However, if the request does not require an impression of the initial state, the next step is to ask if the case requires a meeting with the surgeon to establish the design requirements in detail, but if it does not, the product design will continue. After the above and as discussed, the product design is carried out.

After the product design activity is finished, the designs are reviewed by a second designer to ensure that they are completed with all the specifications, and to validate an adequate product design. On the other hand, if the design does not comply with the design cross-check, it must return to the product design until it is endorsed. Next, if the surgeon wants a physical validation of the designed medical device, it is prepared for 3D printing and sent to the surgeon for physical review. However, if he does not require it, it must be uploaded to DISRP to be approved virtually. It is important to know that if for any reason the medical device is not approved, the recommendations will be taken, and a new version of the solution will be made.

Continuing with the process, as soon as the surgeon has approved, the creation of documents and the preparation of STL files for 3D printing is carried out in parallel. Finally, once these files, documents, and 3D printed models are available, they will be sent to those responsible for quality and logistics. In short, with the activities described above, they complete the flow for cases that only require 3D printing.

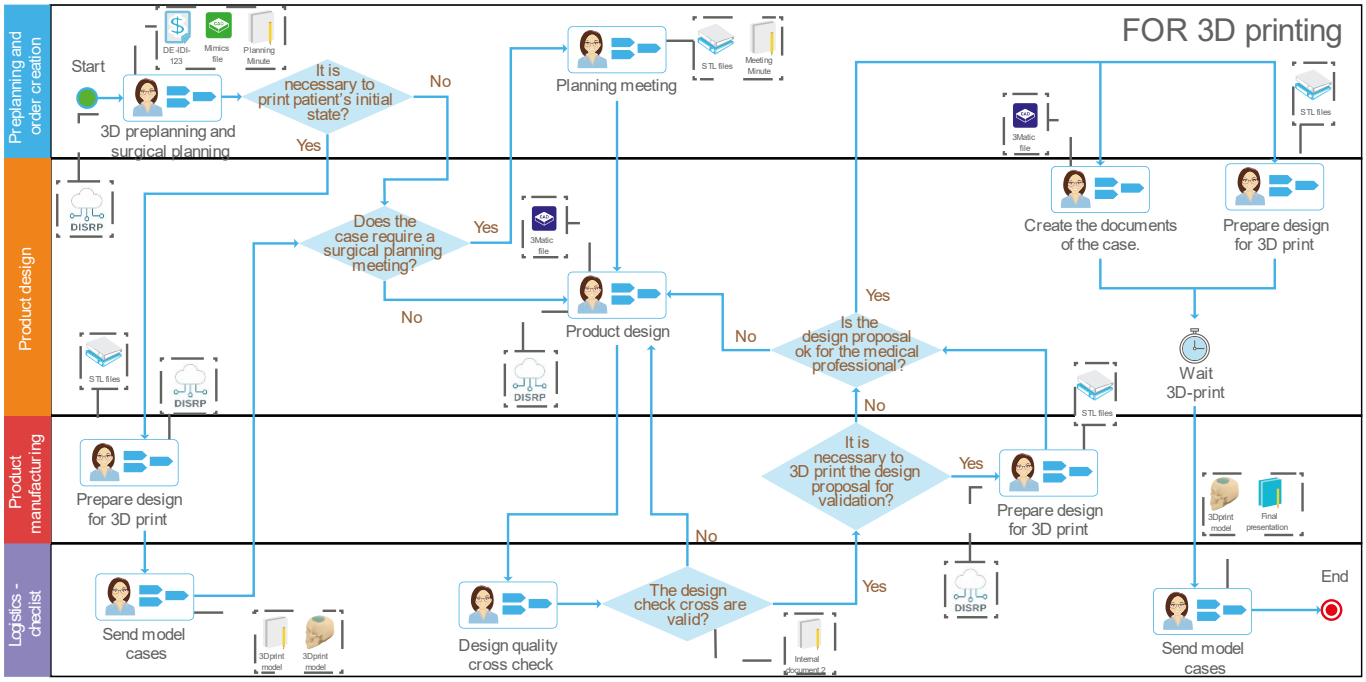

Figure 19 Workflow of planning engineer role for the 3D printing process.

For subtractive manufacturing.

Once the planning engineer has the service documents located in DISRP, the oriented tissues in the mimics file, and the planning act, he can start with 3D pre-planning and surgical planning. Now, according to the planning act, if the surgeon requested the 3D printing of the initial state, he would prepare the STL of the biomodel for 3D printing and then the biomodel will be sent to the surgeon. However, if the request does not require an impression of the initial state, the next step is to ask if the case requires a meeting with the surgeon to establish the design requirements in detail, but if it does not, the product design will continue. After the above and as discussed, the product design is carried out.

After the product design activity is finished, the designs are reviewed by a second designer to ensure that they are completed with all the specifications, and to validate an adequate product design. On the other hand, if the design does not comply with the design cross-check, it must return to the product design until it is endorsed. Next, if the surgeon wants a physical validation of the designed medical device, it is prepared for 3D printing and sent to the surgeon for physical review. However, if he does not require it, it must be uploaded to DISRP to be approved virtually. It is important to know that if for any reason the medical device is not approved, the recommendations will be taken, and a new version of the solution will be made.

After the solution is approved, the 3D printing of the biomodels, the creation of the case documents, and the preparation of the STL files for manufacturing are all done at the same time. All these files are uploaded to DISRP and are expected to be manufactured to send everything together for those responsible for quality and logistics.

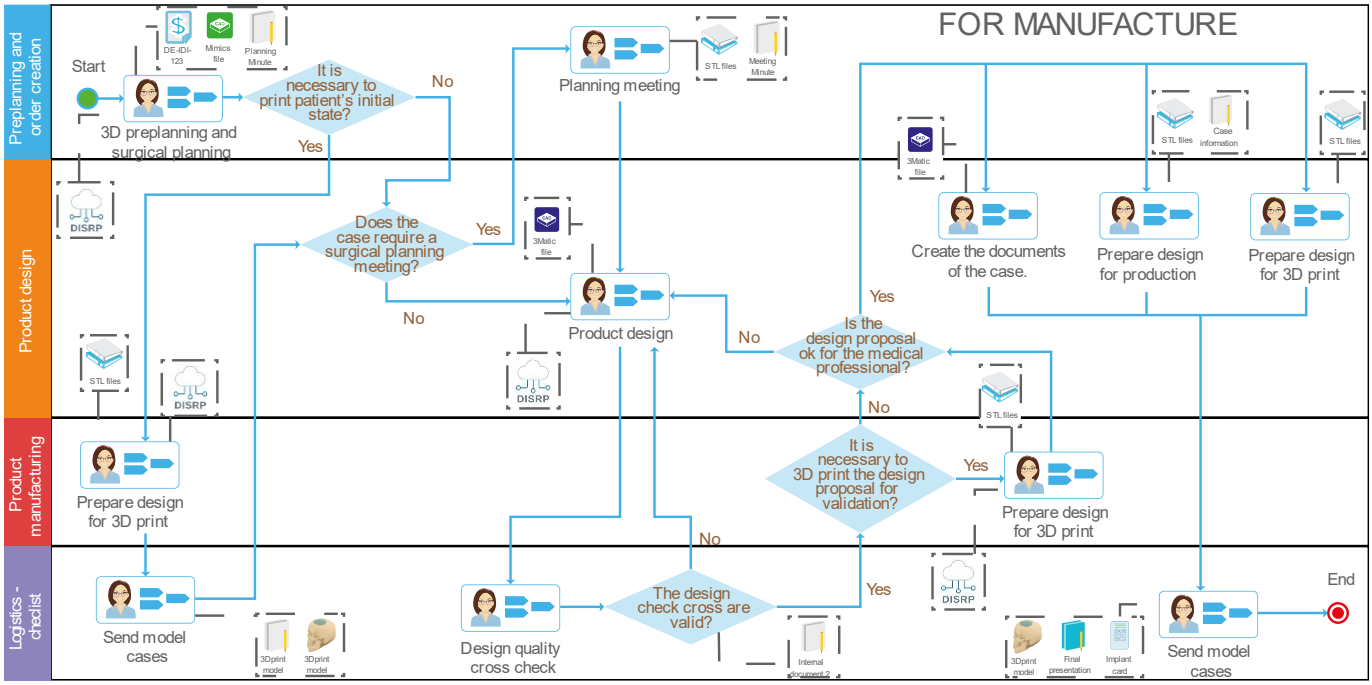

Figure 20 Workflow of planning engineer role for subtractive manufacturing process

4.5. Manufacturing engineer role

Table 34. The role description of a manufacturing engineer

The role description of a manufacturing engineer

Directs the planning, design of manufacturing, and manufacturing processes systems. Responsible for creating and implementing all aspects of manufacturing processes and product specifications. Applies knowledge or use of manufacturing principles and practices to improve manufacturing processes.
It has an impact on work by using continuous improvement tools and the development of manufacturing standards and work methods. Leads communications with key external stakeholders and functional members. Maintains relationships with key stakeholders.

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Tools:

- Autodesk Fusion 360, Inventor, Mastercam.
- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Design for Manufacturing.
- Translate requirements.
- Manufacturing Troubleshooting Techniques.
- verification and validation.

Skills:

Must know about mechanized manufacturing processes, CNC programming, manufacturing code development, and subtractive manufacturing methods. Good communication, multitasking, and manufacturing solution skills for objects with complex geometries.

Contact me for:

- G code file.
- Production logs.
- DE-IDI-103.
- DE-IDI-191.
- Manufacturing requirements.
- Progress status of the manufacturing process.

Decomposition diagram of Manufacturing engineer role.

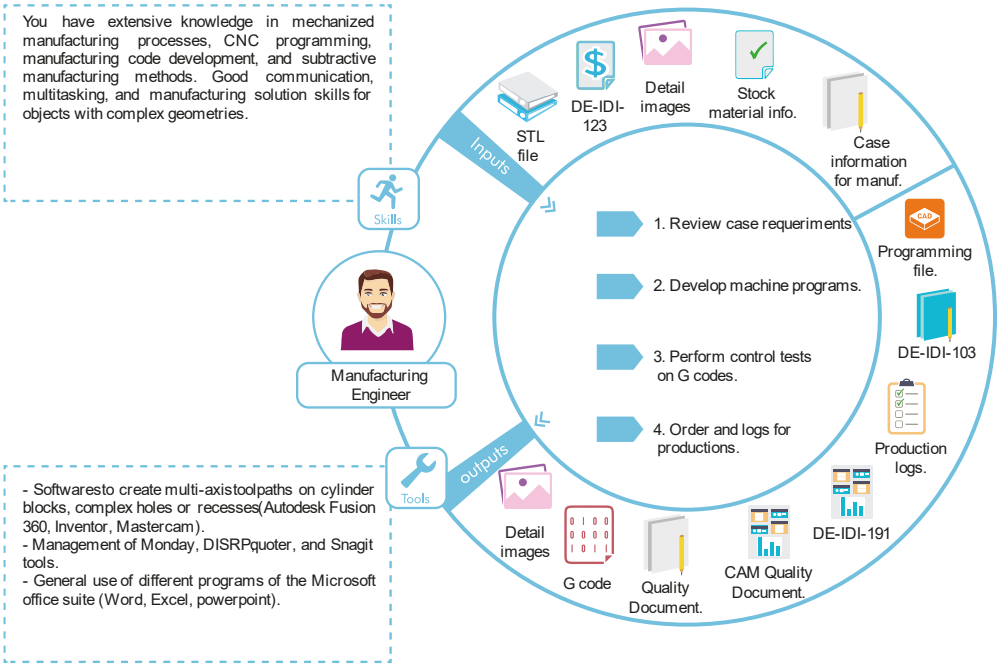

Figure 21 Manufacturing engineer role

Table 35. Activity 1 for the manufacturing engineer role

ACTIVITY 1: Manufacturing engineer Review case requirements

The purpose of this activity is to verify that the design proposal has all the specifications to start manufacturing the parts.

Steps

S1: Review design requirements: Check that the design proposal accomplishes all the specifications to proceed with manufacturing (material, thickness, perforations, orientation) and has been approved by the specialist (See DISRP).

S2: Verify stock materials: Maintain control of the stock of mechanized materials to generate the orders of materials necessary for the manufacturing processes *(case information for manufacturing).*

	INPUTS	OUTPUT
Items	✓ STL to manufacture ✓ Service request (DE-IDI-123) ✓ Stock material info ✓ Case information for manuf. ✓ Detail images.	

Table 36. Activity 2 for the manufacturing engineer role

ACTIVITY 2: Manufacturing engineer Develop machine programs	
The purpose of this activity is to verify the design, create the programming of the subtractive manufacturing machines and specify the requirements for the manufacture of custom parts.	
Steps	**S1: Check the STL part:** Verify that the STL file of the customized part is suitable to be manufactured by material subtraction methods, (Fill out Checklist start to finish). **S2: Model Cutting Paths and Program Machines:** Configure the G code of the subtraction machining machines according to the needs of each personalized part.
	INPUTS / **OUTPUT**
Items	✓ STL file / ✓ Product CAD/CAM

Table 37. Activity 3 for the manufacturing engineer role

ACTIVITY 3: Manufacturing engineer Perform control tests on G codes	
The purpose of this activity is to generate all types of documents resulting from the manufacturing process.	
Steps	**S1: Perform Test Runs and Adjust:** Once the code is done, a virtual machining test is performed to verify that the file does not present manufacturing problems. **S2: Upload G code file:** Upload the G files to the server (Fill in DE-IDI-103).
	INPUTS / **OUTPUT**
Items	✓ Product CAD/CAM / ✓ G code file. ✓ DE-IDI-103

Table 38. Activity 4 for the manufacturing engineer role

ACTIVITY 4: Manufacturing engineer Orders and logs for production		
The purpose of this activity is to perform verification and quality testing of the G-codes before sending the files to production.		
Steps	**S1: Fill out the Quality document:** Fill out the checklist with verifiable parameters for the quality area for Company production bio models. (DE-IDI-191). **S2: Fill out the Program sheet:** Fill out the production document which specifies the manufacturing requirements and the tools that must be used for its manufacture (DE-IDI-191). **S3: Support the manufacturing process:** Verify that the parts have finished the machining process.	
	INPUTS	**OUTPUT**
Items	✓ G code file ✓ Service request (DE-IDI-123)	✓ Production logs (e-mail) ✓ Production order (DE-IDI-191) ✓ Service request (DE-IDI-123) ✓ G code file

Workflow Manufacturing engineer role

The first step for the manufacturing engineer is to review the case requirements and verify that the product design is in order. Otherwise, you will have to go back to the planning engineer, but if everything is correct, the next thing is to evaluate if the Company solution requires the manufacture of implantable medical devices.

The process is extended if subtractive manufacturing is required for the construction of the medical devices, for that, you will have to develop the programming of the machine from the STL files delivered by the Planning Engineer to convert them into a G code. Then you must carry out control tests of the G code and once validated, carry out the order and registration for production in the plant, with this activity you will finish the process.

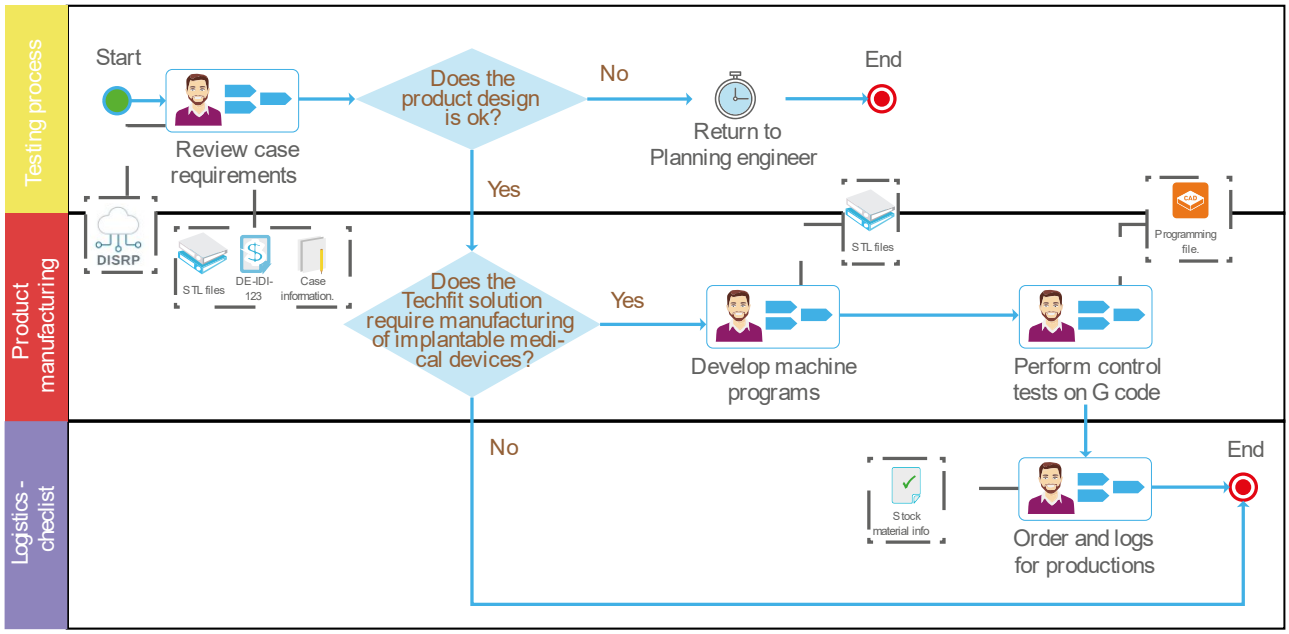

Figure 22 Workflow manufacturing engineer role

4.6. Machine operator role

Table 39. The role description of the machine operator

The role description of the machine operator

Seeks to control the CNC machine safely and accurately, knows materials and their manufacturing processes. Work with great concentration and precision. Know the safety protocols.
Their objective is to oversee the materialization of Company solutions and produce high-quality components and materials through the appropriate operations.

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Tools:

- CNC machine.
- milling machine.
-polishing machine.

Methods:

- Design for Manufacturing.
- Translate informatic commands.
- Mechanical drawing.
- verification and validation.

Skills:

You must establish the controls of the machines by grouping planned machine operations into a set of instructions.
Test the operations of the machines by running a test. Carry out fabrication, control the machine during operation, and adjust the machine in case of malfunctions, problems, or irregularities. The mount, installation, secure tools, joints, fixtures, and workpieces on the machine.

Contact me for:

- Implant

Decomposition diagram of machine operator role.

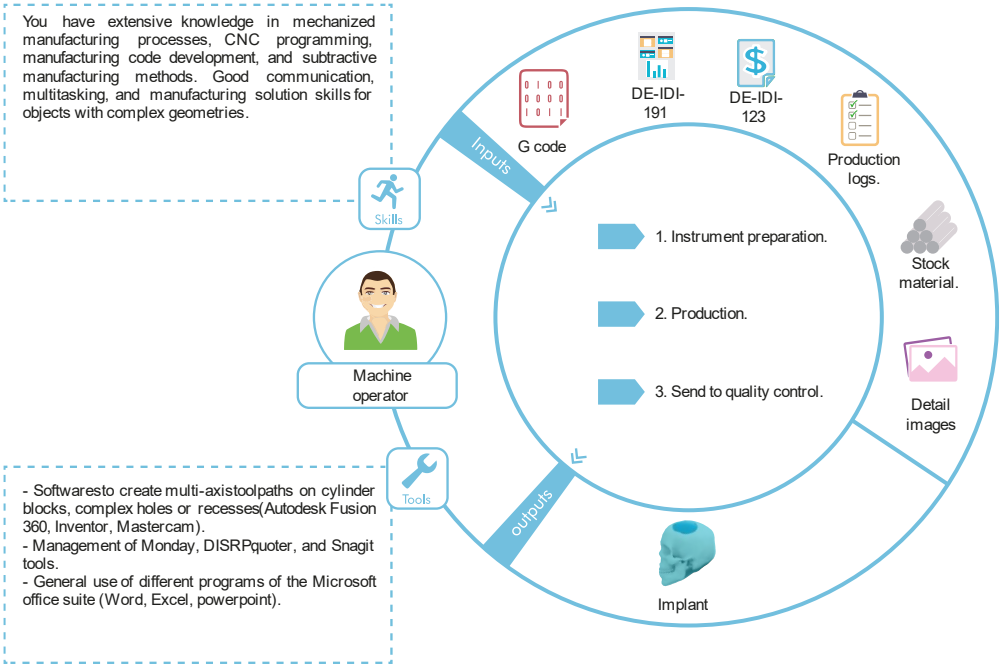

Figure 23 Machine operator role

Table 40. Activity 1 for the machine operator role

ACTIVITY 1: Machine operator
Instrument preparation

The purpose of this activity is to organize the necessary information, the machine, and the material for manufacturing.

Steps

S1: Receive the case information: Receive all the documentation of the case to manufacture.

S2: Receive the stock material: If the stock material was not delivered to you with the case documentation, you can go to the stock to request and receive the material showing the case documentation.

S3: Prepare the machine: Prepare the machine needed to manufacture the part.

	INPUTS	OUTPUT
Items	✓ G code ✓ Production logs (e-mail) ✓ Production order (DE-IDI-191) ✓ Service request (DE-IDI-123) ✓ Stock material ✓ Detail image	

Table 41. Activity 2 for the machine operator role

ACTIVITY 2: Machine operator Production	
The purpose of this activity is to carry out the production process of the parts by machining.	
Steps	**S1: Marked:** Mark the stock material to cut the material and place the pieces in the machine. **S2: Preformed:** It begins with the process of forming the material. **S3: Formed:** Once the preform is ready, the final shaping process of the piece is carried out to obtain the detailed form of the process. **S4: Polished:** The piece is polished to improve the surface and identify construction problems. **S5: Attachment review:** The attachment of the part is reviewed concerning the prototype delivered for construction. **S6: Drilling:** The pieces that are in titanium generally have some perforations to reduce the weight of the piece and allow the support of the soft tissue. **S7: Cleaning:** Once the piece is finished, it is washed to remove material residues. This process is done with special chemicals at a special temperature. *(Follow-up Validation cleaning processes)* **S8: Fixing points:** The perforations are made to fix the implantable piece in the bone tissue, these perforations are made according to the requirements given by the manufacturing engineer.

	INPUTS	OUTPUT
Items	✓ G code ✓ Production logs (e-mail) ✓ Production order (DE-IDI-191) ✓ Service request (DE-IDI-123) ✓ Stock material ✓ Detail image	✓ Implant

Table 42. Activity 3 for the machine operator

ACTIVITY 3: Machine operator Send to quality control
The purpose of this activity is once the part is finished, to deliver it to the quality engineer for review.
S1: Check parts: Check that the manufactured parts are complete and ready to send for quality review.

Steps	**S2: Send to quality engineer:** Deliver the parts to the quality area.

	INPUTS	OUTPUT
Items	✓ Production order (DE-IDI-191) ✓ Service request (DE-IDI-123) ✓ Implant	✓ Implant

Workflow Machine operator role

The fact that its process has fewer steps to perform than the others does not make it less important, since the materialization of the medical device designed to be implanted depends on it.

First, you must prepare the instruments and tools to use the manufacturing machine and have the production logs, G code, stock material, and case information documents that are required. Then, the operator carries out the production of the piece and once it is finished, it is sent to the quality control process.

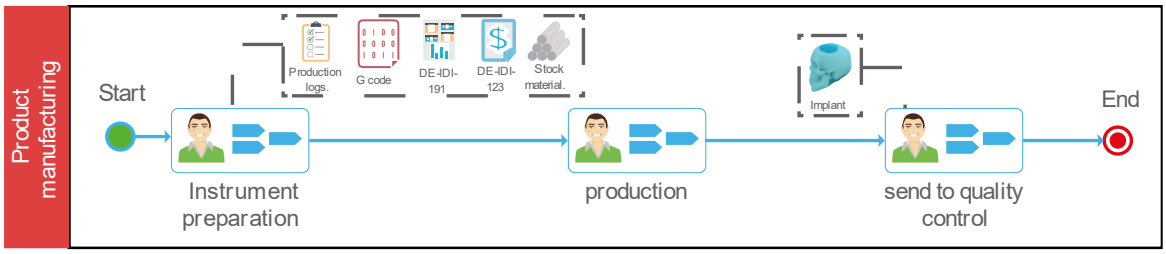

Figure 24 Workflow machine operator role

4.7. Project coordinator role

Table 43. The role description of the project coordinator

The role description of the project coordinator

It covers the organization and planning to develop new solutions that can be incorporated into the portfolio, support the realization of the R+D+I project, and participate in the verification and validation of the products generated in the process.
Also, is responsible for coordinating the development of programs for numerical control machines and participating in the committee that performs risk analysis of medical devices. Leads and oversees work teams with a defined objective.

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Tools:

- Mimics Software.
- 3-Matic Software.
- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Project management.
- Design methods.
- Product design.
- Translate requirements.
- Design troubleshooting techniques.

Skills:

You Must have knowledge of development environments, database analysis, and design, leadership activities, project management, good communication, and creativity to generate new projects for the company.

Contact me for:

- 3-Matic file.
- STL for manufacture.
- New product.
- STL models.
- DE-IDI-92.
– Quote
- Final presentation of the case.
- State of 3D manufacturing.
- R+D+I project.

Decomposition diagram of machine operator role.

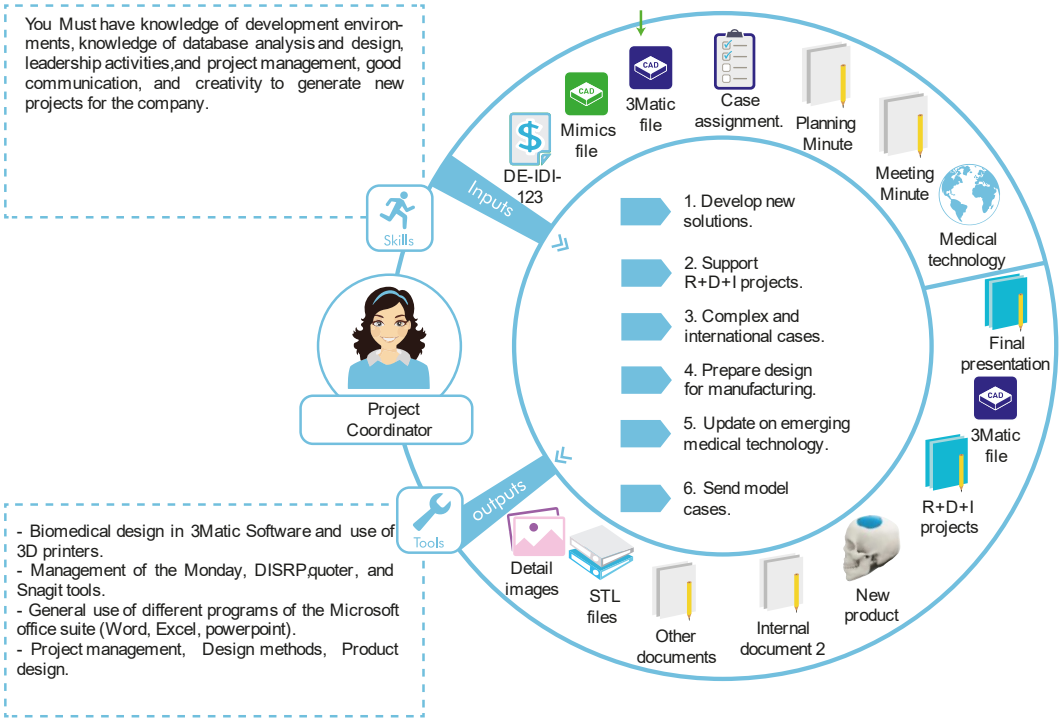

Figure 25 Project coordinator role

Table 44. Activity 1 for the project coordinator role

ACTIVITY 1: The project coordinator
Develop new solutions

The purpose of this activity is the creation of the Company design proposal considering the requirements of the case. For this activity, you must start with the 3D planning and culminate with the detailed design of the new product proposal.

Steps

S1: 3D Planning: The bone cuts must be made; the reflection of the healthy part and the necessary measures must be taken according to the type of case for the planning meeting with the surgeon (follow WI planning).

S2: Digital Surgery Planning: This step is done together with the specialist, the bone movements and/or the outline of the implant and measurements required for the 3D reconstruction are made, taking into account the surgical approach (Follow Planning Minute).

S3: Identify the new solution: Identify the new solution, make the solution proposal, generate the standard disclosure document to inform the new solution, and send it to the R+D+I project.

S4: 3D Design Solutions Tailored: Perform design specifications for the new product creation process

S5: Detailed Design: Once the Company proposal has been validated and approved by the specialist, the manufacturing specifications are designed, such as undercut review, part marking, and mesh error review (Follow WI 3D Design).

S6: Coordinate the numerical control machines: Once the G code for manufacturing the product is created, it is important to verify that it is ok with all the requirements stipulated for its manufacture.

	INPUTS	OUTPUT
Items	✓ 3Matic file ✓ Mimics file ✓ Planning minute ✓ Programming file ✓ Internal document – part 1	✓ STL file ✓ 3Matic file ✓ Bio model STL ✓ New product

Table 45. Activity 2 for the project coordinator role

ACTIVITY 2: The project coordinator Support R+D+I project

The purpose of this activity is to support and monitor the R+D+I project for the creation of new potential products that benefit the company. It is important to have extensive knowledge of the status of the case projects and to contribute to the design process and requirement specification.

Steps

S1: Requirement's specification: Contribute to the specification of requirements for the creation of the R+D+I project.

S2: Design process: Contribute to the design process for the creation of the R+D+I project.

S3: Coordinate the numerical control machines: Once the G code for manufacturing the product is created, it is important to verify that it is ok with all the requirements stipulated for its manufacture.

S4: Verification and validation of the products: support the verification of the product design and its manufacture in the prototyping stage and the validation of the final product manufacturing.

S5: Fill out the R+D+I project document: Fill out the production document which specifies the manufacturing requirements and the tools that must be used for its manufacture (format document).

	INPUTS	OUTPUT
Items	✓ Medical technology ✓ 3Matic file ✓ Mimics file	✓ R+D+I project document ✓ STL file

Table 46. Activity 3 for the project coordinator role

ACTIVITY 3: The project coordinator
Complex and international cases

The purpose of this activity is to carry out those cases that are complex and require greater skill and experience.

Steps

S1: Planning Meeting: Make the bone cuts and, together with the specialist, make the bone movements and/or sketch of the implant and measurements required for the 3D reconstruction, considering the surgical approach (Follow Planning Minute).

S2: 3D Design Solutions Tailored: Carry out the complete design solution for parts that are implantable and/or used during surgery (Follow WI 3D Design).

S3: Create the Documentation of the Case: preparation of all the digital and physical documents that are part of the case. These documents are in the minute's folder (Follow the presentation user manual).

S4: Send Model cases: release the case and finalize the design and manufacturing process (Fill DE-IDI-153; Follow Company - BI - CX).

	INPUTS	OUTPUT
Items	✓ 3Matic file ✓ Mimics file ✓ Bio models STL ✓ Planning minute ✓ Internal document – part 1 ✓ Service request (DE-IDI-123)	✓ Final presentation ✓ Implant card (DE-IDI-92) ✓ Sterilization doc (DE-IDI-150) ✓ Internal document – part 2 ✓ Release document (DE-IDI-153) ✓ Service request (DE-IDI-123)

Table 47 Activity 4 for the project coordinator role

ACTIVITY 4: The project coordinator
Preparing design for manufacturing

The purpose of this activity is to generate the STL files according to the configuration and manufacturing location of the parts through 3D printing or manufacturing process.

Steps

S1: Preparing Design for 3Dprinting: The marking of parts should be checked and there are no edges. For maxillary it is done by automatic orientation. In cutting guides, it is necessary to orient according to grooves so that there is no support material inside them, the cranioplasties must be inclined at 45° to preserve attachment. Check the position of glossing on the object. *(RND-SD-13 3D printing work instruction).*

S2: Support the 3D printing process: Verify that the parts have finished the 3D printing process and the machine is available. *(RND-SD-13 3D printing work instruction).*

S3: Preparing Design for manufacture: Set up parts for the machining process considering part orientation, mesh revision, clamping points, drill guides, and contour revision.

S4: Fill out the case information document: Fill out the case information document and sending to the manufacturing engineer. (Case information for manufacturing)

	INPUTS	OUTPUT
Items	✓ STL files ✓ Bio models STL ✓ 3Matic file ✓ Service request (DE-IDI-123)	✓ STL files ✓ 3D print model ✓ Case information for manufacturing ✓ Detail images

Table 48. Activity 5 for the project coordinator role

ACTIVITY 5: The project coordinator
Update on emerging medical technology

The purpose of this activity is to research and stay updated on new medical devices used internationally that may be of interest to the company.

Steps

S1: Indexed journal article research: maintain a constant search for articles in the indexed journals to update the company's data.

S2: Risk analysis of medical devices: Once the new, processes, technologies, methods, and medical devices are made, it is important to perform the risk analysis based on finite method analysis, mesh analysis, and production.

	INPUTS	OUTPUT
Items	✓ Medical technology ✓ STL files ✓ Bio models STL ✓ 3Matic file	✓ STL files ✓ 3Matic file ✓ R+D+I project ✓ New product

Table 49 Activity 6 for the planning engineer role

ACTIVITY 6: The project coordinator
Send model cases

The purpose of this activity is to send the model cases to the responsibility to deliver the Company solutions.

Steps

S1: Send the patient's initial state: For this process is necessary to deliver a logistics engineer.

S2: Send the case to Quality: Once all documentation and the 3D printing process are finished, you must send the case to check by the quality engineer. This is the final process for each case performed by the planning engineer.

S3: Follow the case evolution: Deliver to the quality area to be released for the logistics area, the evolution of the document located in Design/Biomodels/Soft Company management (Fill DE-IDI-153; Follow Company - BI - CX).

	INPUTS	OUTPUT
Items	✓ 3D print model ✓ Final presentation ✓ Implant card (DE-IDI-92) ✓ Sterilization doc (DE-IDI-150) ✓ Internal document – part 2 ✓ Release document (DE-IDI-153)	✓ Sterilization doc (DE-IDI-150) ✓ Company solution ✓ Release document (DE-IDI-153)

Workflow project coordinator role

This role can perform different activities at the same time. One of them is the development of new solutions taking into account the cases that are being carried out. Then, he must simultaneously support the R+D+I project and perform complex and international cases. These new projects may or may not require 3D printing processes for validation. So, if necessary, you will first prepare the design for production using the STL files. If the proposal is not adequate, it is started again to start a new version of the project, but if it is correct, it is prepared to produce the final product and finally, the models of the case will be sent to those responsible for logistics and quality.

On the other way, the project coordinator is responsible for the coordination of the designers, an activity that he carries out together with the clinical leader considering the assignment of cases delivered by the operational manager. Another of his activities is keeping up to date on emerging medical technology.

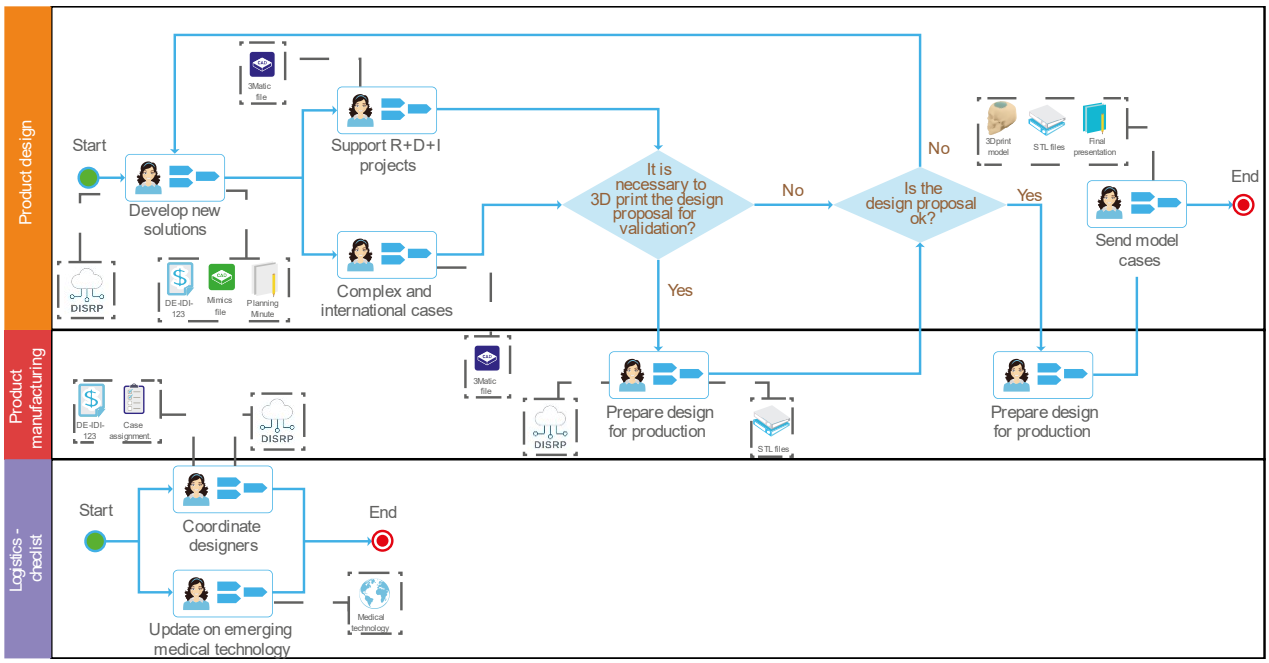

Figure 26 Workflow project coordinator role

4.8. Clinical leader role

Table 50. The role description of a clinical leader

The role description of a clinical leader

It is responsible for leading and managing active projects during the generation of Company solutions. Manage workgroups, motivate their members, and ensure delivery compliance times to achieve customer satisfaction. Participate in the design of solutions associated with the requirements and collaborate in the definition of solutions. In addition, you must track each phase of the project, monitoring times, costs, quality, and risks. Detect possible deviations to schedule intermediate deliveries with the client to mitigate errors.

At the same time, you must ensure that the projects are closed properly and formally. Collaborate with the business unit, to help establish the sale price and ensure communication to improve visibility to the team and progress to the client.

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Tools:

- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Project management.
- Design troubleshooting techniques.
- Translate requirements.

Skills:

You must know management and organizational skills, responsibility and commitment to Customer Orientation, and sales skills. You must have assertive communication with the workgroup and the customer.

Contact me for:

- 3-Matic file.
- STL for manufacture.
- New product.
- STL models.
- DE-IDI-92.
– Staff counselling
- Final presentation of the case.
– Case information.
- R+D+I project.

Decomposition diagram of Clinical leader role.

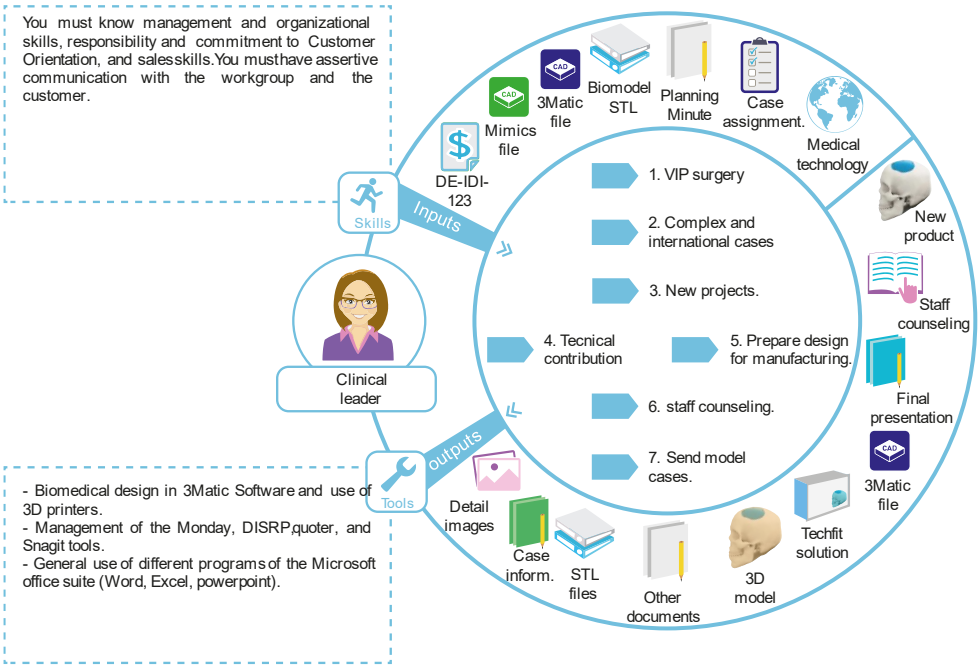

Figure 27 Clinical leader role

Table 51. Activity 1 for the Clinical leader role

ACTIVITY 1: Clinical leader
VIP surgery

The purpose of this activity is to attend and collaborate with the meetings of the VIP surgeons.

Steps

S1: Onboarding surgery: If we have a new surgery, the clinical leader performs the onboarding and the workflow of the company.

S1: Planning Meeting: Organize meetings with VIP surgeons who require special attention. Follow-up meetings and search for innovative cases (Follow Planning Minute).

S2: VIP surgery: Carry out the complete design solution of the VIP surgery for innovative cases.

S4: Send Model cases: release the case and finalize the design and manufacturing process (Fill DE-IDI-153; Follow Company - BI - CX).

Items

INPUTS	OUTPUT
✓ 3Matic file	✓ Final presentation
✓ Mimics file	✓ Implant card (DE-IDI-92)
✓ Bio models STL	✓ Sterilization doc (DE-IDI-150)
✓ Planning minute	✓ Internal document – part 2
	✓ Release document (DE-IDI-153)

Table 52. Activity 2 for the clinical leader role

ACTIVITY 2: Clinical leader
Complex and international cases

The purpose of this activity is to carry out those cases that are complex and require greater skill and experience.

Steps

S1: Planning Meeting: Make the bone cuts and, together with the specialist, make the bone movements and/or sketch of the implant and measurements required for the 3D reconstruction, considering the surgical approach (Follow Planning Minute).

S2: 3D Design Solutions Tailored: Carry out the complete design solution for parts that are implantable and/or used during surgery (Follow WI 3D Design).

S3: Create the Documentation of the Case: preparation of all the digital and physical documents that are part of the case. These documents are in the minute's folder (Follow the presentation user manual).

S4: Send Model cases: release the case and finalize the design and manufacturing process (Fill DE-IDI-153; Follow Company - BI - CX).

	INPUTS	OUTPUT
Items	✓ 3Matic file ✓ Mimics file ✓ Bio models STL ✓ Planning minute ✓ Internal document – part 1	✓ Final presentation ✓ Implant card (DE-IDI-92) ✓ Sterilization doc (DE-IDI-150) ✓ Internal document – part 2 ✓ Release document (DE-IDI-153)

Table 53. Activity 3 for the clinical leader role

ACTIVITY 3: Clinical leader
New projects

The purpose of this activity is the creation of the Company design proposal considering the requirements of the case. You must identify the new projects for innovation in the Company solution set.

Steps

S1: 3D Planning: The bone cuts must be made; the reflection of the healthy part and the necessary measures must be taken according to the type of case for the planning meeting with the surgeon (follow WI planning).

S2: Digital Surgery Planning: This step is done together with the specialist, the bone movements and/or the outline of the implant and measurements required for the 3D reconstruction are made, taking into account the surgical approach (Follow Planning Minute).

S3: Identify the new solution: Identify the new solution, make the solution proposal, generate the standard disclosure document to inform the new solution, and send it to the R+D+I project.

S4: 3D Design Solutions Tailored: Perform design specifications for the new product creation process

S5: Detailed Design: Once the Company proposal has been validated and approved by the specialist, the manufacturing specifications are designed, such as undercut review, part marking, and mesh error review (Follow WI 3D Design).

S6: Coordinate the numerical control machines: Once the G code for manufacturing the product is created, it is important to verify that it is ok with all the requirements stipulated for its manufacture.

	INPUTS	OUTPUT
Items	✓ 3Matic file ✓ Mimics file ✓ Planning minute ✓ Programming file ✓ Internal document – part 1	✓ STL file ✓ 3Matic file ✓ Bio model STL ✓ New product

Table 54. Activity 4 for the clinical leader role

ACTIVITY 4: Clinical leader Technical contribution

The purpose of this activity is to accompany designers with their knowledge during the process of creating Company solutions, to clarify doubts and concerns.

Steps

S1: Update on surgical approaches: The clinical leader must update on all surgical approaches that the company can accompany with the designs of medical devices.

S2: Technical contribution: If the planning engineer requires it, he can make technical contributions to the design of the medical devices that are being developed, through advice and compliance with the design requirements.

S3: New methodologies: Make new methodologies for the design and process that the company would need.

S4: Support design process: Follow up on cases to validate their compliance, doubts, and concerns.

S5: collaborate with the project coordinator: Carry out the compelling activities with the help of the project coordinator. The new projects, and the R+D+I project.

	INPUTS	OUTPUT
Items	✓ 3Matic file ✓ Mimics file ✓ Planning minute	✓ Other documents ✓ Improvement proposal

Table 55 Activity 5 for the clinical leader role

ACTIVITY 5: Clinical leader
Preparing design for manufacturing

The purpose of this activity is to generate the STL files according to the configuration and manufacturing location of the parts through 3D printing or manufacturing process.

Steps

S1: Preparing Design for 3Dprinting: The marking of parts should be checked and there are no edges. For maxillary it is done by automatic orientation. In cutting guides, it is necessary to orient according to grooves so that there is no support material inside them, the cranioplasties must be inclined at 45° to preserve attachment. Check the position of glossing on the object. *(RND-SD-13 3D printing work instruction).*

S2: Support the 3D printing process: Verify that the parts have finished the 3D printing process and the machine is available. *(RND-SD-13 3D printing work instruction).*

S3: Preparing Design for manufacture: Set up parts for the machining process considering part orientation, mesh revision, clamping points, drill guides, and contour revision.

S4: Fill out the case information document: Fill out the case information document and sending to the manufacturing engineer. (Case information for manufacturing)

	INPUTS	OUTPUT
Items	✓ STL files ✓ Bio models STL ✓ 3Matic file ✓ Service request (DE-IDI-123)	✓ STL files ✓ 3D print model ✓ Case information for manuf. ✓ Detail images

Table 56. Activity 6 for the clinical leader role

ACTIVITY 6: Clinical leader
Staff counseling

The purpose of this activity is to create the staff training, and protocols, and update the standards for the company

Steps

S1: Create protocols: Identify missing protocols in the company to carry out, and update processes, and innovation processes that facilitate design and manufacturing activities.

S2: Training ID: Being in constant search and updating of new processes that can improve the design process, complex cases executed to train junior designers.

S3: Create the training document: Create the presentation document that explains the executed process, design details and processes, technical explanation, and type of solution created (Guide document must be created?).

S4: Training Meeting: Expose the training to the interested parties to improve the skills of the designers.

S5: Standards: It is important that the clinical leader is updated on the standards and the new standards created by the medical device and gives out the rules for interesting roles.

S6: Improvement continuous: It is important to innovate in the process for all roles, if required the company to improve the specific process.

	INPUTS	OUTPUT
Items	✓ Other documents ✓ Case assignment	✓ Training presentation ✓ Improvement proposal ✓ Protocols ✓ Standards

Table 57 Activity 7 for the clinical leader role

ACTIVITY 7: Clinical leader
Send model cases

The purpose of this activity is to send the model cases to the responsibility to deliver the Company solutions.

Steps

S1: Send the patient's initial state: For this process is necessary to deliver a logistics engineer.

S2: Send the case to Quality: Once all documentation and the 3D printing process are finished, you must send the case to check by the quality engineer. This is the final process for each case performed by the planning engineer.

S3: Follow the case evolution: Deliver to the quality area to be released for the logistics area, the evolution of the document located in Design/Biomodels/Soft Company management (Fill DE-IDI-153; Follow Company - BI - CX).

	INPUTS	OUTPUT
Items	✓ 3D print model ✓ Final presentation ✓ Implant card (DE-IDI-92) ✓ Sterilization doc (DE-IDI-150) ✓ Internal document – part 2 ✓ Release document (DE-IDI-153)	✓ Sterilization doc (DE-IDI-150) ✓ Company solution ✓ Release document (DE-IDI-153)

Workflow Clinical leader role

This role performs different activities at the same time. One of them attends the VIP surgery and continues with the development of new projects. On the other way, you can perform complex and international cases. These two ways come together and go on to verify if the 3D printing of the proposal is necessary to be validated. If that answer is positive, the STL file is prepared for production and then it is checked if the proposal is ok. Then, if the proposal is not adequate, the proposal returns to the new project activity, but if it is adequate, it is prepared for production and, finally, the case is sent to those responsible for logistics and quality to finalize the design process.

In the logistics area, the clinical leader is a key role in the management of the cases that come to the company, those process is carried out together with the project coordinator through the designer coordination activity. In parallel, he performs the staff counseling, and according to these activities, he proceeds to make the technical contribution to the designers and other roles that require it.

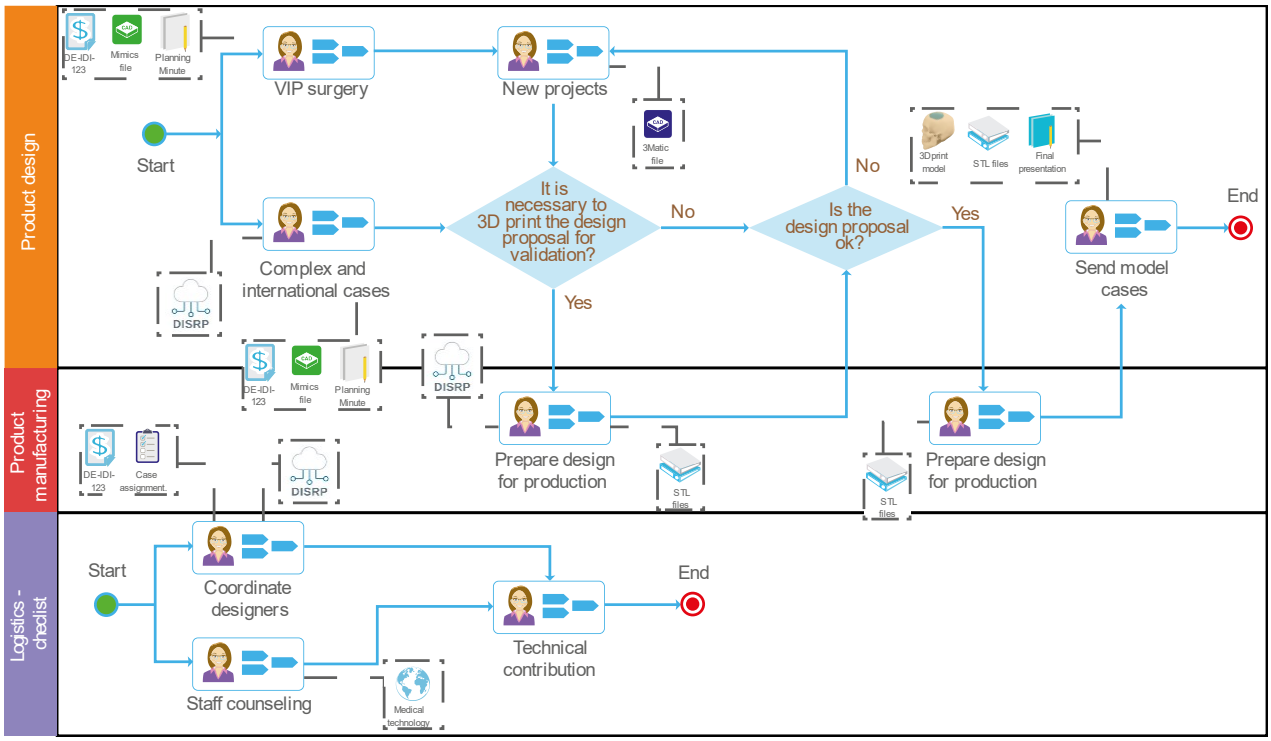

Figure 28 Workflow clinical leader role

4.9. Software developer role

Table 58. The role description of a software developer

The role description of a software developer

It is responsible for designing algorithms and flowcharts that will integrate software components and third-party programs to create software based on requirements and specifications. He verifies and implements programs and systems, troubleshoots, debugs, and updates existing software by evaluating user feedback to recommend and execute improvements.
Also, gather and scrutinize data using specialist tools to generate information that helps others make decisions and create technical documentation for reference and reporting.

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Tools:

- Python (Pandas, NumPy, SciPy, Plotly, Matplotlib, Seaborn, Scikit Learn, TensorFlow, Keras).
- Anaconda – Spider.
- Git – GitHub.
- Visual Code Studio.
- Stack Overflow.
- Microsoft Power BI.

Methods:

- Waterfall development method.
- Rapid application development.
- Agile development methodology.

Skills:

You must know about algorithms, object-oriented programming, knowledge of coding languages (e.g., Python, Java, C++), frameworks/systems, experience with databases, and the ability to learn new languages and technologies. In addition, you must have resourcefulness and problem-solving skills, excellent communication skills, analytical skills, and above all, be creative and innovative.
Problem-solving skills, Analytical skills, creativity and innovation, interpersonal and communication skills.

Contact me for:

- DISRP
- user's manual
- Quoter program
- Technical manual
- Scripting tools

Decomposition diagram of software developer role.

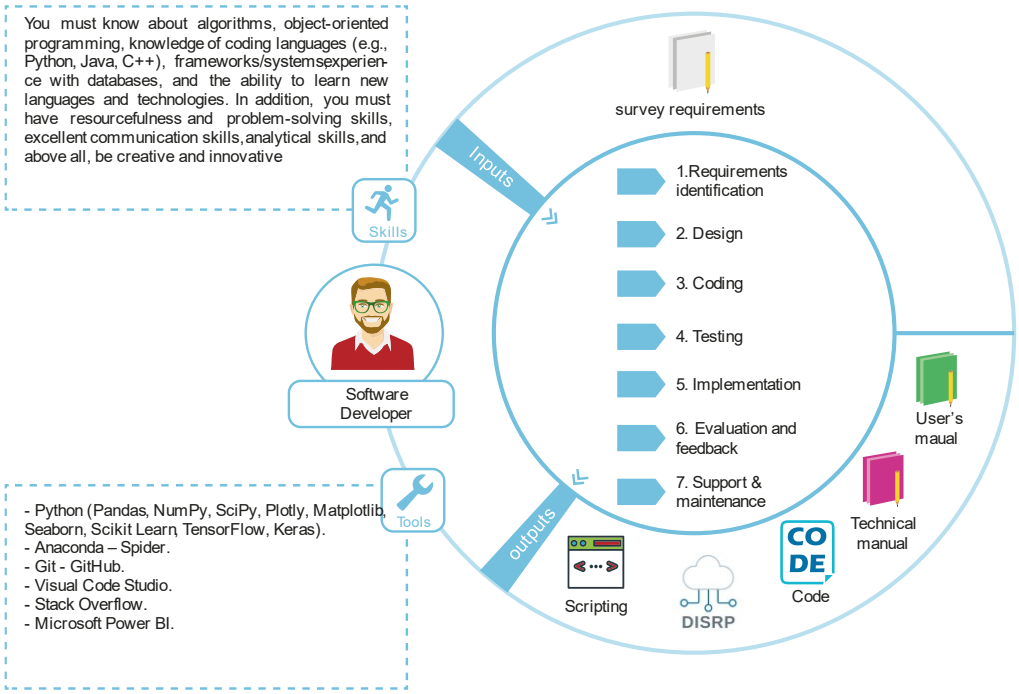

Figure 29 Software developer role

Table 59. Activity 1 for the software developer role

ACTIVITY 1: Software developer Requirements identification

The purpose of this activity is to recognize and analyze the requirements to define a workflow with traditional tools and understand the process to automate it.

Steps

S1: Identity: Compile the difficulties that the roles of the company may have.

S2: Analyze: Analyze these difficulties to define the functions and find a way to provide a successful solution.

S3: create requirements: Establish the general requirements to define the scope of the application.

	INPUTS	OUTPUT
Items	✓ Survey requirements	✓ Survey requirements

Table 60. Activity 2 for the software developer role

ACTIVITY 2: Software developer Design		
The purpose of this activity is the transformation of the requirements gathered in the previous activity, to later convert them into a sequential process for automation as an algorithm.		
Steps	**S1: Automatization:** Design the steps of the process for the program to work. **S2: Documentation:** Document the possible variations of the process and list the functions to solve the requirements. **S3: Create requirements:** Raise the general requirements to start the process of searching for solutions.	
	INPUTS	**OUTPUT**
Items	✓ Survey requirements	

Table 61. Activity 3 for the software developer role

ACTIVITY 3: Software developer Coding		
The purpose of this activity is to divide the tasks found by modules and develop the code.		
Steps	**S1: Coding:** Make the code to automate the process, this code is complemented with external libraries that expand the capacity of the code. **S2: Automatization:** Implement the process automation code.	
	INPUTS	**OUTPUT**
Items	✓ Survey requirements	✓ Code ✓ Scripting ✓ DISRP

Table 62. Activity 4 for the software developer role

ACTIVITY 4: Software developer Testing
The purpose of this activity is to carry out the tests and validations of the application.
S1: Testing: Perform code testing to review the functionality of the code.

Steps	**S2: Validation:** Validate the functions of the application concerning the requirements of the proposal.

	INPUTS	OUTPUT
Items	✓ Survey of requirements ✓ Code ✓ Scripting ✓ DISRP	✓ Code ✓ Scripting ✓ DISRP

Table 63. Activity 5 for the software developer role

ACTIVITY 5: Software developer Implementation	
The purpose of this activity is to deploy the application to the end-user.	
Steps	**S1: Implementation:** Upload the user version for the company. **S2: Create the documentation:** Makes the user manual, and the technical manual for possible modifications if required. **S3: Meeting:** Organize a meeting to socialize the application solution and train the roles with the application.

	INPUTS	OUTPUT
Items	✓ Survey requirements ✓ Code	✓ User's manual ✓ Technical manual

Table 64. Activity 6 for the Software developer role

ACTIVITY 6: Software developer Evaluation	
The purpose of this activity is the evaluation and feedback of the application by the end-user.	
Steps	**S1: Evaluation:** Carry out the evaluation and feedback of the application by the end-user.

	INPUTS	OUTPUT
Items	✓ Scripting ✓ DISRP	✓ Survey requirements

Table 65. Activity 7 for the software developer role

ACTIVITY 7: Software developer Support & maintenance	
The purpose of this activity is the support and maintenance of the application and the feedback received.	
Steps	**S1: Support:** If required, modifications are made to the application taking into account the user's voice. **S2: Maintenance:** Give maintenance for the correct functioning of the application. **S3: Identity:** Repeat the steps of activity 1 and start the process flow again.
	INPUTS	**OUTPUT**
Items	✓ Scripting ✓ DISRP ✓ Survey requirements	✓ Survey requirements

Workflow Software developer role

It starts with the collection of information by the roles of the company, according to this data, it makes the design for automation, then it makes the code of the algorithm and performs the testing, Now, if the coding is wrong, it will have to be done again the coding activity, but if ok, it will continue with the implementation, evaluation, and feedback of the proposed automation to finally obtain support and maintenance.

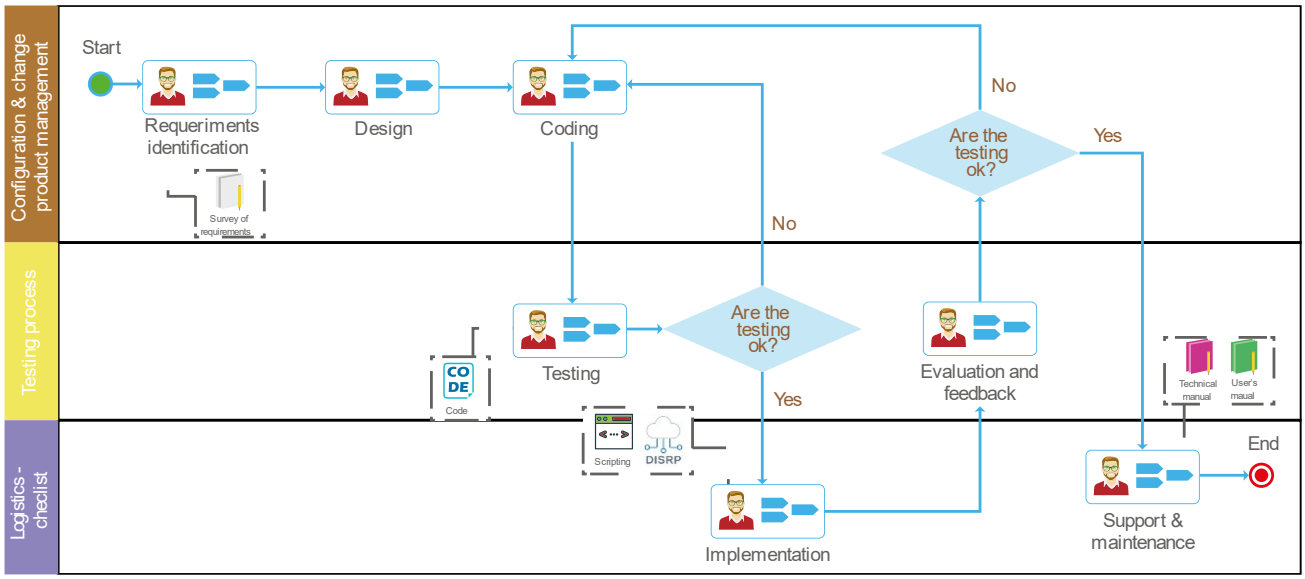

Figure 30 Workflow software developer role

4.10. logistics role

Table 66. The role description of logistics

The role description of logistics

It is responsible for the organization, supervision of the warehouse, and distribution of the product. It oversees supervising the sterilization of the Company solution and the surgical instruments required for the surgical procedures of each case.
It aims to manage the entire order cycle to improve business development and ensure sustainability and customer satisfaction. In addition, he is responsible for the purchasing area of the company.

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Tools:

- DISRP.
- Microsoft office suite.
- Logistics software.

Methods:

- Administration and management.
- Supply chain.
- Organization troubleshooting techniques.

Skills:

You must strategically plan and manage logistics, warehousing, transportation, and customer services. You must direct, optimize and coordinate the entire order cycle. You must also collaborate and know how to negotiate with suppliers, manufacturers, merchants, and consumers.

Contact me for:

- Sterilization certificate
- Delivery of Company solution
- Stock material
- Surgical instrument
- TI inventory
- Providers

Decomposition diagram of logistics role.

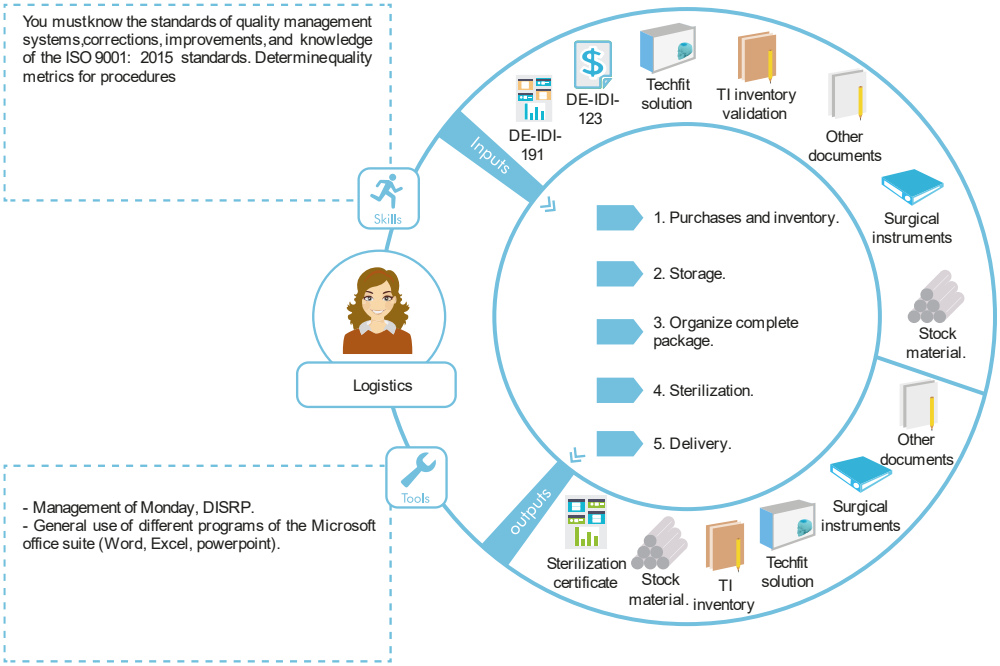

Figure 31 Logistics role

Table 67. Activity 1 for the logistics role

ACTIVITY 1: Logistics Purchases and inventory	
The purpose of this activity is the oversee purchases and inventory of stock material, and other elements required for the manufacture of Company solutions.	
Steps	**S1: Purchases:** Make the purchases of stock material, box for sending the solutions, surgical instruments, office items, and other elements required for the company **S2: Request the material quality:** All stock material that enters must be reviewed by the quality engineer to ensure the criteria and the approval use. **S3: Inventory:** Oversee the storage of all elements that the company receives and sends.
	INPUTS / **OUTPUT**
Items	✓ Stock material ✓ TI inventory validation ✓ Surgical instruments ✓ Stock material ✓ Surgical instruments

Table 68. Activity 2 for the logistics role

ACTIVITY 2: Logistics Storage	
The purpose of this activity is to control and distribute all elements for the correct operation of the company.	
Steps	**S1: Storage:** All elements that be in the storage must be inventoried, marked, and controlled for their distribution. **S2: Divulgation:** Once the material or element is found in the storage, it is important to divulge the availability **S3: Delivery:** You must control the distribution of the material for the area that required it.
	INPUTS / **OUTPUT**
Items	✓ Stock material ✓ TI inventory validation ✓ Surgical instruments TI inventory

Table 69. Activity 3 for the logistics role

ACTIVITY 3: Logistics Organize the complete package	
The purpose of this activity is to organize and ensure that the Company solution is complete according to the request.	
Steps	**S1: Review:** You must review the package is complete. If requires the sterilization process, go to activity 4. **S2: Organize:** You must organize the complete package to send to the hospital or surgery.
	INPUTS / **OUTPUT**
Items	✓ TI inventory validation ✓ Surgical instruments ✓ Company solution ✓ Service request (DE-IDI-123) ✓ Production order (DE-IDI-191) ✓ Release document (DE-IDI-153) ✓ Quality report ✓ Company solution ✓ Surgical instrument ✓ Release document (DE-IDI-153)

Table 70. Activity 4 for the logistics role

ACTIVITY 4: Logistics Sterilization		
The purpose of this activity is to control and distribute the elements required sterilization process.		
Steps	**S1: Send:** You must send the products to the allied sterilization company and wait for your return. **S2: Care of sterilization items:** Once the material is sterilized, you must have care of your handling. (RND-EX-381 Validation sterilization method – protocol and report) **S3: Packed:** You must check that the packaging is adequate, then go to activity 5.	
	INPUTS	**OUTPUT**
Items	✓ Sterilization doc (DE-IDI-150) ✓ TI inventory validation ✓ Surgical instruments ✓ Sterilization certificate	Sterilization certificate

Table 71. Activity 5 for the logistics role

ACTIVITY 5: Logistics Delivery		
The purpose of this activity is to oversee delivering Company solutions to the requesting surgeon or hospital.		
Steps	**S1: Delivery:** You must send the products to the allied sterilization company and wait for your return. *(PRD-SD-133 Instructions for final release).* **S2: Report:** Finally, you must report on the document delivery of the case. (Fill out Company - BI - CX).	
	INPUTS	**OUTPUT**
Items	✓ Company solution ✓ Surgery instruments ✓ DE-IDI-123	Company solution Surgery instruments

Workflow logistics role.

The logistics role performs some activities in parallel, one way he starts with the purchases and inventory activity, and finally, the storage activity with the stock material and the TI inventory validated.

The other way is to organize a complete package of the Company solution, then support the sterilization process, the sterilization is performed by an external company. and once the sterilization is finished the complete package is delivered.

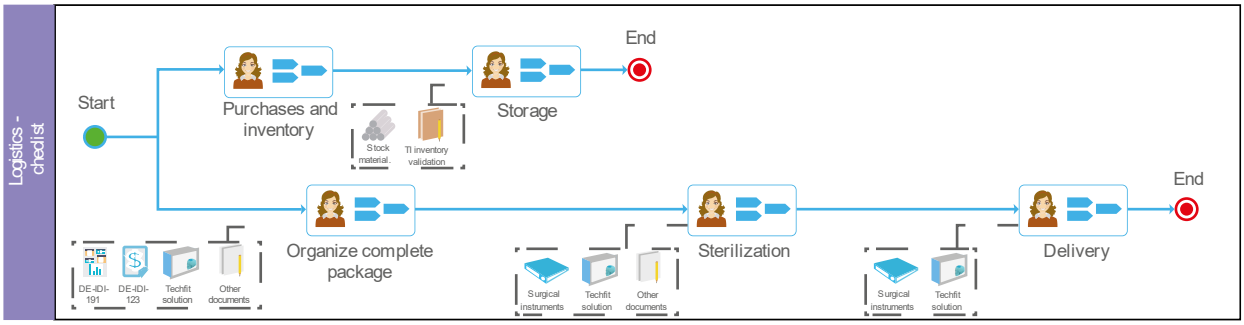

Figure 32 Workflow logistics role.

4.11. Quality engineer role

Table 72. The role description of a quality engineer.

The role description of a quality engineer

It is responsible for supervising, testing, and reporting the quality status of products, and inspecting stock materials, components, mechanical systems, and final products. Check the dimensional, thickness, and perforation metrics of the final product.

Also, is responsible for identifying technical issues and ensuring that the Company solution has all the necessary components and documentation for case release.

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Tools:

- DISRP.
- Microsoft office suite.

Methods:

- Inspection sheets.
- Control charts.
- verification and validation.

Skills:

You must know the standards of quality management systems, corrections, improvements, and knowledge of the ISO 9001: 2015 standards. Determine quality metrics for procedures.

Contact me for:

- Quality report
- Delivery report
- TI validation
- Database history
- Future test evidence

Decomposition diagram of quality engineer role.

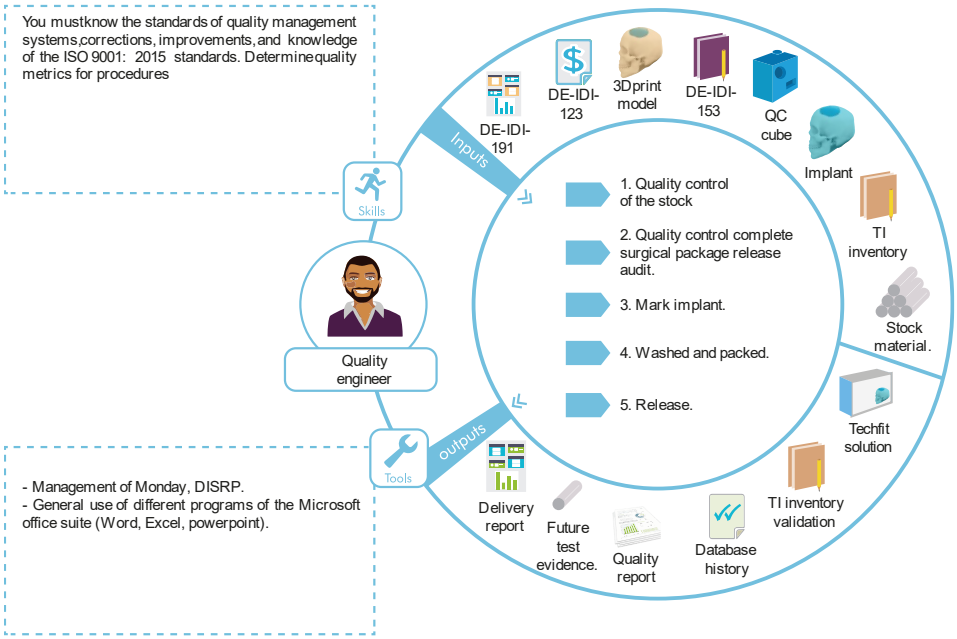

Figure 33 Quality engineer role

Table 73. Activity 1 for the quality engineer role

ACTIVITY 1: Quality engineer
Quality control of the stock

The purpose of this activity is to check that stock material obeys the chemical and physical specifications.

Steps

S1: Receive the stock material: check that the stock material code is the same as the product code.

S2: Audit stock material: Check that the material specifications comply with the composition and testing standards. *(LOG-SD-162 Supplier Quality agreement)*

S3: Audit 3D printed cube: Check that the measures of the 3D printed cube satisfy the quality criteria to validate the printing machines and allow their use

S4: Cut the future test evidence: Once the raw material is reviewed, a sample of material is cut to have as evidence in case of any complication, complaint, or claim for material failure.

S5: TI inventory validation: Fill out the document TI inventory validator to report whether the material is approved or not.

	INPUTS	OUTPUT
Items	✓ TI inventory ✓ Stock material ✓ QC cube	✓ TI inventory validation ✓ Future test evidence ✓ Database history

Table 74. Activity 2 for the quality engineer role

ACTIVITY 2: Quality engineer
Quality control complete surgical package release audit

The purpose of this activity is to receive the complete package and carry out the quality review of the pieces to be approved or not.

Steps

S1: Receive the complete package: Check that the package is complete according to the received deliverable package checklist.

S2: Audit implantable parts: Check that the implantable pieces achieve the dimensions, thickness, perforations, and other manufacturing requirements. *(PRD-SD-99 / PRD-SD-207)*

S3: Audit the 3D printing parts: Check that the 3D printing plastics achieve the dimensions, thickness, perforations, and other manufacturing requirements. *(PRD-SD-104 / PRD-SD-105)*

S4: Audit the documents: Prepare the machine needed to manufacture the part.

	INPUTS	OUTPUT
Items	✓ Production order (DE-IDI-191) ✓ Service request (DE-IDI-123) ✓ Release document (DE-IDI-153) ✓ Company solution	✓ Quality report

Table 75. Activity 3 for the quality engineer role

ACTIVITY 3: Quality engineer
Mark implant

The purpose of this activity is to mark the implant with the code and other specifications required for the implantable parts.

Steps

S1: Prepare machine: Locate the implantable part into the machine for the marking process.

S2: Mark implant: write in the program the code of the case and place the text in the marked area. Once finished, remove the implantable part.

	INPUTS	OUTPUT
Items	✓ Implant	✓ Implant ✓ Database history

Table 76. Activity 4 for the quality engineer role

ACTIVITY 4: Quality engineer Washed and packed

The purpose of this activity is to send all the pieces that are going to be used in the surgery room from the Company solution to be washed to remove fragments or manufacturing residues.

Steps	**S1: Washed:** Parts of the Company solution are washed using the ultrasonic process to remove manufacturing residues **S2: Packed:** once the pieces have been washed, they are packed and left on the shipping table

	INPUTS	OUTPUT
Items	✓ Company Solution	✓ Company solution

Table 77. Activity 5 for the quality engineer role

ACTIVITY 5: Quality engineer Release

The purpose of this activity is to report to logistics that the Company solution is ok to deliver the case.

Steps	**S1: Quality report:** If the case requires it, fill out the Quality report document to send to all interested. *(STR-RC-46 Quality plan)* **S2: Release:** You must send an email informing that the quality process has been completed and the case has been released to logistics

	INPUTS	OUTPUT
Items	✓ Company Solution	✓ Company solution ✓ Quality report

Workflow quality engineer role

There are two possible routes that the quality engineer can take: The first is to evaluate the quality control of the Stock material. If the answer is positive, I would immediately proceed to make the delivery to a warehouse managed by logistics. However, if it is not okay, it should be returned to the supplier.

The second is to carry out the audit quality control and check that everything is in perfect condition since if it is not, it will be sent back to the planning engineer. However, if the result is satisfactory, the marking of the implant will be carried out. Then, they got to wash and pack to finally deliver it.

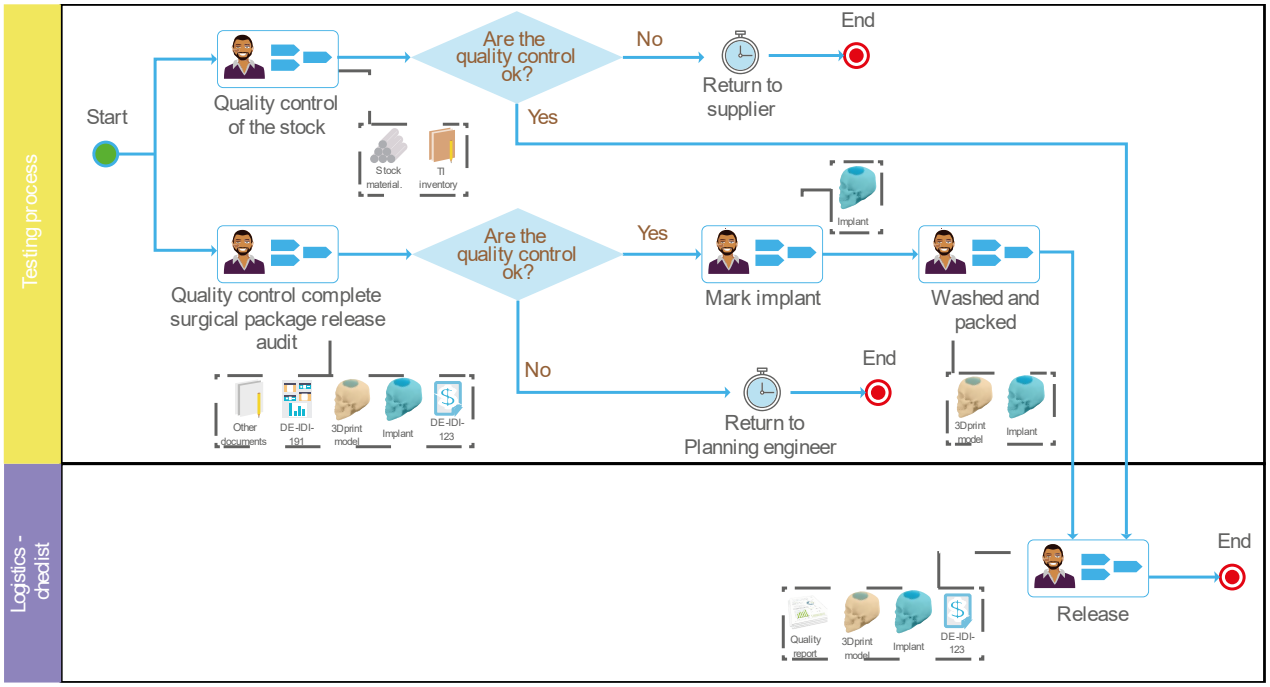

Figure 34 Workflow quality engineer role

4.12. Regulatory affairs specialist role

Table 78. The role description of regulatory affairs specialist.

The role description of regulatory affairs specialist.

Is responsible for managing, coordinating, and documenting internal regulatory processes, which may include inspections, internal audits, license renewals, registrations, and several other processes under certain regulations.
Also, help to obtain and maintain government approval for materials medical devices, and other related materials for collecting, gathering, compiling, and preparing the materials needed for registration and submission to regulatory agencies such as the Food and Drugs Administration (FDA).

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Tools:

- QT9.
- DISRP.
- Monday.
- Teams.
- Microsoft office suite.

Methods:

- Coordinate complex activities.
- Verification and validation.
- Potential regulatory pathways.
- International Standards.

Skills:

You must be able to work in a demanding environment where strict timelines and protocols must be met. Work on managing and documenting information and must be adept at working with databases and other information management tools. Attention to detail is extremely important, as is the ability to adapt quickly to changing regulations. They must have excellent organizational, analytical, project management, written, and communication skills. You work frequently with other employees and team members to coordinate complex activities, often with competing priorities.

Contact me for:

- Regulatory control.
- Medical device files.
- QT9 docs.
- Validation

Decomposition diagram of regulatory affairs specialist role.

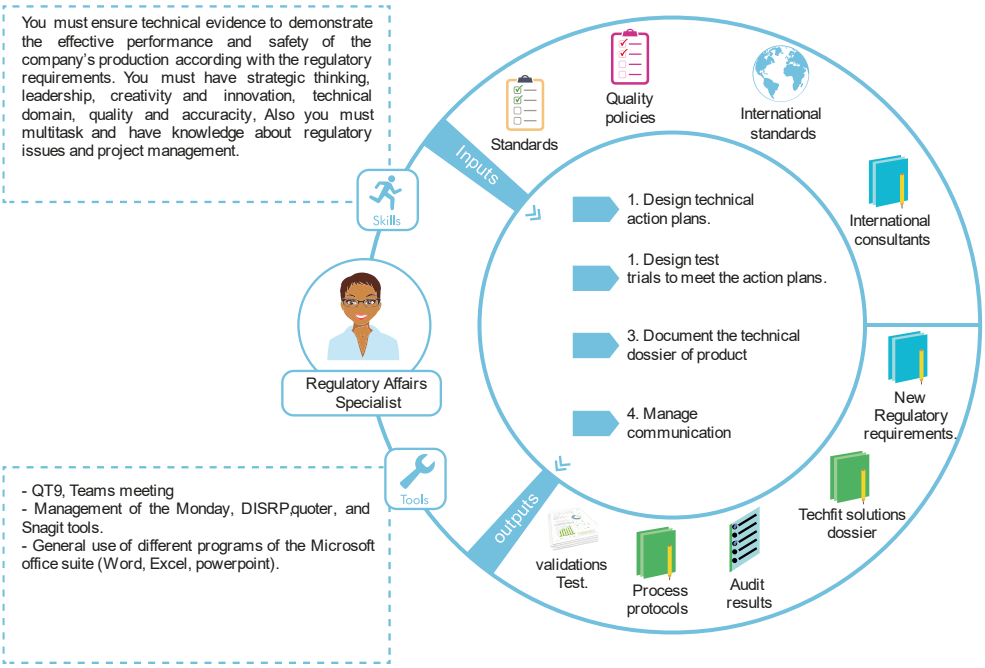

Figure 35 Regulatory affairs specialist role

Table 79. Activity 1 for the regulatory affairs specialist role

ACTIVITY 1: Regulatory affairs specialist Design technical action plans.

The purpose of this activity is to create action plans according to the regulatory requirements to close regulatory gaps, for this activity, you shall know the international standards.

Steps

S1: Identify regulatory gaps: The first step is to identify the regulatory gaps in the company, then action plans can be analyzed.

S2: Design Technical action plans: It is important to create technical action plans to solve the regulatory gaps, for this step, you must know the international standard. *(STR-PR-07 Procedure for corrective and preventive action)*

S3: Execute technical action plans: Once the technical action plan is created, this must execute in the company.

S4: Technical answer: You must make the technical response to the regulatory requirements.

S5: Carry out an action plan: Once the technical action plan is approved, it is important to carry out the action plan to ensure the regulatory gaps have been closed.

S6: Close regulatory gaps: Once it is developing the action plans, it is possible to close regulatory gaps.

	INPUTS	OUTPUT
Items	✓ International standards	

Table 80. Activity 1 for the regulatory affairs specialist role

ACTIVITY 2: Regulatory affairs specialist
Design test trials to meet the action plans.

The purpose of this activity is to design a test trial according to the regulatory requirements.

Steps

S1: Build evidence: Build evidence to support the Substantial Equivalence of Sampedro products with other counterparts.

S2: Test design: Structure the requirements to create a test for validation with the adequate component and organize the component list. (budgets, chronogram, resource planning).

S3: Validation: You must validate the test in the company to evaluate the process and products. *(All RND-EX documents).*

S4: Tabulate the data: You must analyze the data of the test run.

S5: Conclusion: Once the collected data has been analyzed, the conclusions of the results must be generated.

	INPUTS	OUTPUT
Items	✓ Standard ✓ Quality policies	✓ Validations test

Table 81. Activity 3 for the regulatory affairs specialist role

ACTIVITY 3: Regulatory affairs specialist
Document the technical dossier of products

The purpose of this activity is to control and document the technical dossier of products and give access to confidence documents for the project of management and design validation.

S1: Compiling: You must write the regulatory requirements proposed for the company.

Steps	**S2: Disclosure:** Then, it is important to discuss with the CEO, Technic Director, and operational manager to evaluate the proposal, if approved, you can go to the next activity. **S3: Update to QT9:** You must keep updating all documents on QT9, and version control. **S4: Perform audit:** Perform audits to validate the general process of the company, these can be internal or external audits. *(STR-PR-25 Procedure for internal audit).*

	INPUTS	OUTPUT
Items	✓ International standards ✓ Standard ✓ Quality policies	✓ New regulatory requirements ✓ Process protocols ✓ Audit results ✓ Company solution dossier

Table 82. Activity 4 for the regulatory affairs specialist role

ACTIVITY 4: Regulatory affairs specialist Manage communication	
The purpose of this activity is to manage communication with the process areas and regulators' advisers.	
Steps	**S1: Meeting with consultants:** You must have meetings with consultants, and regulators advisers, and have training or suggestions to create new regulatory requirements. **S2: Share Knowledge:** You should share the knowledge and other regulatory affairs. **S3: General communication:** Communicate to the technical director the progress of design validation and verification test projects.

	INPUTS	OUTPUT
Items	✓ New regulatory requirements ✓ Process protocols ✓ Audit results ✓ Company solution dossier	

Workflow regulatory affairs specialist role

The regulatory affairs specialist role has its activities within the logistics checklist and configuration & change product management process areas. First, he performs the design test trials for production validations taking into account the standard and quality policies previously used in the company, and the

international standards updated by the control entities. Now, if the test trials are not correct, this activity must be carried out again, but if it is positive, it proceeds to create new regulatory requirements. In parallel, the role can perform the Design test trials for production validations.
The next activity to be carried out is action plans to close regulatory gaps based on the international standard. Then, create new regulatory requirements will be executed, adding the international standard and the recommendations of the international consultants. Finally, he must carry out the management communication of the new guidelines from the regulatory area to the different processes and roles in charge through training and official disclosures in the company.

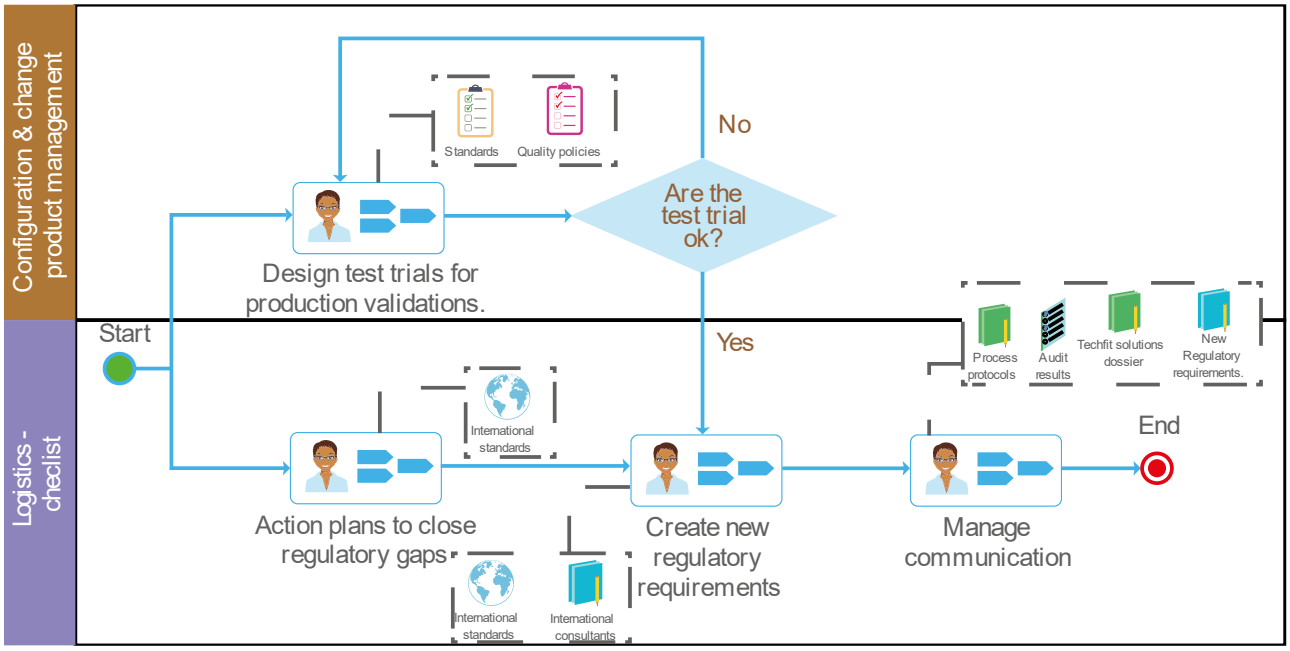

Figure 36 Workflow regulatory affairs specialist role

4.13. Technical director role

Table 83. The role description of the technical director.

The role description of the technical director.

He is responsible for ensuring that legal bearings, normative and regulatory requirements through the implementation of the Integrated Quality Management System, oriented to the strategic objectives of the company, the requirements of ISO 13485, 21 CFR 820, and other applicable regulations.

You must disclose any irregularity that occurs in the integrated management system, or process, or that compromises the safe use of medical devices, and report to the general management of the Management indicator and other requested reports.

Last Name, Name

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Tools:

- QT9.
- DISRP.
- Microsoft office suite.

Methods:

- Coordinate complex activities.
- Verification and validation.
- Potential regulatory pathways.
- International Standards.

Skills:

You must know about products, production processes, management of non-conforming products, documentation of the Integrated Management System (SIG), solid waste management, process procedures, environmental aspects, and impacts of the organization.

Contact me for:

- Regulatory control.
- ISO 13485.
- QT9 docs.
- Standards.
- Validation

Decomposition diagram of technical director role.

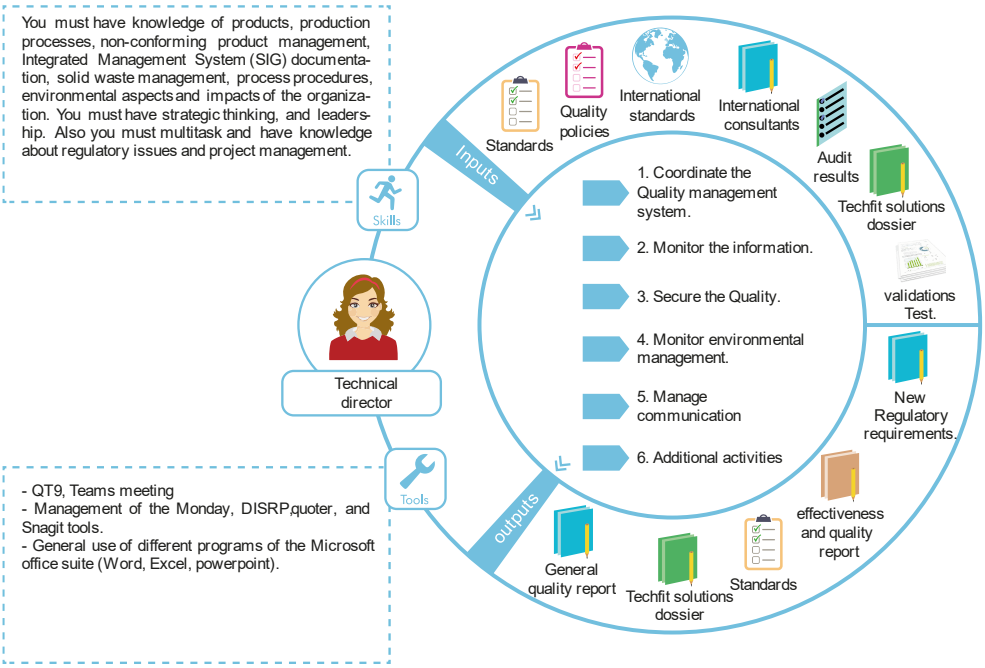

Figure 37 Technical director role

Table 84. Activity 1 for the technical director role.

ACTIVITY 1: Technical director
Coordinate the quality management system.

The purpose of this activity is coordinate and keep the SIG according to the ISO 13485, 21 CFR 820, and applicable regulations.

Steps

S1: Collect indicators: Collect indicators of management of the process for your analysis.

S2: Guide staff: Guide staff on the Quality management system, advise on the construction of documents, lifting of non-conformities, construction of action plans, and corrective, and preventive actions.

S3: Support continuous improvement of the SIG.

S4: Make and analyze the process indicators.

S5: Ensure that the processes necessary for the quality management system are established, implemented, and maintained.

S6: Report to CEO on the performance of the quality management system and any need for improvement

	INPUTS	OUTPUT
Items	✓ Standards ✓ Quality policies ✓ International standards ✓ Company solutions dossier	✓ General quality report ✓ Company solutions dossier

Table 85. Activity 2 for the technical director role.

ACTIVITY 2: Technical director
Monitor the information

The purpose of this activity is the surveillance the information of the company to comply with the standard ISO 13485.

Steps

S1: Monitoring: Raise and monitor the effectiveness of actions from the Technovigilance Committee, Management Committee, and internal and external audits.

S2: Personal data surveillance: Ensure the company's Personal Data Processing Policies.

S3: Define the criteria: Define the criteria for the classification of the information.

	INPUTS	OUTPUT
Items	✓ Standards ✓ Quality policies ✓ International standards ✓ Company solutions dossier	✓ Standards ✓ Effectiveness and quality report. ✓ New regulatory requirements.

Table 86. Activity 3 for the technical director role.

ACTIVITY 3: Technical director
Secure the quality

The purpose of this activity is to ensure that the quality process and manufacturing process must be controlled according to the regulatory requirements.

Steps

S1: Monitor and control: Secure through monitoring and control the traceability of medical devices for the company's activities and surveillance with medical device surveillance programs corresponding to the health authorities.

S2: Maintenance: Guarantee the quality maintenance of the medical devices.

S3: Medical devices manufacturing: Guarantee the medical devices manufacturing, to ensure compliance with the regulatory and quality requirements of medical devices.

S4: Ensure awareness of regulatory and customer requirements throughout the organization.

	INPUTS	OUTPUT
Items	✓ Standards ✓ Quality policies ✓ Audit results ✓ Validation test	✓ New regulatory requirements

Table 87. Activity 4 for the technical director role.

ACTIVITY 4: Technical director
Monitor environmental management

The purpose of this activity is the surveillance of the environmental management in the company taking into account the national and international standards.

Steps

S1: Carry out the procedures: Carry out procedures before the environmental authority and guarantee environmental legal compliance.

S2: Coordinate the environmental management: Coordinate the company's environmental programs.

	INPUTS	OUTPUT
Items	✓ International standards ✓ Standards ✓ International consultants	✓ New regulatory requirements ✓ Standards ✓ Company solutions dossier

Table 88. Activity 5 for the technical director role.

ACTIVITY 5: Technical director
Manage communication

The purpose of this activity is to ensure the management communication of the new regulatory requirements that the company must meet.

Steps

S1: Comply with the procedures: Abide by and comply with the procedures, rules, and regulations of the company.

S2: Staff training: Ensure that permanent training of personnel is carried out and that it is adapted to the needs.

S3: Attend the QPR: Be responsible for the procedures for handling complaints and withdrawing medical devices from the market. As well as the follow-up of the adverse incidents that they present and their report to the health entity.

	INPUTS	OUTPUT
Items	✓ International standards ✓ Standards ✓ International consultants ✓ Effectiveness and quality report ✓ New regulatory requirements	✓ General quality report

Table 89. Activity 6 for the technical director role.

ACTIVITY 6: Technical director
Additional activities

The purpose of this activity is to consider the extracurricular activities that can be carried out by the technical director.

Steps

S1: Provide technical advice to the legal representative: Take into account the characteristics of medical devices and respond to the requirements of current regulations regarding their quality.

S2: Support the selection process: Support the selection process of the company's suppliers and distributors, participate in the structure of the purchasing processes for imported medical devices, and the advising external parties to achieve compliance with the technical and regulatory requirements of medical devices.

S3: Ensure storage process: Ensure that the stored medical devices are in the established conditions, the documentary support, and the records.

S4: Approve storage operations: Approve the procedures for the operations of storage, packaging, delivery, and distribution of medical devices.

S5: Verify records: Verify that the storage and/or distribution records are completed.

S6: Control scheduled maintenance: The maintenance of the storage and/or general process of each area must be assured.

	INPUTS	OUTPUT
Items	✓ International standards ✓ Standards ✓ International consultants ✓ Effectiveness and quality report ✓ New regulatory requirements	✓ General quality report ✓ Company solutions dossier

Workflow technical director role

The process begins by coordinating the quality management system, then the QMS communication management is important. After this, several functions are derived: monitor the information, secure the quality, monitor environmental management, and execute additional activities.
Finally, the technical director must manage the communication to disclose the new rules and regulations to all the company's personnel and generate the conclusions to deliver to the CEO.

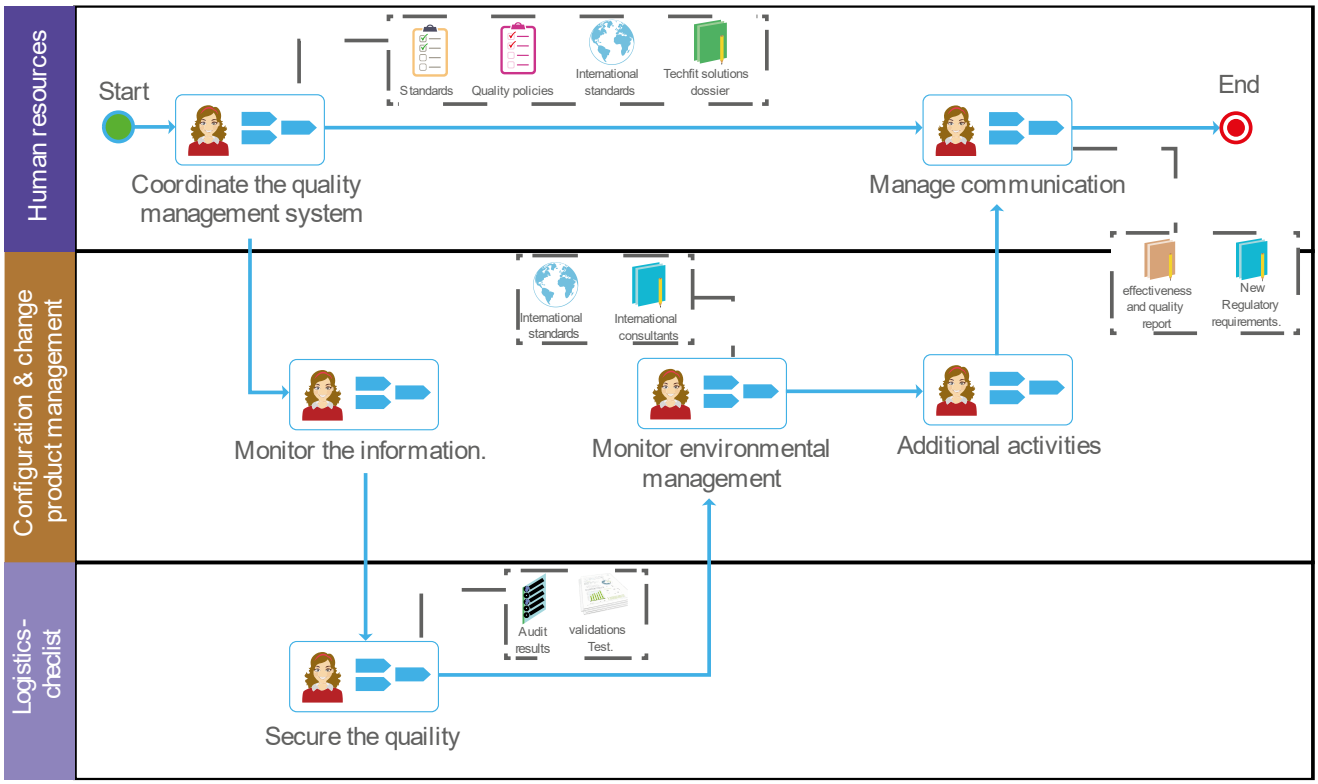

Figure 38 Workflow technical director role

4.14. Account executive role

Table 90. The role description of account executive.

The role description of account executive.

Is responsible for managing the company's customers to keep them satisfied and optimize company performance. It is also responsible for monitoring the user experience.

You must take care of the company's accounts, and review the accounts to see if it is feasible to maintain, increase or reduce the value of sales invoices.

Last Name, Name

Medellín, Colombia

@Company.com.co

+57 (300 000 0000)

Tools:

- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Marketing models.
- Sales strategies.

Skills:

You must have experience dealing with overseas customers for export, understand international trade logistics and negotiation terms, knowledge about the marketing mix, and social media marketing. Also, you must have communication and negotiation skills.

Contact me for:

- Regulatory control.
- ISO 13485.
- QT9 docs.
- Standards.
- Validation

Decomposition diagram of account executive role.

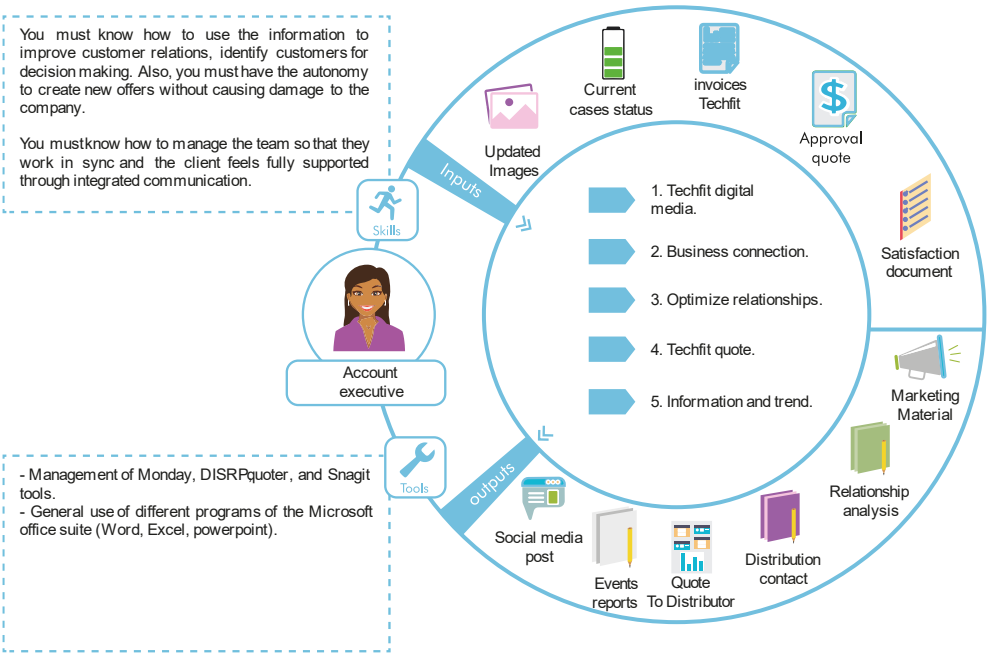

Figure 39 Account executive role

Table 91. Activity 1 for the account executive role.

ACTIVITY 1: Account executive Company digital media	
The purpose of this activity is the management of digital media and marketing and advertising events of the company.	
Steps	**S1: social media updated:** Manage social networks, information disclosure, and company advertising. **S2: Organize Digital and Physic Events:** Organize and search for potential business events to increase business visibility and national and international business connections. **S3: Look for global events:** Identify potential commercial events for the company's participation and thus increase business visibility and international commercial connections.
	INPUTS / **OUTPUT**
Items	✓ Updated images ✓ Social media post ✓ Marketing material ✓ Events reports

Table 92. Activity 2 for the account executive role.

ACTIVITY 2: Account executive
Business connection

The purpose of this activity is to lead the commercial connections of the company with distributors, search for new potential allied companies, and commercial staff.

Steps

S1: Assist Current Distributors: Manage the company's social networks and information disclosure and advertising.

S2: Find New Distributors: Organize and search for potential business events to increase business visibility and national and international business connections.

S3: Distributors Meeting: A control must be carried out with distributors to identify new cases, projects, advances, and commercial improvements to provide a good service in Company solutions.

	INPUTS	OUTPUT
Items	✓ Current cases status	✓ Distributor contact

Table 93. Activity 3 for the account executive role.

ACTIVITY 3: Account executive
Optimize relationships

The purpose of this activity is to maintain active relationships with customers.

Steps

S1: Optimize relationships: You must surveillance all the needs of the clients, attend to the connections between the client and the company, and finally maintain this relationship in a satisfactory manner

	INPUTS	OUTPUT
Items	✓ Satisfy document	✓ Relationship analysis

Table 94. Activity 4 for the account executive role.

ACTIVITY 4: Account executive
Company quote

The purpose of this activity is to create and coordinate the Company quote for the distributors and/or surgeons. In this activity is important to know the approval quote of the cases.

Steps	**S1: Create the Company invoice:** Manage the company's social networks and information disclosure and advertising. *(GRT-SD-198 invoice template).* **S2: Send the Company invoice:** Send the Company invoice to the CEO to close the deal.	
	INPUTS	**OUTPUT**
Items	✓ Approval quote ✓ Invoices Company	✓ Company invoice

Table 95. Activity 5 for the account executive role.

ACTIVITY 5: Account executive Information and trend		
The purpose of this activity is to stay updated according to the new medical devices, trends, and innovative products that Company could create.		
Steps	**S1: Update:** Research and identification of new possible Company product **S2: Plan proposal:** Once you know the international information and trend, you could have a plan proposal for new Company products.	
	INPUTS	**OUTPUT**
Items	✓ Approval quote ✓ Invoices Company	✓ Company invoice

Workflow of account executive role.

You must first carry out and supervise the Company digital media to increase the scope of the company, then you must coordinate the business connection. Once the connection is established, the account executive must optimize the relationship, taking into account the satisfaction documents and improving the relationship between the client and the company.
He is also responsible for making the Company quote taking into account the business plan agreed with the distributor. Finally, keep up to date with the international information and trend

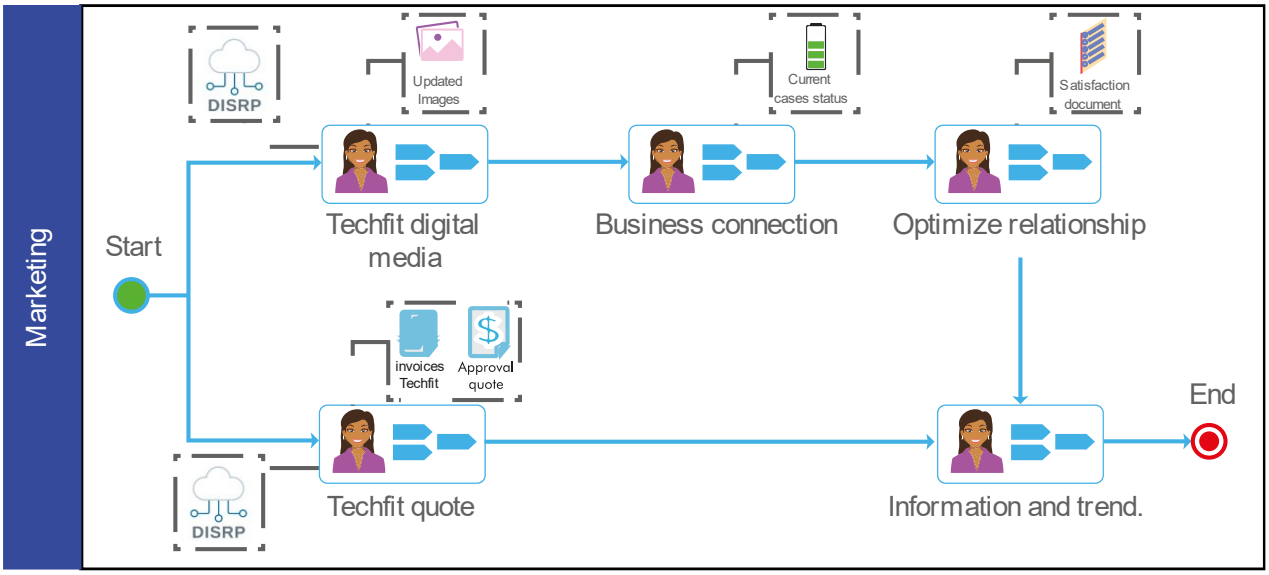

Figure 40 Workflow Account executive role.

4.15. Growth coordinator role

Table 96. The role description of growth coordinator.

The role description of growth coordinator.

Is responsible of keep the company's social media updated and publish content to attract the interest of physicians and potential distributors. Organize digital and physical events where cases and knowledge of Company are shared with the public of interest. Also, look for global events where we can scout for new distributors and partners.
identify key opinion leaders in the global market and help them gain a platform for surgeon training in the use of our products. Be the point of contact with existing distributors and work to organize shipments and quotes, to increase satisfaction and help them grow their market.

Last Name, Name

Medellín, Colombia

@Company.com.co

+57 (300 000 0000)

Tools:

- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Marketing models.
- Sales strategies.

Skills:

You must have experience dealing with overseas customers for export, understand international trade logistics and negotiation terms, knowledge about the marketing mix, and social media marketing. Also, you must have communication and negotiation skills.

Contact me for:

- Distributors contact
- Quotes
- Invoice Company
- DISRP control
- Marketing material

Decomposition diagram of the growth coordinator role.

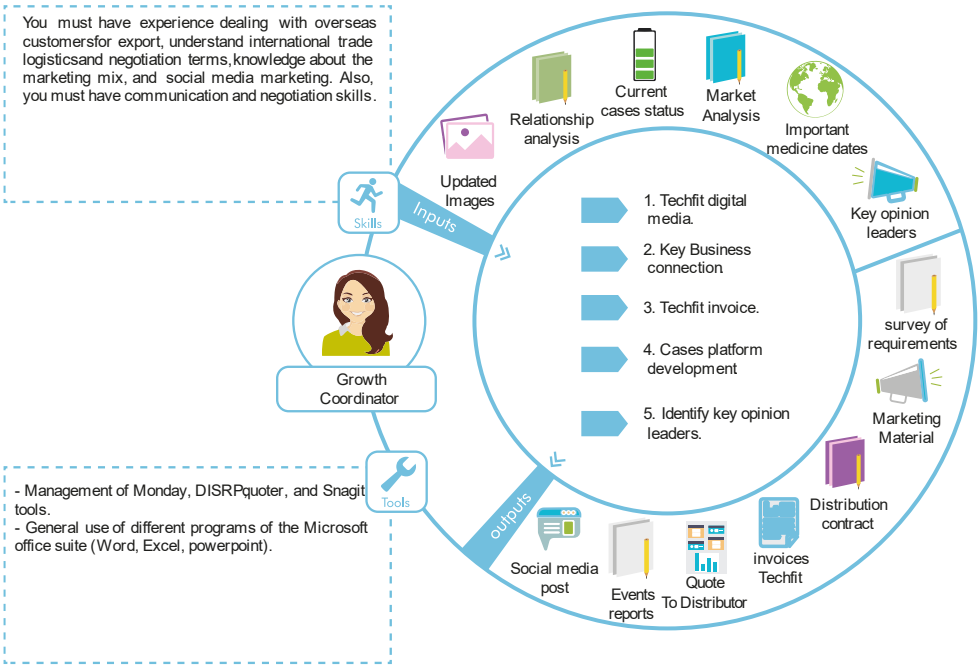

Figure 41 Growth coordinator role

Table 97. Activity 1 for the growth coordinator role

ACTIVITY 1: Growth coordinator Company digital media	
The purpose of this activity is the management of digital media and marketing and advertising events of the company.	
Steps	**S1: social media updated:** Manage social networks, information disclosure, and company advertising. **S2: Organize Digital and Physic Events:** Organize and search for potential business events to increase business visibility and national and international business connections. **S3: Look for global events:** Identify potential commercial events for the company's participation and thus increase business visibility and international commercial connections.
Items	**INPUTS** ✓ Updated images ✓ Important medicine dates ✓ Relationship analysis **OUTPUT** ✓ Social media post ✓ Marketing material ✓ Events reports

Table 98. Activity 2 for the growth coordinator role

ACTIVITY 2: Growth coordinator
Key business connection

The purpose of this activity is to lead the commercial connections of the company with key distributors, and search for new potential allied companies, and commercial staff. Also, to create the news Company invoice for the new distributors and partners.

Steps

S1: Assist Current Distributors: Manage the company's social networks and information disclosure and advertising.

S2: Find New Distributors: Organize and search for potential business events to increase business visibility and national and international business connections.

S3: Key Distributors Meeting: A control must be carried out with distributors to identify new cases, projects, advances, and commercial improvements to provide a good service in Company solutions.

S4: Create the Company invoice: Manage the company's social networks and information disclosure and advertising *(GRT-SD-198 invoice template)*

S5: Send the Company invoice: Send the Company invoice to the CEO to close the deal.

	INPUTS	OUTPUT
Items	✓ Current cases status ✓ Market analysis ✓ Relationship analysis	✓ Distributor contact ✓ Company invoice

Table 99. Activity 3 for the growth coordinator role

ACTIVITY 3: Growth coordinator
Technological surveillance of PSI

The purpose of this activity is to research and coordinate the publication of new articles.

Steps

S1: Technological surveillance: Research the technological surveillance of news technologies and medical devices made in the medical industry, new design processes, manufacturing methods, and companies dedicated to the commercialization of PSI.

S2: Coordinate the publication: Perform the search for journals for the publication of articles that give greater visibility in the medical industry.

	INPUTS	OUTPUT
Items	✓ Relationship analysis ✓ Market analysis ✓ Important medicine dates ✓ Key opinion leaders	✓ Events reports ✓ New publications

Table 100. Activity 4 for the growth coordinator role

ACTIVITY 4: Growth coordinator Cases platform development

The purpose of this activity is to look for improvements and opportunities for the DISRP platform or new platforms that help facilitate the Company processes.

Steps

S1: Support the DISRP processes: Identify improvements and opportunities for the DISRP platform. *(RND-RC-71 DISRP validation checklist).*

S2: Identify new platforms: Identify new opportunities to create and improve the Company processes.

S2: Meeting with the software developer: Socialize the new improvement requirements for the DISRP platform and the new platform.

	INPUTS	OUTPUT
Items	✓ Current cases status ✓ Market analysis	✓ DISRP control ✓ Survey of requirements

Table 101. Activity 5 for the growth coordinator

ACTIVITY 5: Growth coordinator Identify key opinion leaders

The purpose of this activity is to identify new key opinion leaders and generate opportunities for the company.

Steps

S1: Identity: Identify the key opinion leaders to improve the company and update the new opportunities.

S2: Analyze: Analyze the opinion and generate the opportunity for the company.

S3: Socialize: Divulgate the opportunity with the other members of the company to reach an agreement of use or not.

	INPUTS	OUTPUT
Items	✓ Key opinion leaders ✓ Relationship analysis	✓ Events reports

Workflow growth coordinator role

To begin with, he is in charge of managing and creating COMPANY's digital media. then you can carry out the development of the case platform, and from the digital media seek the growth of the company with the business connections. If a new connection is generated, you must create the business invoice together with the CEO and finish the process.

In turn, constant identification of key opinion leaders is also necessary for the work to be considered complete.

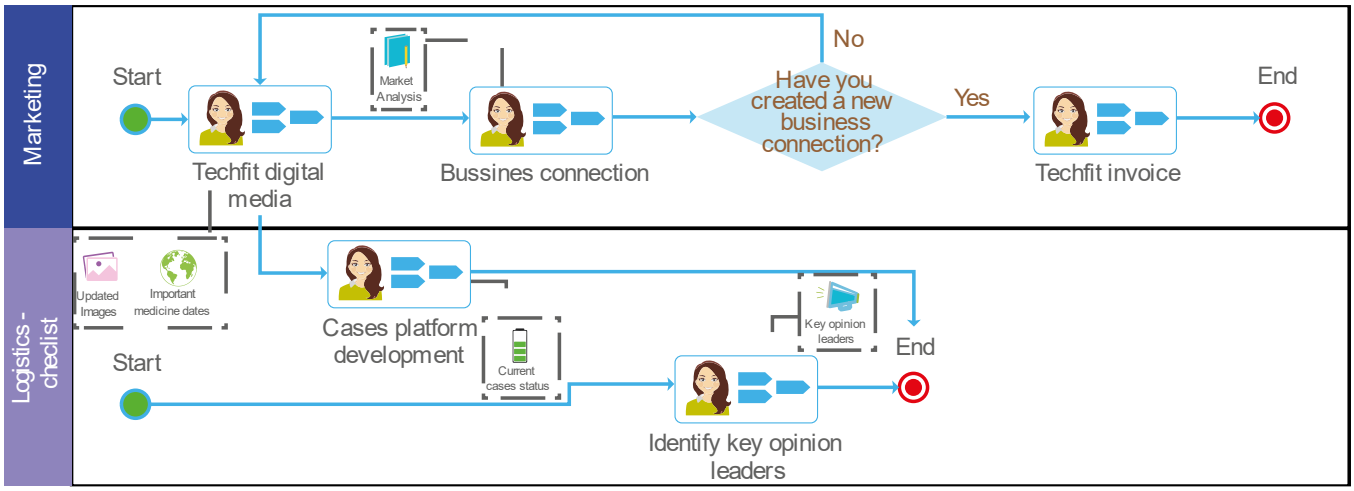

Figure 42 workflow growth coordinator role

4.16. Operational manager role

Table 102. The role description of the operational manager.

The role description of the operational manager.

Leads the processes and compliance with the strategic objectives of the Institution. Manages the design and execution of the company's work plan that responds to the strategic guidelines defined by the management bodies. Ensures the good performance of the Company design procedure, manufacturing, and quality processes.
Promotes and generates inter-institutional relations that contribute to the achievement of the company's objectives. Coordinate the publication of studies and works carried out using this technology.
Ensure compliance with current legislation in the countries where these systems are implemented.
Legally represents the Institution.

Last Name, Name

Medellín, Colombia

@Company.com.co

+57 (300 000 0000)

Tools:

- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Coordinate complex activities.
- Project management.
- Design troubleshooting. techniques.
- Sales strategies.

Skills:

You must have knowledge and experience in designing tools for the development of institutional strategies work plans and budgets. Assertive communication with the workgroup and business partners. Database management. Coordination of work teams and estimation of responsibilities. Knowledge in the development of specialized medical devices.

Contact me for:

- Case assignment
- sales order
- Distributor contact
- Quality policies
- Overview report

Decomposition diagram of the operational manager role.

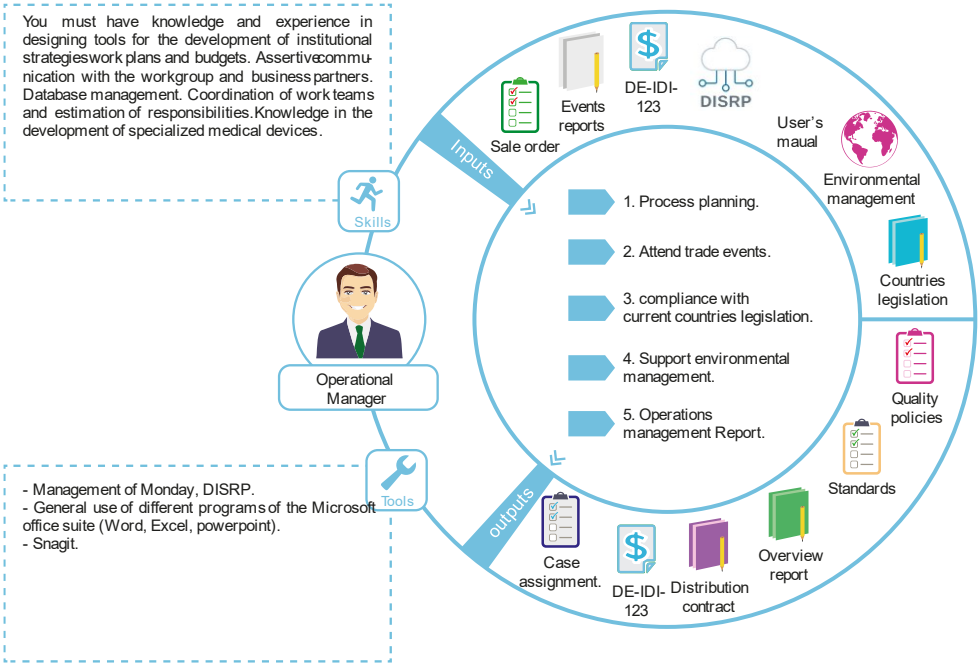

Figure 43 Operational manager role

Table 103. Activity 1 for the operational manager role

ACTIVITY 1: operational manager Process planning

The purpose of this activity is to compliance all process planning of the company to create the Company solutions.

Steps

S1: Case assignment: Receive the cases from the Company coordinator and assign the cases to each designer according to their workload.

S2: Technical direction: Coordinate the design, manufacturing, logistic, and quality process of the Company solutions. If required, you must perform the technical revision to the cases. *(RND-PR-41 procedure for case flow).*

S3: Support process: Follow-up on cases to validate the process of design for manufacturing.

S4: Quality monitoring: Coordinate the quality process for all Company solutions.

S5: Assurance of service proposal time: You are responsible to coordinate and monitor the time compliance of the Company solutions.

S6: Follow-up of agreement dates: You are responsible for the follow-up of agreement dates. *(RND-PR-41 procedure for case flow).*

S7: Case approval: Once the case is complete, you must approve the Company solution. *(RND-PR-41 procedure for case flow).*

	INPUTS	OUTPUT
Items	✓ Sale order ✓ Service request (DE-IDI-123) ✓ DISRP ✓ User's manual	✓ Service request (DE-IDI-123) ✓ Case assignment

Table 104. Activity 2 for the operational manager role

ACTIVITY 2: Operational manager
Attend trade events.

The purpose of this activity is to attend the events that the company requires your assistance to expand the participation of Company in the market.

Steps

S1: Expand the market: Search for new distributors, expand the company, and the contacts,

S2: State of the art: Identify new solutions that can be added to Company solutions, and the technologies CAD/CAM.

S3: Expand the market share: It is important to expand the contacts and the market share.

	INPUTS	OUTPUT
Items	✓ Events reports	✓ Distribution contract

Table 105. Activity 3 for the operational manager role

ACTIVITY 3: Operational manager
Compliance with current countries' legislation.

The purpose of this activity is to ensure compliance with international laws and ensure compliance with them from manufacturing and logistics.

S1: Identify the international laws: Identify the quality process, manufacturing process, and logistics process that can compliance the international laws.

Steps	**S2: Create standards for the company:** Once, you identify the international laws, you could create the quality standards for the company. *(RND-EX-118 Template for standards)*

	INPUTS	OUTPUT
Items	✓ Countries legislation	✓ Standards

Table 106. Activity 4 for the operational manager role

ACTIVITY 4: Operational manager
Support environmental management.

The purpose of this activity is to support the environmental management of the countries to comply with the environmental standards.

Steps	**S1: Identify the environmental standards:** Search solutions for the environmental standards of the countries that can improve the process. **S2: Create the Quality policies:** Once, you identify the environmental standards, you must create the quality policies for the company.

	INPUTS	OUTPUT
Items	✓ Environmental management	✓ Quality policies

Table 107. Activity 5 for the operational manager role

ACTIVITY 5: Operational manager
Operations management report.

The purpose of this activity is to generate the reports and meetings with the CEO for the socialization of the monthly report on the general operations of the company.

Steps	**S1: Report:** You must create the general report of the operations carried out during the stipulated time to deliver it to the CEO. **S2: Create the Quality policies:** Once, you identify the environmental standards, you must create the quality policies for the company.

	INPUTS	OUTPUT
Items	✓ Environmental management	✓ Quality policies

Workflow operational manager role

The most important activity of the operational manager is the process planning from the sales order, DE-IDI-153, and the User´s manual that you can find on DISRP, then you must check that processes are ok until finish the Company solution for each case. If processes aren't ok the operational manager must restructure the process planning.

In another way, is possible that the operational manager attends trade events and generates the reports of events with the growth coordinator. Also, he does the compliance with current countries' legislation and finally supports environmental management.

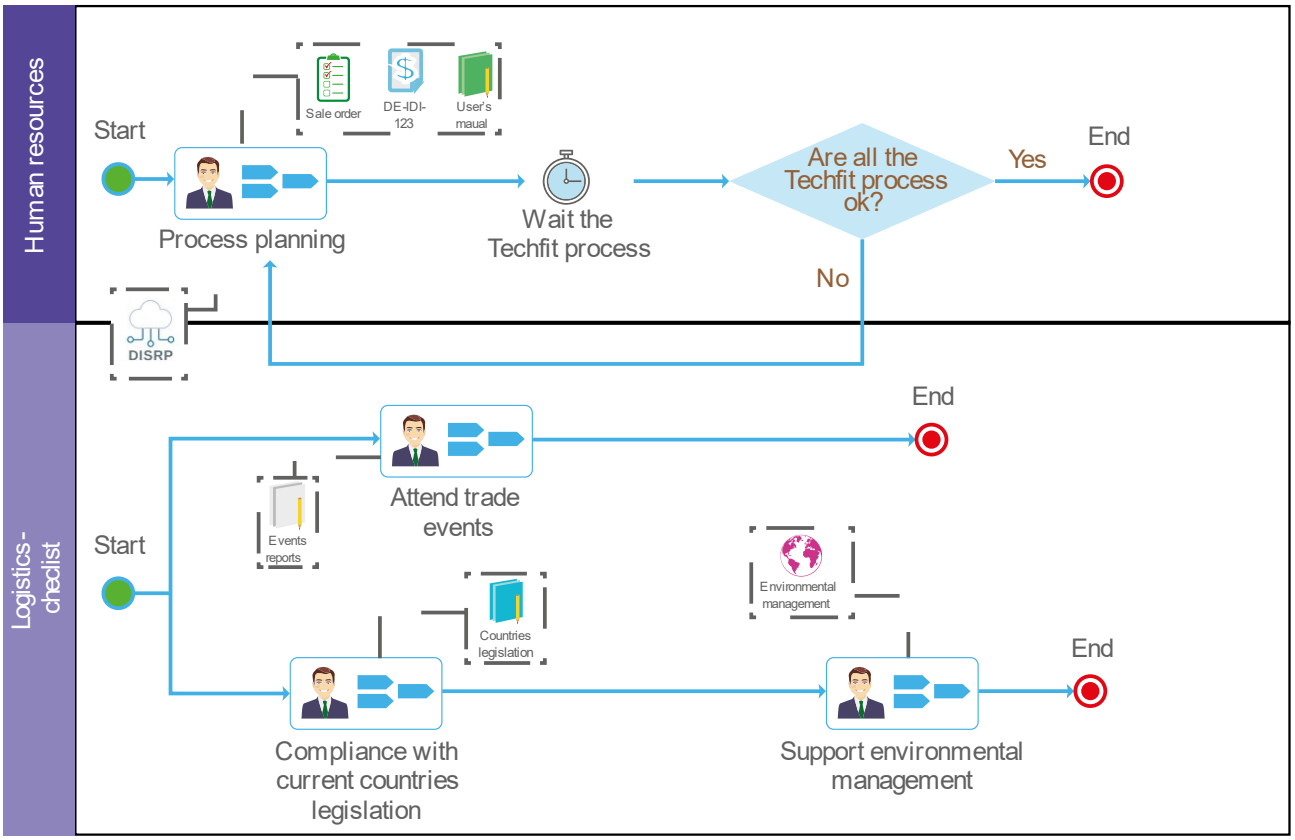

Figure 44 Workflow operational manager role

4.17. CEO role

Table 108. The role description of the CEO

The role description of the CEO.

You have the highest responsibility within a company. His global vision of the company allows him to define with great accuracy and precision the vision, purpose, and mission of the organization, fundamental premises that guide Company's daily activity.
Maintains relations with investors and shareholders, identifies opportunities, sets priorities by periods, organizes the company's calendar, and defines the company's global strategies.

Last Name, Name

Medellín, Colombia

@Company.com.co

+57 (300 000 0000)

Tools:

- DISRP.
- Monday.
- Snagit.
- Microsoft office suite.

Methods:

- Project management
- Design troubleshooting techniques.

Skills:

Recognize the work of your team, skills to generate a good work environment, promote a solid organizational culture, act decisively, even if you do not initially satisfy the claims of other employees, trust your staff, and create confidence to achieve better development and identify new tools and skills for the growth of the company.

Contact me for:

- Distributors contact
- Quotes
- Invoice Company
- DISRP control
- Marketing material

Decomposition diagram of the CEO role.

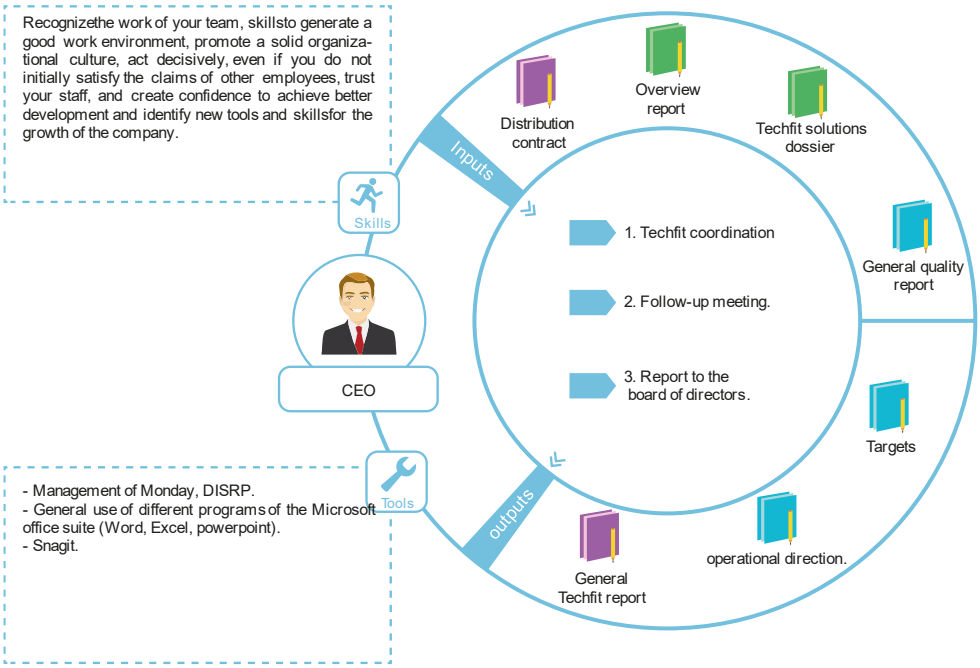

Figure 45 CEO role.

Table 109. Activity 1 for the CEO role.

ACTIVITY 1: CEO Company coordination.	
The purpose of this activity is to create and coordinate the operational direction for the company according to the company targets.	
Steps	**S1: Create the company targets:** Create the general objectives of the company for the fulfillment of the short and long-term goals. **S2: Company coordination:** Direct the staff to meet the proposed objectives.
	INPUTS / **OUTPUT**
Items	✓ Overview report ✓ Company solutions dossier / ✓ Targets ✓ Operational direction

Table 110. Activity 2 for the CEO role.

ACTIVITY 2: CEO Follow-up meeting
The purpose of this activity is to coordinate the meeting with the roles and the board director for the follow-up of the company.

Steps	**S1: Meeting with the managers:** To follow up, receive the report of the activities and give the work plans for the operation of the company **S2: Meeting with the board director:** To receive the new targets for the company

	INPUTS	OUTPUT
Items	✓ Overview report ✓ Company solutions dossier ✓ Distribution contract ✓ General quality report	

Table 111. Activity 3 for the CEO role.

ACTIVITY 3: CEO
Report to the board direction

The purpose of this activity is to report the general overview, marketing results, new proposals, and other reports of the company.

Steps	**S1: Create the general Company report:** Once each manager delivers the general report of their responsibilities, you must create the general report to deliver to the board of directors **S2: Deliver the general report:** Finally, the general report is delivered and the new guidelines for the company are received.

	INPUTS	OUTPUT
Items	✓ Overview report ✓ Company solutions dossier ✓ Distribution contract ✓ General quality report	✓ General Company report

Workflow CEO role

First, the CEO must have the Company coordination taking into account the overview report and the Company solutions dossier, then he has the follow-up meeting and finally, perform the report to the board of directors.

This process is cyclical, so it continuously performs these three activities.

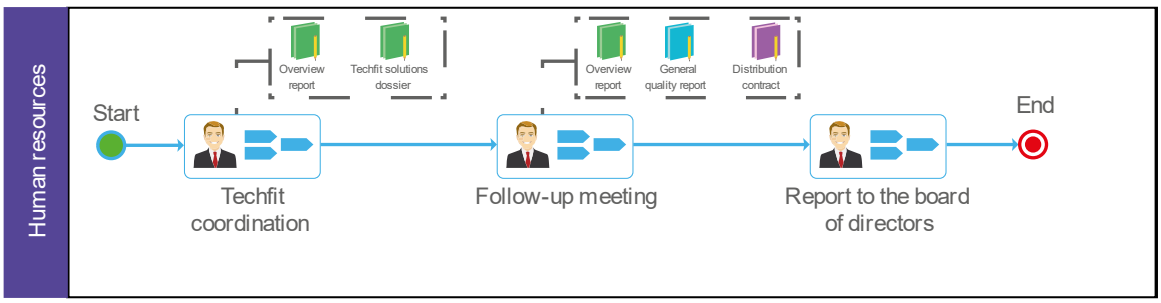

Figure 46 Workflow CEO role.

Hallazgos

relacion de nodos - reduccion

Costo =

Calidad =

Tiempo =

A través del diseño de procesos se modificaron las practicas que mejoran impactar los KPI en ciertas medidas
Que esto reduce tantos cosas
Como lo logre, se recomendo un flujo de procesos. Reducción de tiempos

Sugerencias continuar el proceso de mejora, mejorar en tanto y tal

Para el diseño, cual fue la pertinencia en cuanto al proceso de diseño contestada desde la hipótesis cualitativa,
Los diseñadores no estaban formados para el diseño de manufactura aditiva influyendo en reprocesos y demás.
Este proyecto se baso en establecer unas practivas que pueden mejorar los procesos y capacidades de mejorar estos procesos

El estudios sugiere que la creación de flujos de trabajo establecidos permite mejorar los procesos organizativos de las empresas

Se analizaron tantos casos para el desarrollo de estos dispositivos.

Preguntale a melisa por los KPI.