Regulatory Affairs and Quality Assurance of Medical Device

A Dissertation Report

submitted in partial fulfilment of the requirement

for the award of degree of

Masters of Technology

in

Biotechnology

under the guidance of

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and

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Certificate

*This is to certify that the work which is being presented in this report entitled '**Regulatory Affairs and Quality Assurance of Medical Device**' submitted in partial fulfilment of the requirements for the degree of Masters of Technology in Biotechnology by **Deepnita** (Roll No. 801704009) is a bonafide record of work carried by her under my supervision and guidance at Stryker Gurgaon.*

This is further certified that this work has not been submitted elsewhere for any degree or diploma.

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Candidate Declaration

I hereby declare that the work being presented in the M. Tech dissertation entitled "**Regulatory Affairs and Quality Assurance of Medical Device**" has been carried out by me during the period July 2018 to July 2019, under the guidance of Mrs. Jyoti Dhaniyasth, Stryker Team Lead and Dr. Vikas Handa, Assistant Professor, Department of Biotechnology, Thapar Institute of Technology, Patiala. Further, I declare that I have not submitted the matter embodied in this dissertation for the award of any other degree or any other qualification of any university or examining body in India/elsewhere.

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Place: Patiala

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Signature: Deeprita

Date: 26/09/2019

Abstract

The regulatory affairs (RA) department of a Medical Device company is responsible for obtaining approvals for new products and ensuring that approval is maintained for as long as the company wants to keep the product on the market.

The department serves as the interface between the regulatory authority and the project team. It is also the channel of communication with the regulatory authority as the project moves forward. The goal is to correctly anticipate the needs of the regularity authority in order for the product to seek approval.

It is the responsibility of RA to stay on top of current legislation, changes, guidelines and other regulatory intelligence. The RA department plays an important role in helping the project team understand the regulatory needs and work accordingly.

The purpose and principles of RA were studied, and the framework of legislation was understood that helped in understanding the process of working with project teams and interacting with the regulatory health agencies.

An important proactive task of the RA is to provide input when legislative changes are being discussed and proposed. European Union – Medical Device Regulation (EU-MDR) is the new legislation that will come into force in May-2020. The EU's current Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC) are being replaced by EU-MDR. In order to understand the development process and to discuss the divergence of guidelines, the detailed study of Medical Device Directive is being done. Further, in-depth study of new directive *i.e*. EU-MDR is being done to know the new requirements for the new devices intended to be marketed in Europe (EU).

Also, determination of EU Importer was done under EU – MDR Project to identify the supply chain in Corporate Division.

In **Stryker Orthopedics Division (Joint Replacement)**, three requests of regulatory documents for country specific registration purposes were handled in Global Product Registration Database (GPRD). This database is the platform to request and exchange regulatory documentation between Design Division RA and Distribution Division RA for registration purposes.

PTC Integrity Lifecycle Manager (software) is a system that was used to create templates for design and risk control documents within Stryker Hardware Instance Lifecycle Manager. The use of this

software is required for all new product development products projects to increase accuracy and efficiency.

Divisional Customer Complaints process and the relationship between the associated procedures were handled which includes complaints associated with manufactured medical devices by **all Joint Replacement** manufacturing facilities. Complaint Intake by following the CIC protocols, its management by following the CMC protocols and further Investigation was done by following the PAC protocols.

In Orthopedics Division, all complaints are handled using **Trackwise** database. This is used to manage complaints ("Product Inquiries"), Medical Vigilance Reports ("MDVs"), and Medical Device Reports ("MDRs") associated with medical device.

Keywords: EU – MDR, Stryker Orthopedics Division, GPRD, PTC Integrity Lifecycle Manager, Trackwise database, Medical Device Report, Medical Vigilance Report

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Abbreviations

EU	European Union
MDD	Medical Device Directive
MDR	Medical Device Regulation
CFR	Code of Federal regulations
EP	European Parliament
Council	Council of the European Union
ISO	International Standard of Organization
CAs	Competent Authorities
NBs	Notified Bodies
US – FDA	United States - Food and Drug Administration
CE	European Conformity
CS	Common Specifications
UDI	Unique Device Identification
IVDR	In Vitro Diagnostic Regulations
RMF	Risk Management File
QMS	Quality Management System
IFU	Instruction for Use
MDR	Medical Device Report
MDV	Medical Vigilance Report
CMC	Complaint Management Centre
CIC	Complaint Intake Centre
PAC	Product Assessment Centre

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Introduction

Regulatory Affairs

In today's world, medical devices and drugs are one of the most strictly regulated entities. The essential principles and ideas behind the laws helps us perceive the importance of compliance.

The general legislative framework is focused on creating regulations and identifying the core legal texts that are further used to regulate such products in the European Union (EU) and the United States of America (USA).

The protection of public health is the ultimate aim of the regulation.

Although this seems an easy goal, its action needs the event of intensive and complicated laws.

To achieve its goal, the regulation is dependent on several core principles and concepts. Its core principles include –

- Safety
- Efficacy
- Intended Use
- Risk / Benefit
- Quality

Product safety is a basic requirement for all merchandise. Ideally, the merchandise ought to do no damage. Thus, the laws are devised in a way that suggest the developers or manufacturers to follow certain guidelines to ensure their product is safe to use.

Efficacy is another challenge in achieving the goal of regulation. The principle of efficacy is to evaluate the effectiveness of the product.

Intended use is defined as the purpose of the product.

Risk / Benefit is the ratio of risk: benefit wherein benefit should be higher than its risk. Although, there should be no risk but it is only ideally possible. So, various steps are followed in order to minimize the risk and maximize its benefits. The main point to be taken care in this whole procedure is to always minimize the risk so that there is no severe harm or death of the patient.

Quality: It is the final element that regulation addresses. Quality of the product means conformity with standards, purity and stability. Two characteristics are also associated with this quality product. They

are safety and fitness. Also, reliability and consistency of the product is always expected.

The Importance of Regulatory Affairs

Modern market conditions have become quite brutal. Every company faces an immense pressure to launch its product into the market in minimum time.

It has become very important for any regulatory affairs professional to get the details right the very first time. It is also a key factor for the company to ensure cost-effective utilization of its resources. This department acts as the first point of contact between the company and government authorities. Companies with knowledgeable and scientifically accurate representatives have higher chances of getting a response from the authorities than the ones without these qualities.

Commercializing a product after it is developed has become a highly regulated affair. Any device that has to enter the market undergoes rigorous scrutiny conducted by both the government authorities and company's internal checks. Regulation affects everyone included in the cycle of a product. Even patients who are at the receiving end must receive regulated product to ensure their safety.

The interaction of Regulatory Affairs with other company entities has been diagrammatically shown on the subsequent page.

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Source: https://www.raps.org/

Figure 1: Interaction of Regulatory Affairs with other company entities

Regulatory Affairs department is linked with the company, its product and regulatory authorities.

MDD – Medical Device Directive

The **Medical Device Directive** (Council Directive 93/42/EEC) of 14 June 1993 refers to the medical device industry. This directive has the guidelines for medical device to comply with the rules and instructions relating to medical devices within European Union. Thus, manufactures needs to follow all the rules in order to legally sell the product in the EU market. The indication of the product conformity to the MDD is the CE mark on the device. The product must have CE marking to sell legally in the EU market.

MDD contains 23 articles and 12 annexes.

Manufacturer must be aware of the basic fundaments of medical device before starting its conformity process. They are:

The device satisfying one of the following definitions*:

a) **'medical device'**: means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification of the anatomy or of a physiological process,
- Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

b) **'accessory'**: This is not a device but is used together with a specific device. This enables the main device to fulfill its intended purpose as demonstrated by the manufacturer of the device. Without the help of accessory, device may not give full result as per intended.

The Manufacturer

The person who is legally responsible for the product's whole lifecycle from its production to its marketing. Product lifecycle includes designing of the product, manufacturing, packaging and labelling of a product before it has come in the market. The whole responsibility is taken up by the legal

authorized person, regardless of whether these operations are carried out by that person himself or by a third party on his behalf.

The device risk classification

The risk classification of device is done by following the rules of Annes IX of the Directive or its support documents meddev latest version.

There are now 6 risk classifications of EU MDR*:

a) Risk Class I
b) Risk Class I plus measuring function
c) Risk Class I plus sterilization
d) Risk Class IIa
e) Risk Class IIb
f) Risk Class III

*Source: Regulation (EU) 2017/745

Once these three points have been covered, the compliance process begins.

To start the compliance process, conformity assessment procedures are given on the basis of device risk classification.

Compliance requires:

1) QMS (ISO 13485);

2) Technical file;

3) Notified body for auditing and certificate

4) Country specific authorized representative selection for regulatory affairs

The manufacturers shall comply with all the set requirements using EU Standards, and EU Notified Body shall also be in compliance with the laws of directive.

EU - MDR – European Union Medical Device Regulation

Europe's new Medical Device Regulation (MDR) will bring substantial changes to the way medical device manufacturers bring their devices to the European market, and how they maintain compliance throughout the product's life cycle.

The European Single Market comprises 28 Member States of the European Union (including the United Kingdom), the European Economic Area (Iceland, Liechtenstein, and Norway) and, through bilateral treaties, Switzerland and Turkey. It is the largest single market with a wealthy, aging population of over 500 million consumers.

Free movement of goods is one of the difficult tasks of the European Single Market. To enable this free movement concept, a product allowed on the market in one-member state will also be allowed on the markets of other member states. The 2016 version of the Blue Guide on the implementation of EU products lists three conditions that must be met for goods to move freely:

1. Essential requirements for the products involved must be defined.
2. Methods must be established to describe how product compliance with the requirements is addressed.
3. Mechanisms to supervise and control the actions of all economic operators and others involved in the manufacturing and distribution of the products must be created.

These directives defined Essential Requirements and introduced harmonized standards, helping to demonstrate conformity.

Product safety and its quality manufactured in or imported into Europe is maintained as per the standards.

Compared to the MDD, the MDR promotes a shift from the pre-approval approach to a life-cycle approach. This life-cycle approach includes post market surveillance *i.e.* monitoring of the safety and efficacy of the product even after it has been released in the market. While pre-approval approach is limited to the CE marking of the product but does not include pharmacovigilance.

The compliance of all devices with Essential Requirements has to be reassessed, with reference made to current standards and state of the art. This means there will be no grandfathering.

The main concepts introduced in the MDR described in more detail are:

1. The complete overhaul of EU database (EUDAMED). Introducing UDI and international nomenclature on medical devices as well as on incidents (Chapter 3 and Annex VI).
2. The inclusion into the scope of products without a medical purpose (Annex XVI).
3. Supply chain regulation that obliges each entity in the supply chain to check compliance of the previous supplier. (Chapter II).
4. The introduction of a special procedure for NBs for certain high-risk devices. (Article 54).
5. The introduction of manufacturers' liability specific to medical devices and in line with the Liability Directive 85/374/EEC. Authorized Representatives will be jointly and severally liable for the devices they represent. (Articles 10(16) and 11(5) respectively)
6. Substances that are carcinogenic or that have other potential high-risk effects on the human body can only be used together with a strictly defined justification (Annex I, Section 10.4).
7. The introduction of strict rules for clinical investigations and alignment to the Clinical Trials Regulation. (Chapter VI, Articles 62-82).
8. The introduction of detailed rules for the execution and the results of Post-Market Surveillance and Post-Market Clinical Follow-up.
9. Reprocessing of single-use devices is only allowed under specific conditions – permission by the member state is one of them. (Article 17).
10. Rules for devices produced in hospitals to be used exclusively for its own patients have been added. (Article 5(5).

11. The rules for designation of NBs have tightened. These are provided in Chapter IV, Annex VII and Annexes IX to XII. Procedures for vigilance and post-market surveillance are described in more detail, and the fact that they have to be used for ongoing conformity assessment of the device are given in detail. (Chapter VII)

The introduction of new Regulation gives more transparency of standard data. EU database gives better customer satisfaction and enhanced product quality.

To understand the gap in between the MDD and EU – MDR, thorough Gap Analysis was done by analyzing the similarities and differences.

Project - Gap Analysis of MDD & MDR

Introduction

Medical Devices Regulation is the new regulation of Europe. The new European device regulation has been approved and is going to apply from 26th May 2020, all medical device manufacturers need to follow the guidance on how best to prepare.

A vital step is to do the gap assessment in detail to understand the current potential and future requirements. This analysis should include product that are already in market as well product that are in development stage. Cost prediction and resources required to meet the new regulation requirements is done here. The result predicts impact of changes on profitability of the product. This work is very time consuming and so making early action is always fruitful.

Another important step is to identify the risk class of the product. Technical files, QMS, labels and quality check is required to do the classification of device. Compliance is determined by then, providing potential for valuable market differentiation.

The key changes to MDR are –

- There is new classification rule for the devices with software.
- New classification is introduced. All medical devices are classified into classes I, IIa, IIb or III according to the intended use and risk profile
- AIMD + MDD = MDR
- Clinical evaluation and its investigation is extensive.
- Labeling, technical documentation and clinical data are updated
- Biological process is also considered now *i.e.* ADME in general safety and performance requirements
- QMS, PMS, and PMCF are now in detailed version are more emphasized.
- UDI is more strengthened
- EUDAMED is new platform for public access.

- Liability for defective product and compensation is on manufacturer now.

Pre-Approval

- Four (4) device classifications
- New “clinical evaluation consultation procedure” for all class III and certain Class IIb devices
- Mandatory clinical investigations for implantable devices and Class III devices with few exceptions
- Common [Technical] Specifications (CS) to be devised and followed for product groups

Post-Approval

- Centralized Post Market Surveillance System (PMS) for all devices classes
- New and different reporting requirements

Post-Market Surveillance, Vigilance and Market Surveillance have been updated – More stringent rules applied for manufacturers to meet the quality, performance and safety of devices placed on the market:

— Post-Market Surveillance (PMS) Plan.

— Periodic Safety Update Report (PSUR)

— New centralized databases (EUDAMED)

Quality Management System (QMS) Requirements:

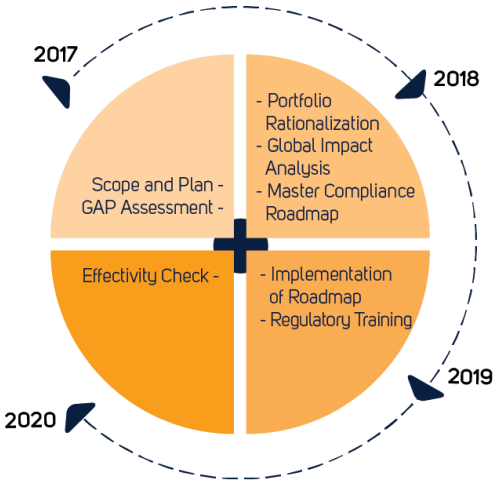
- Greater emphasis and detailed QMS responsibilities
- Legal Manufacturer
- Person responsible for Regulatory Compliance- a new provision with explicitly defined
- Qualification requirements- specific education, training and experience
- Responsibilities- conformity of device verified before product release, technical documentation are kept up-to-date, PMS obligations are complied with, etc.

- Provision for ability to make decision

Transition Stage

The Medical Device Regulation was officially published on May 5th 2017 and came into force on May 25th 2017. Already approved medical devices have a transition period of three years until May26th 2020 to comply the requirements of EU MDR.

The timeline is pictorially depicted in Fig: MDR Timeline on the subsequent page.



Source: https://www.qservegroup.com/de/eu-mdr-expert

Figure 2: MDR Timeline

Applications of Gap Analysis

- To know the New Regulatory Requirements
- To understand Pre-Market Clinical Data Requirements
- To get Post-Market Reporting Requirements
- To acknowledge UDI & Distribution Channels
- To update QM System and Manufacturing
- To know the Changing Notified Body Role

Hence, gap analysis helps in understanding what steps we must take to meet requirements of the EU Medical Device Regulations, and consequently helps to stay informed, be prepared, identify opportunities and implement in time.

Conclusions

- The gap assessment is a crucial step for manufacturing industry to ensure compliance wuth the new EU device regulations. This step should be initiated in the product development phase without any delay.
- Key challenges of this transition should be focused. Challenges include mainly the key changes. They are reclassified and up-classified devices, elevated testing requirements, Increase in demand of notified body, however less number available and more strengthened post market surveillance.
- Safety and performance requirements has nearly doubled compared to the MDD regulation and EU MDR is four times longer than MDD.
- The MDR includes a lot of new and detailed information on clinical areas and does detailed examination of the Regulation.
- A medical device is ready to place in the market with CE mark certificate after addressing all the changes and complying with rules of MDR.

Project - Determining EU Importer – MDR Project

Introduction

EU Importer - EU entity that first makes a device available on the Union market = First EU entity to own a finished medical device or accessory when it is first received in the EU.

- **Finished Medical Device** - A medical device or accessory released after production within its final packaging, with its final labeling, if applicable after sterilization for products intended to be made available in sterile condition, with defined final inspection passed successfully, inconformity in all aspects of its technical specifications as defined in the Technical file.
- Medical device or accessory should be at the status to be made available to end-users and to be used without additional operations or inspection aiming to ensure product quality or performance.

EU Importer is different from manufacturer. It is a part of Economic Operator in MDR.

- **Economic Operator (EO)** – It is a Supply chain under EU – MDR which includes Manufacturer, European Authorized Representative (EAR), Importer and Distributor.
  Depending on Supply Chain set up, EOs may have more than one role.

Economic Operators are specifically regulated under the MDR, while the MDD do not provide any rules regarding their role or obligations.

Objective

The objective of this project is to identify all finished medical devices and accessories that are imported into the EU by Stryker European Supply Chain Services (ESCS) from either a Stryker or non-Stryker supplier.

The purpose of this is to define and identify the Stryker Economic Operators that are involved in the EU supply chain process (Stryker Importers, Distributors, EARs)

Information Required**:**

1. List of all saleable products (including medical devices, accessories and also non-medical products e.g. spare parts) extracted from Venlo Oracle r11 ERP system
2. Division master file attribute lists from the following divisions:

a) CMF

b) Endo

c) Instruments

d) Joint Replacement

e) Medical

f) NV

g) Spine

h) SSS

i) T and E

Procedure

- MDR data was extracted from Venlo Oracle r11 ERP System
- Division master file attribute lists from MDR SharePoint was downloaded
- Cross comparison of the catalog numbers of files using VLOOKUP (to map suppliers outside EU and EU importers) was done
- For identical match, entered appropriate EU importer entity in file 2 for all divisions
- If no match found, highlighted for further investigation
- Done for all divisions

Result

Table 1: List of identified medical devices for all nine Stryker divisions

S. No	Division	Total No of Catalog Numbers	Identical Match Found	Identical Match Not found
1	CMF	287	219	68
2	Endo	1,850	851	999
3	Instruments	2,516	2,053	463
4	Joint Replacement	82,861	8,579	74,282
5	Medical	48,639	400	48,239

6	NV	407	255	152
7	Spine	48,539	1,154	47,385
8	SSS	21	19	2
9	T and E	14,539	2,651	11,888

This table contains total catalog numbers for all the divisions and corresponding to it, identical match found for them from the Master Attribute File. Catalog Numbers which are not identical are sent to respective division for further investigation.

Thus, all the discrepancies are identified and cleared from the database successfully.

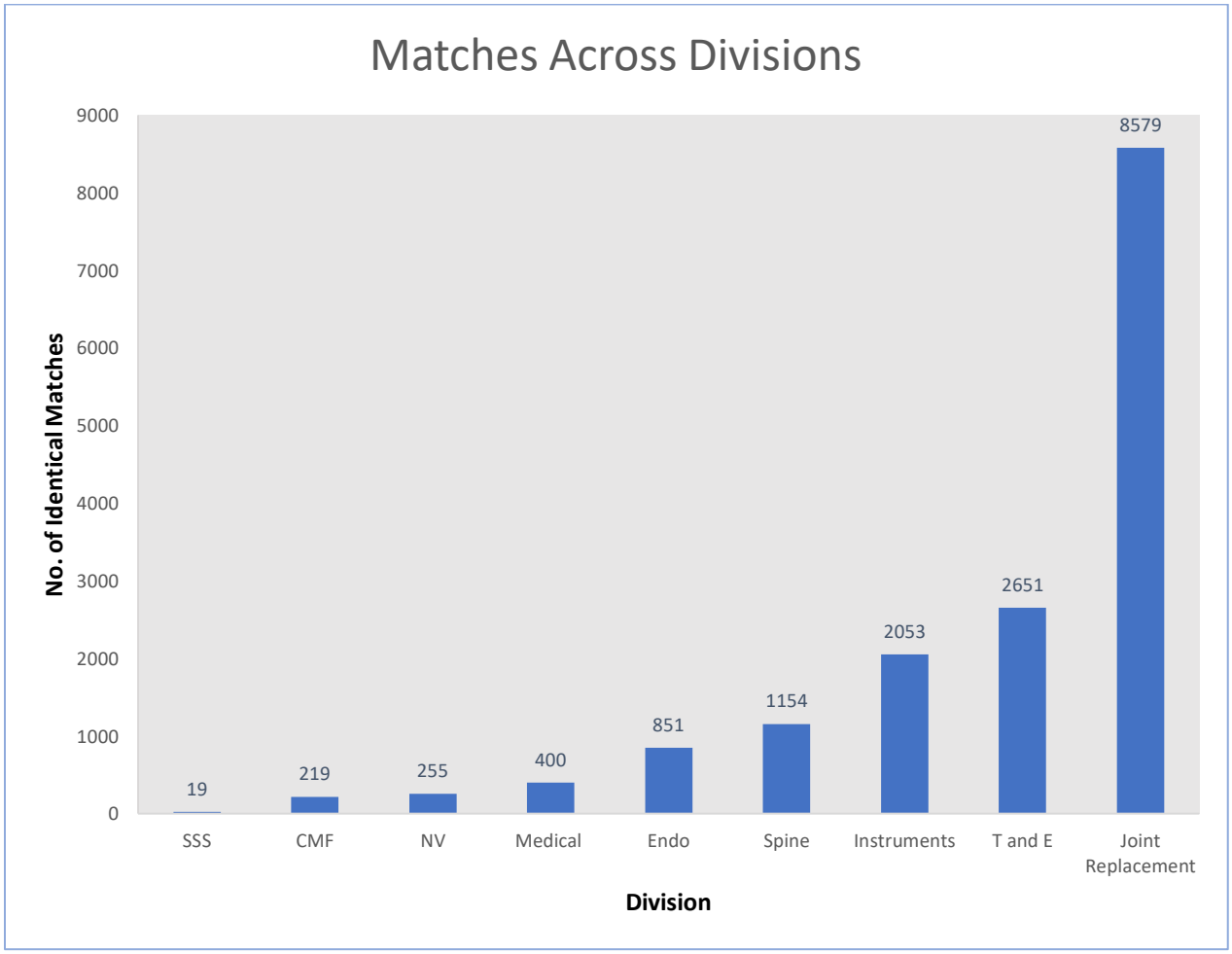


Figure 3: Representation of every Identical match data for respective division

Maximum identical data is found in Joint replacement while SSS has the least perfect match. This shows Joint Replacement has minimum discrepancies.

Conclusion

Cross compare activity was done successfully. Thus, mapping of EU Importer was done correctly, and unknown suppliers' data was highlighted for further investigations**.**

Orthopedics / Joint Replacement (JR)

Introduction

It is a division at Stryker that spans instruments related to **Hip and Knee Implants.**

Hip replacement implants mainly include primary and revision surgery device that are designed in many different ways to provide implants variants and instruments associated with it.

Osteoarthritis in the hip joint is the most common reason for hip replacement surgery.

However, a hip replacement surgery may also be suggested for:

• Rheumatoid arthritis (causing pain, firmness and swelling)

• Osteonecrosis (leads to joint bones death)

• Damage to the hip joint

• Certain tumors that break down the joint

Affected parts of a hip joint are removed by the surgery and human-made parts designed to move similar to a joint are used to replace them.

The goal of hip replacement surgery is to:

• Ease pain

• Assist the hip joint in its activities

• Make movements, like walking, easier

For example: Accolade II Femoral Hip System – It's a hip Implant that provides mobility to the patient. It is made up of new technology that gives biocompatibility to the body and consequently provides very less or no allergic reaction.

Source: https://www.stryker.com/us/en/portfolios/orthopaedics/joint-replacement.html

Figure 4: Accolade II Femoral Hip System

It is a morphometric wedge femoral stem

While in case of knee, partial of total knee replacement is done. It can be primary surgery or revision surgery of the patient. As per the convenience and types of injury, different types of knee implants variant are manufactured and associated instruments. New technology is used for the manufacturing of the device which includes biocompatibility to the human body.

The knee is the largest joint in the body and is central to nearly every routine activity.

It consists of 3 main bones:

– The femur

– The tibia

– The patella

Knee pain is most commonly caused by brushing away of the joint's cartilage lining. In this scenario, the bones rub against each other, and that causes crucial pain and swelling. Osteoarthritis is the most common cause.

A knee replacement removes the diseased bone-ends and resurfaces them with a combination of metal and plastic components.

The goal of Total Knee Replacement (TKR) surgery is to:

• Relieve pain

• Restore movement

For example: Triathlon Total Knee System variants are the category of device which is used for total knee replacement in either primary surgery or revision surgery. This device promotes natural mobility of the patient's knee and allows it to move in circular motion. It helps in relieving pain and restoring its function. The cement less fixation of this devices gives an ease to the doctors also in fixing it in the bone of patients.

Source: https://www.stryker.com/us/en/portfolios/orthopaedics/joint-replacement.html

Figure 5: Triathlon Total Knee System

This is an implant designed to replace complete damaged knee of the human body to restore its function.

Project – Handling Requests on Global Product Registration Database (GPRD)

Introduction

A System used by Stryker to request and exchange regulatory documentation between Design Division RA and Distribution Division RA for registration purposes.

Source: GPRD Portal

Figure 6: Screenshot of login page

It is the page where we need to login with the provided password and user ID to start the process.

When should GPRD be USED?

- To request **country specific registration documentation** not already included within Stryker documentation platforms or repositories such as Global RADAR.
- To request information to address registration deficiency notifications from Competent Authorities.
- The designated RA Representative must complete a Regulatory Plan for Implants as required during all new product development, product acquisition, line extension, product modification, and Concept Development processes

Objective

- **GPRD Request 1** -Label and Shelf Life Report (Brazil)
- **GPRD Request 2 -** IFU (Canada)
- **GPRD Request 3 -** Updated CE (Switzerland)

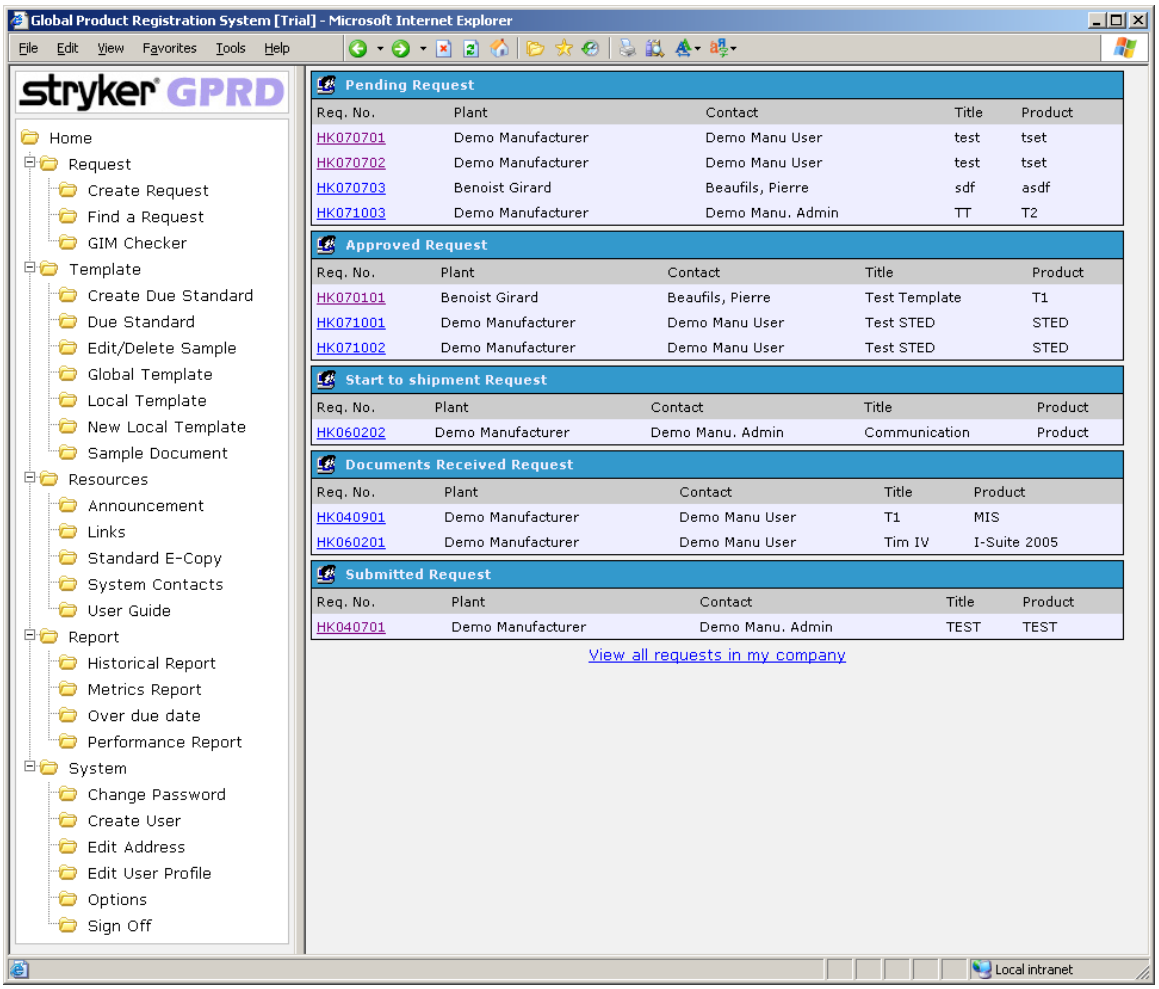
Procedure

1. Logon to the system

Open Internet Explorer enter the site address, type in User ID and password, and click the “GO” button to enter.

2. Home Page

After you have entered the system, you will see a navigation menu tree in left frame, and all incomplete requests separated by status in right frame. The user can also click the “View all requests in my company” to check the requests sending from/to their location.



Source: GPRD Portal

Figure 7: Screenshot of the dashboard of the GPRD requests

This is the dashboard view of GPRD where all functions are performed to handle various request coming from different countries.

3. Toolbar

The toolbar provides basic functions for the system.

		
	Back button	Go back to previous page
	Maximize button	Maximize the right frame in window
	Restore button	Restore frames as default left/right mode

Source: GPRD Portal

Figure 8: Screenshot of the toolbar that provides basic function

4. Request Detail Page

A request contains several areas showing the different kind of information.

4.1 Basic Information Box

Display the basic information for request:

1. Request number and internal reference number
2. Title: The title/subject of the request
3. Product: The product description
4. Plant/Contact: Manufacturer / the contact in manufacturer
5. Due date: expected due date of the request, automatically reset by manufacturer's due standard
6. Planned completion date: entered by manufacturer for completion estimation
7. Request from/by: Requester's country / contact person
8. Status bar: date stamp for different status of request

9. Primary / secondary request: requester is not able to add required document once the request is approved, requester needs to create a separate secondary request for the extra documents.

Source: GPRD Portal

Figure 9: Screenshot of status of one GPRD request

This is the tab where we can see all the information of the request like from where it is coming and for what it is raised. Its due date and the current status can also be seen here.

4.2 Required Document List Box

Monitor the status of required documents

Priority

For reference only, state the importance of the required document.

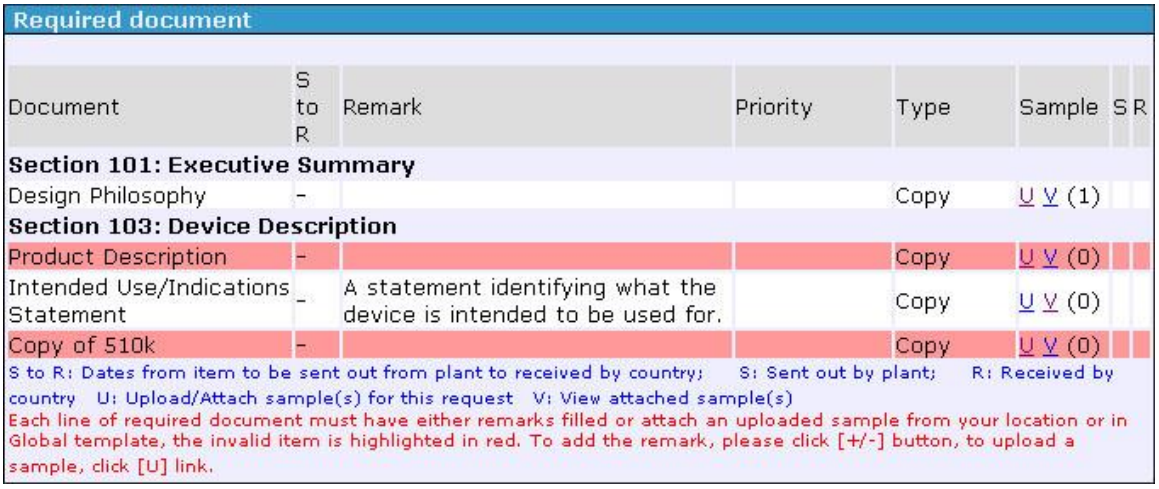
- Urgent (within 3 business days)
- High (within a week)
- Medium (2+ weeks)
- Low (By due date)

Type

Document requirement:

- Copy
- Original
- Apostille
- Notarize by public

Notarize via local embassy



Required document

Document	S to R	Remark	Priority	Type	Sample	S	R
Section 101: Executive Summary							
Design Philosophy	-			Copy	U V (1)		
Section 103: Device Description							
Product Description	-			Copy	U V (0)		
Intended Use/Indications Statement	-	A statement identifying what the device is intended to be used for.		Copy	U V (0)		
Copy of 510k	-			Copy	U V (0)		

S to R: Dates from item to be sent out from plant to received by country; S: Sent out by plant; R: Received by country U: Upload/Attach sample(s) for this request V: View attached sample(s)

Each line of required document must have either remarks filled or attach an uploaded sample from your location or in Global template, the invalid item is highlighted in red. To add the remark, please click [+/-] button, to upload a sample, click [U] link.

Source: GPRD Portal

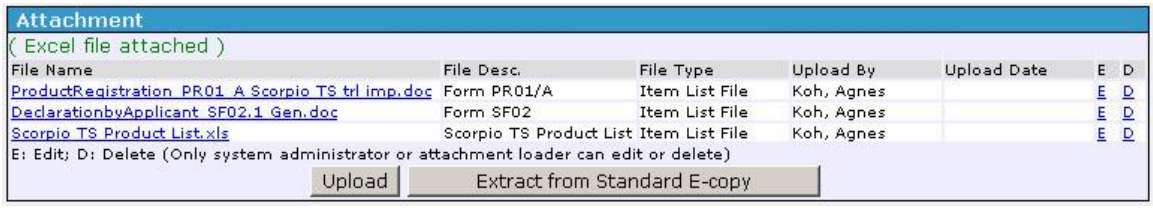
Figure 10: Screenshot of status required documents

This is the section of the portal where status of all required documents can be monitored.

Note: Each line of required document should be either filled with remark or attach a sample, otherwise, the line will be highlighted with red and regarded as invalid.

4.3 Attachment Box

Allow users to upload or download attachments for the request, click the file name to view the attachment.



Attachment

(Excel file attached)

File Name	File Desc.	File Type	Upload By	Upload Date	E	D
ProductRegistration_PR01_A Scorpio TS trl imp.doc	Form PR01/A	Item List File	Koh, Agnes		E	D
DeclarationbyApplicant_SF02.1 Gen.doc	Form SF02	Item List File	Koh, Agnes		E	D
Scorpio TS Product List.xls	Scorpio TS Product List	Item List File	Koh, Agnes		E	D

E: Edit; D: Delete (Only system administrator or attachment loader can edit or delete)

Upload | Extract from Standard E-copy

Source: GPRD Portal

Figure 11: Screenshot of the attachment files

This is the section of GPRD portal where we can upload or download all the required documents for a particular request.

4.4 Message History Box

Let users to communicate directly in request, an alternative of Email.

Source: GPRD Portal

Figure 12: Screenshot of message history box

This is the tab to communicate directly to the requestor for a particular request.

4.5 System Message Box

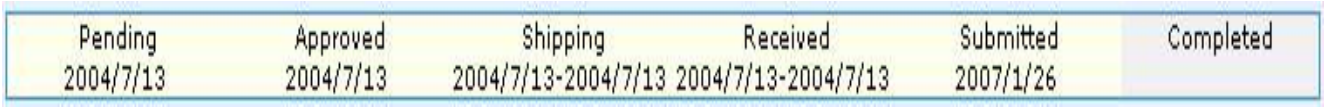
Source: GPRD Portal

Figure 13: System Message box

This is the system generated message to keep track of the operation and status of request

5. Request Life Cycle

The system defines 6 statuses for registration request, the status bar is shown in the request detail page:



Pending	Approved	Shipping	Received	Submitted	Completed
2004/7/13	2004/7/13	2004/7/13-2004/7/13	2004/7/13-2004/7/13	2007/1/26	

Source: GPRD Portal

Figure 14: Status of request

These are the status of any request for their various stages of process

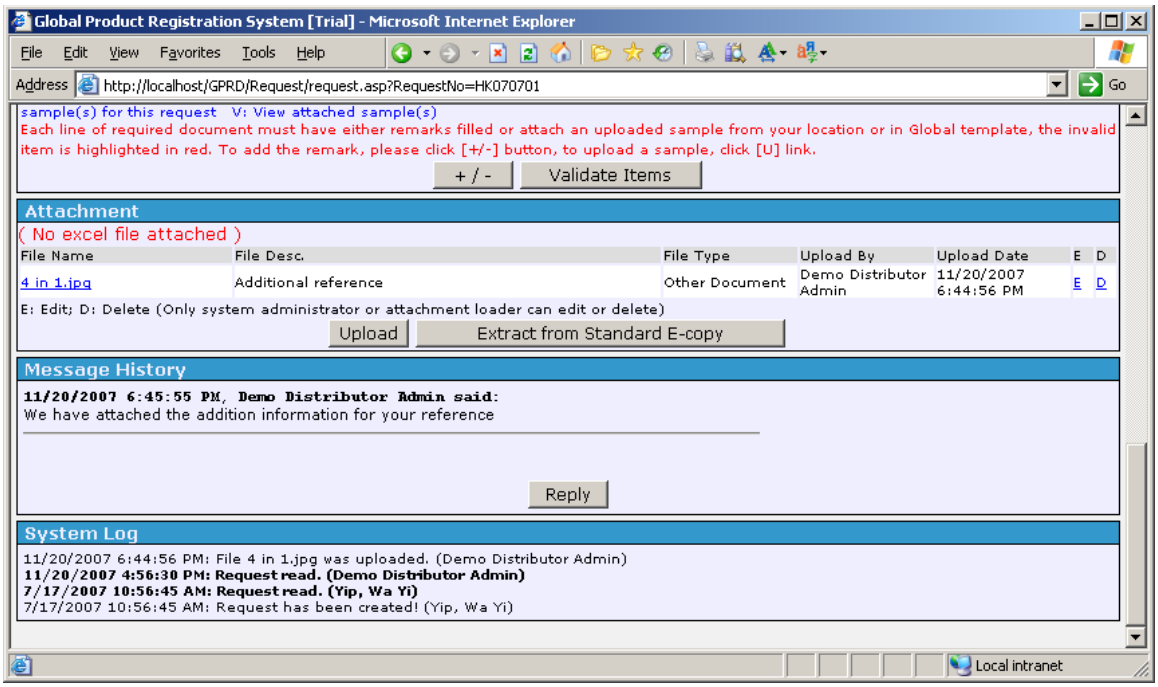
Table 2: Status of the GPRD request

Pending	Once the request is created, the status will be set as Pending, and it will wait for approval of company administrator (CA). Note: only approved requests would be handled by manufacturer.
Approved	The request has been approved,
Shipping	Manufacturer has started to shipping documents
Received	All documents were received by requestor
Submitted	The request & documents has been submitted to local registration department
Completed	The request was approved by local registration department, request completed
Deleted	The request is deleted form system.

These all statuses are shown in request detail page and are defined for registration purposes.

Attachment

There are 2 ways to put additional reference attachments in the request, both the manufacturing RA and the requester may upload the attachment from local hard driver; or link with standard e-copy.



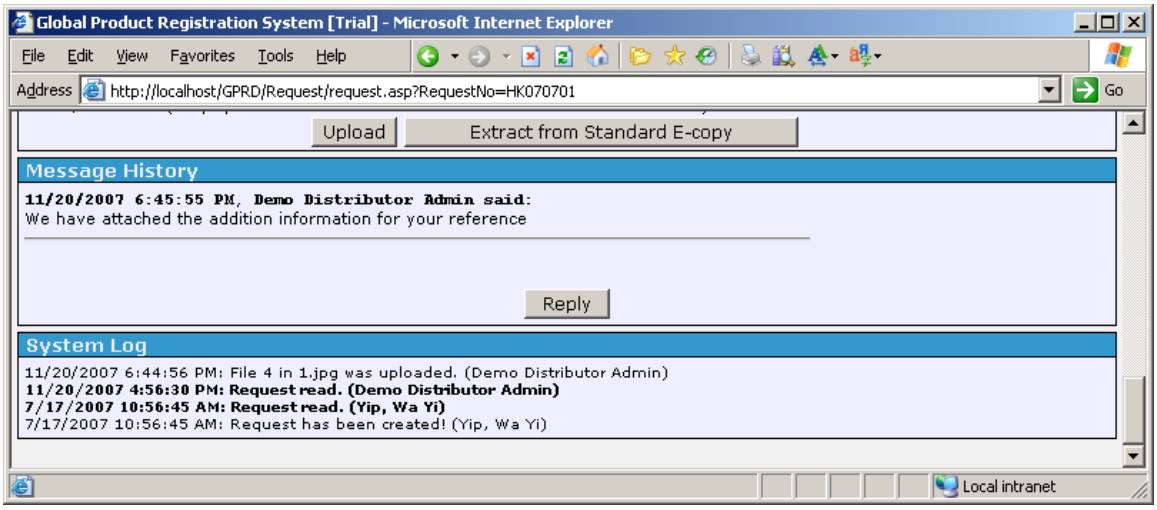
Source: GPRD Portal

Figure 15: Screenshot of additional reference attachments

This is the section where additional attachment can be put by both the manufacturing RA and the requester for their reference.

Message log and System log

Requester may review the message communication log and system log in the request detail page.



Source: GPRD Portal

Figure 16: Screenshot of message Log and system log

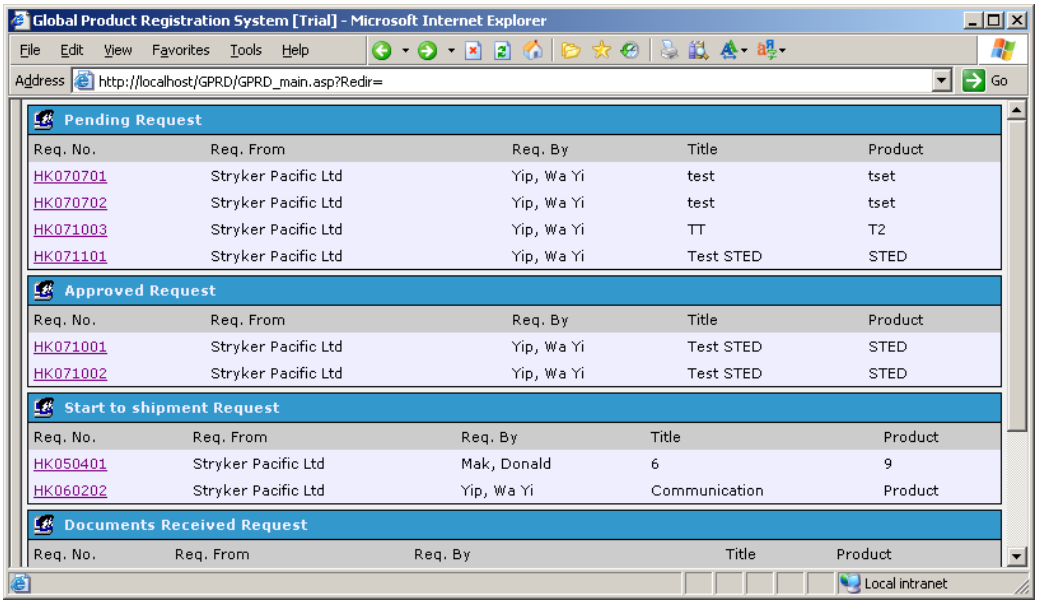
This is for the requestor to review the message communication in the request detail page.

Receive document

While the requester received the required documents from manufacturer, they must mark the document as received.

Shipping document

1. Click “Home” in left frame, all outstanding requests will be displayed, click the “Req. No.” to view the detail of the request

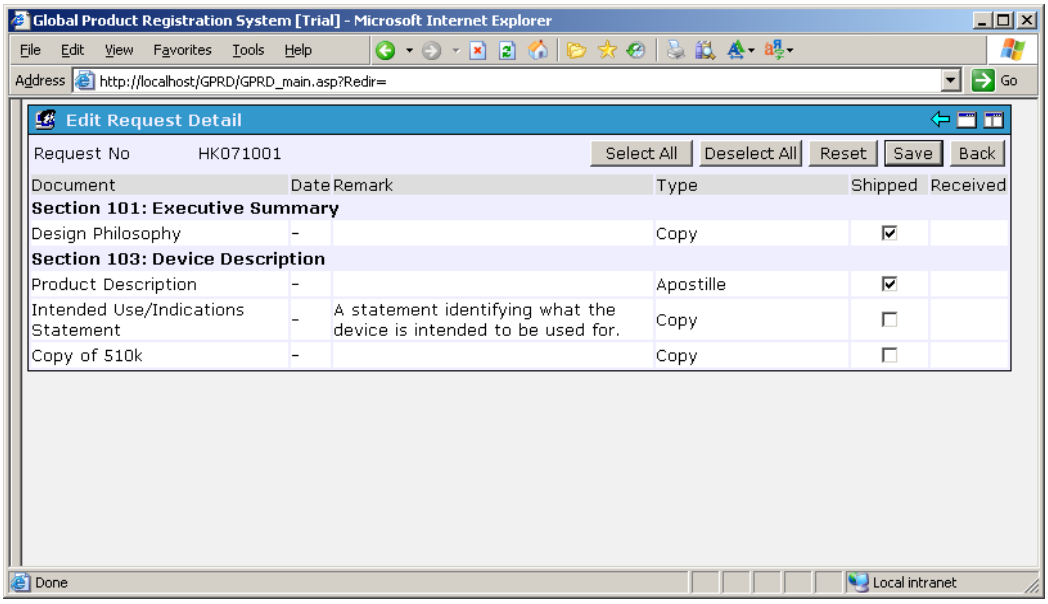


Source: GPRD Portal

Figure 17: Screenshot of all outstanding requests

This is the first page where all requests are shown and by clicking on request no, one can view the detail of the request.

2. Click the “Ship” button in request detail page
3. Tick the checkbox to identify that the required document has been shipped to country, press the “Save” button to save modifications (Status set to “Shipping”)



Source: GPRD Portal

Figure 18: Screenshot of check box of shipping documents

This is the check box of shipping to identify that the required document has been shipped to country.

Due Standard

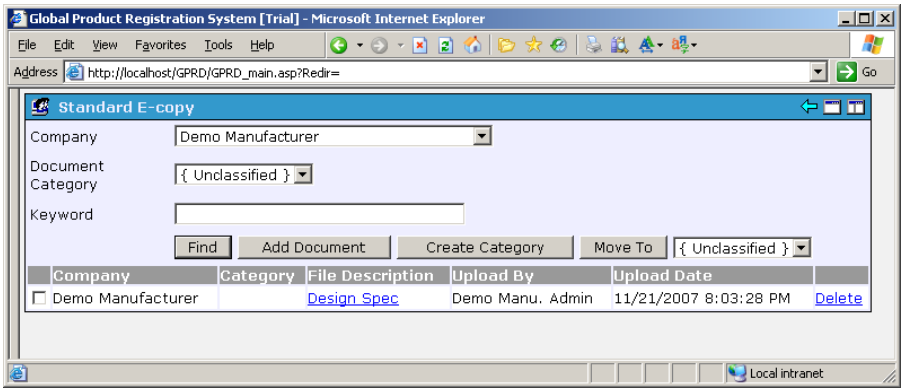
The due date standard defines expected processing days required to handle the documents in request, manufacturer can set up different kind of standards to automatically calculate the expected due date in request.

Validate Documents

Regulatory person does verify and validate the requirements and then after fetching from authentic tool or site they do upload in the GPRD.

Standard E-copy

The standard E-copy allows users to upload files to be used in system, and managed by different user-defined category, it can be downloaded and linked to requests if necessary.



Source: GPRD Portal

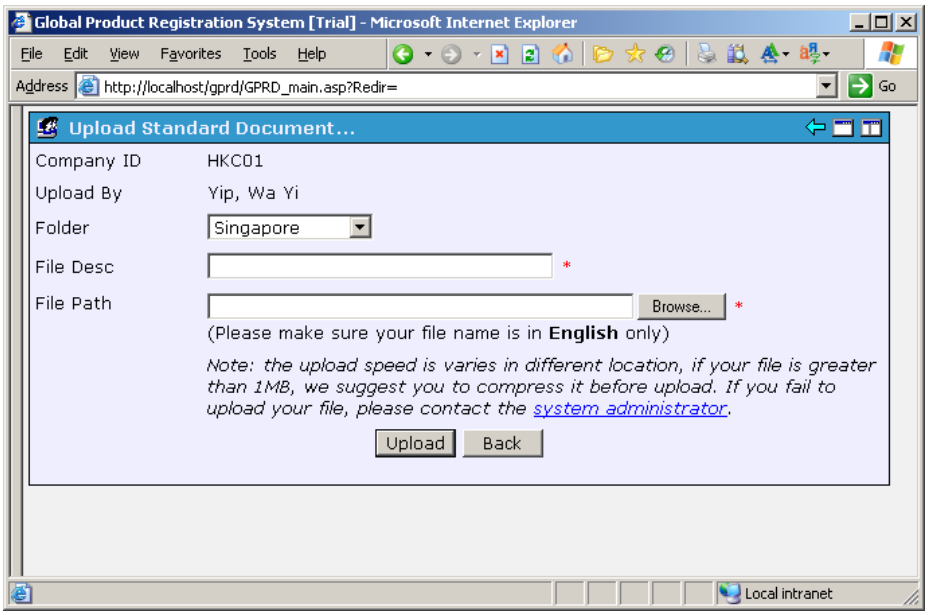
Figure 19: Screenshot of standard E – copy

This is the section where we upload the document by selecting its category and thus send them to the requestor.

Add document

1. Click “Add Document”
2. Select the category
3. Enter file description

4. Select the file to be upload
5. Click “Upload”



Source: GPRD Portal

Figure 20: Screenshot of ‘Add file’ section

This is the section where we upload the document by selecting its category and thus send them to the requestor.

Tools Used for my GPRD Requests –

Figure 21: Tools for GPRD Requests

These are all seven tools used to handle GPRD requests.

Lifecycle code (LCC)

Indicates the current production status and can be found in **Global Item Master (GIM).**

Table 3: Indication of Life cycle code for any product

50 or 100 – Item number reserved (do not register)
200 – Recently launched product (Approximately 0-18 months following product launch)
300 – Normal production
400 – Phase Out (only allow re-registrations)
500+ – Obsolete (do not register)
X99/399 – Specialty/Custom (do not register)

This LCC number of the table is the number found in GIM database and indicates the current production status of manufactured products.

Mostly used product code is 300 *i.e.* in Normal production phase

Item owner

The site responsible for the part as indicated in **Global Item Master (GIM)**. It is the distribution site and usually the manufacturing location, but not always.

SHO: Mahwah

SHC: Cork – could be C*-LISI (check the DoC)

LIM: Limerick- could be L*-LISI (check the DoC)

Labels

Labels for product made in Mahwah, Cork and Limerick are available in **Prisym.**

*If a label is not available in Prisym, contact a member of the labeling team.

Shelf Life Report

The implants are provided dry-heat / moist heat sterilization with a 5-year shelf life from the date of sterilization.

Shelf life test reports must be requested from the report owner when needed. A list of the applicable reports is sometimes included in DD section 23. If the reports are contained within the DD folder, verify with the appropriate contact that there are no newer revisions.

Sterilization method

General information available in section 24 of DD. To determine specific sterilization method for a product, the label is checked.

Technical File (TF)

Collection of documents to support CE marking of Class I, Class IIa and Class IIb products. Instruments and some other devices fall in to these categories. TFs do not get DE certs like DDs.

Design Dossier (DD)

The collection of files submitted for review by our notified body (BSI) for CE marking on Class III devices. All Design Dossiers are in RegAff\INTERNATIONAL RA\EU SUBMISSIONS\DESIGN DOSSIERS and are the main source of information to support GPRD requests.

Windchill - Access by going to "Search for Content" off the Windchill link in myStryker and clicking "Search for Content" and "QMS Documents and Forms", we can find out IFUs, Engineering Drawings, Design History File, CE certificate.

Regaff Drive – It's a database where all the updated documents are kept including Technical files (TF) and Design Dossiers (DD).

Lisi - Labels for product made by Lisi are available here.

Surgical protocols

Surgical protocols can be obtained through the **Global Content System (GCS)** by searching on a product family name or part number.

Global Radar – It's a system where all regulatory documents can be uploaded and downloaded.

Conclusions

Successfully submitted all the GPRD Requests within the given timeframe.

- **GPRD Request 1** - Label and Shelf Life Report (Brazil) - US19XXXX
  GPRD Request Approval Date – 8 Jan 2018
  Due Date – 9th March 2018
  Completed On – 17th Jan 2018
- **GPRD Request 2 -** IFU (Canada) – CN71XXXX
  GPRD Request Approval Date – 11th Jan 2018
  Due Date – 2nd Feb 2018
  Completed On – 21st Jan 2018
- **GPRD Request 3 -** Updated CE (Switzerland) – CH19XXXX
  GPRD Request Approval Date – 27th Jan 2018
  Due Date – 15th March 2018
  Completed On – 5th March 2018

Project – Create Template for Design Control and Risk Management Documents in PTC Integrity Lifecycle Manager

Introduction

This is a system used to create design control and risk management documents within Stryker Hardware Instance Integrity Lifecycle Manager (will refer to as Integrity throughout the rest of the document).

The design control and risk management documents within scope of this project are:

- DIOVV
- Functional Analysis
- Risk Table
- dFMECA

The use of PTC Integrity is required for all New Product Development Products (NPDP) projects to increase the accuracy and efficiency.

Definitions

Design Input Output Validation (DIOV) – A formal document of the DIOVV process that highlights the relationships between user needs, design inputs (requirements), performance requirements and validation activities.

Design Input Output Verification/ Validation (DIOVV) – This refers to the process, defined by D00012 which governs how Design Inputs are translated into Design Outputs and are subsequently verified and/or validated.

Downstream Relationship – A trace relationship that has been created between a category and the next lower (downstream) category in the Integrity outline

External Traces – Trace relationships that are created between categories that are not in the same Integrity document.

Functional Analysis (FA) – Systematic identification of the functional structure of a medical device, including functional inputs and functional outputs (including environmental influences) and medical device/system borders and interfaces.

Integrity Document – There are 9 unique integrity documents: Input document, Design

Specification document, Validation and Verification Document, Functional Analysis Document, Hazard Analysis Document, Harm Document, Risk Benefit Document, Failure Mode Document, and Failure Effect Document. Documents are linked together using trace relationships within Integrity to generate Integrity Reports.

Integrity Reports – There are 4 unique reports that can be generated within PTC Integrity: DIOVV, Functional Analysis, Risk Table, and dFMECA. The reports are generated using integrity documents and trace relationships.

Internal Traces – Trace relationships that are created between categories that are in the same Integrity document.

Risk Table – A standardized table for documenting risk analysis, risk evaluation, and risk control activities.

Suspect Flag – A red flag in the trace status column letting the user know that a change has been made to a category that is linked or has a trace relationship to another category.

Trace Relationship – A linked dependency that exists between two categories (e.g. hazard, functional output, etc.) of the same integrity document or between different integrity documents.

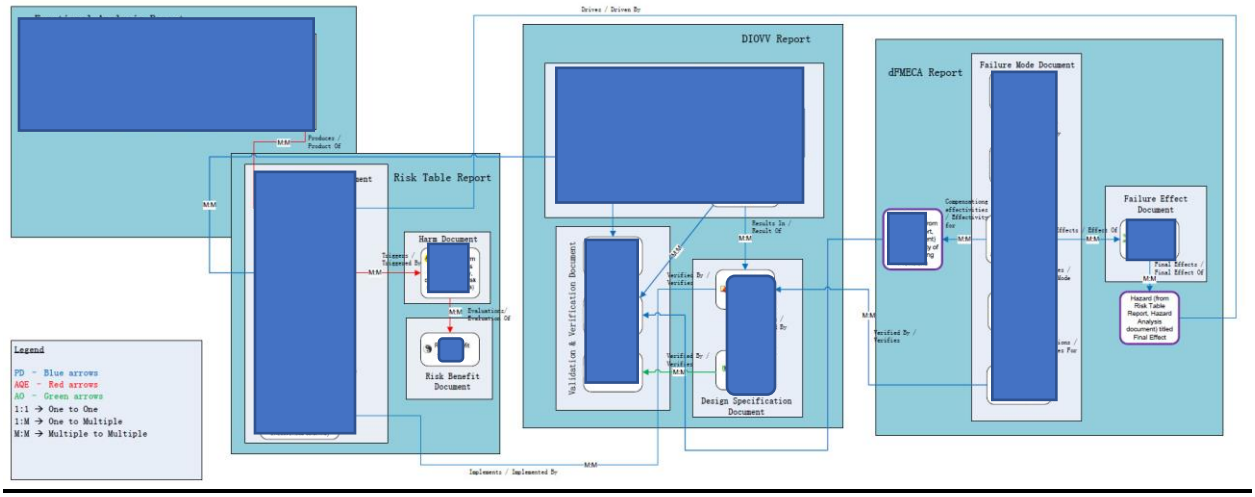
Trace Status – a column that can be added to any Integrity document that allows the user to know if there is an upstream or downstream trace relationship created for that category. Also referred to as linking.

Upstream Relationship – A trace relationship that has been created between a category and the next higher (upstream) category in the Integrity outline

Objective

To create templates for DIOVV, DFMECA, RISK TABLE and FUNCTIONAL ANALYSIS

Procedure



Source: Integrity Work Instruction: Document No: D04405 Ver.: 2

Figure 22: PTC Integrity Lifecycle Manager

This has been configured as shown by the workflow diagram in order to generate all the reports.

Creating a Document with the aid of a template

- Select the “Document” drop down menu, select “Create from Template”.
- Select the document you want to create.
- Some examples are:
  - Master Harm Document
  - Risk Table Template
  - Functional Analysis Template
  - dFMECA Template
  - DIOVV Template
- Select the project folder where the document should be saved, select “OK

Create a Trace Relationship Manually

- Ensure that the two different documents in which you want to link categories are both open.
- Create a side-by-side view of the two Integrity documents by selecting the window tab for 1 of the 2 documents. Drag the tab all the way over to the right of the screen until a split screen outline appears.

NOTE: The document locations do not matter as long as the content of both is visible.

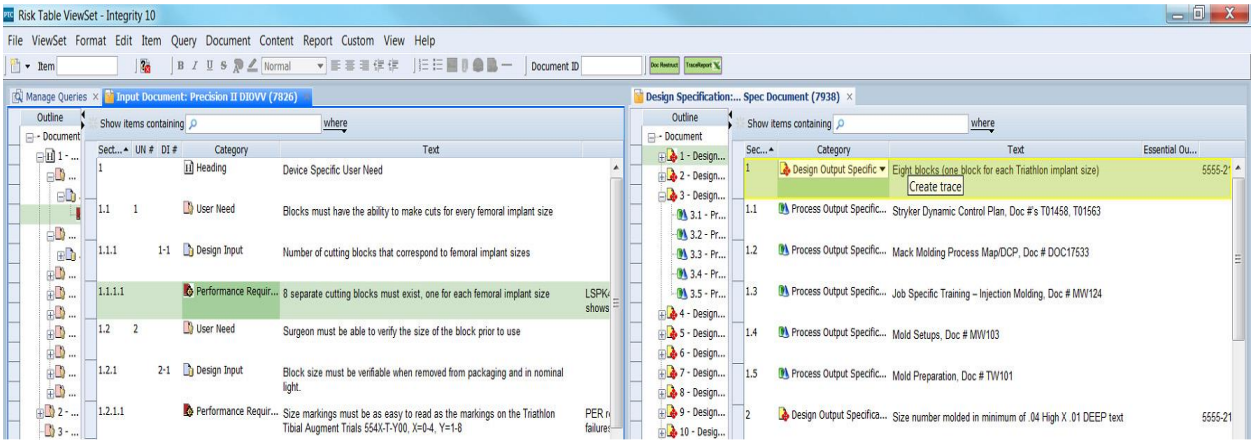
- Select the desired category in the first document.

- Hold down the “ALT” key and drag and drop the selected category over the desired category in the other Document.

If successful, message will appear stating “Item XXXXX
Validates/Verifies of Item XXXXX”.

NOTE: It is possible to link more than one (1) category at a time. Hold down the “Ctrl” key and select the Design Validation line item(s) to include in the trace and then repeat the operations.

NOTE: It does not matter which direction you drag and drop the categories to create a trace relationship.



Source: Integrity Work Instruction: Document No: D04405 Ver.: 2

Figure 23: Screenshot of traced document in Integrity

This is screenshot of two documents separated in two tabs and the selected two lines are the linked documents.

A window will appear to state the creation of the trace relationship was successful:

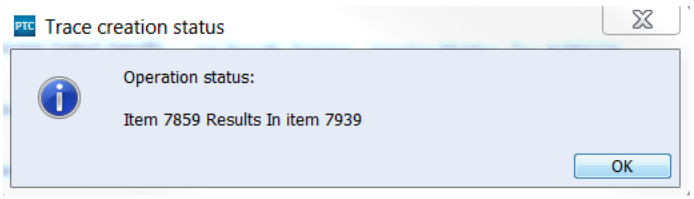


Figure 24: Screenshot of work successful status

This is the notification that says trace has been successfully created between two files.

Refresh the Page

Click F5 to refresh the Integrity document view.

Following Reports are generated by using the above methods in Integrity:

Table 4: Documents that are required to generate reports

Report	Document 1	Document 2	Document 3
DIOVV	Input Doc	Design Specification	Validation and Verification Document
FA	Functional Analysis (FA)		
Risk Table	Hazard Analysis Document	Harm Document	Risk Benefit Document
dFMECA	Failure Mode Document	Failure Effect Document	

Conclusion

Template of dFMECA has been created successfully and further reports generated.

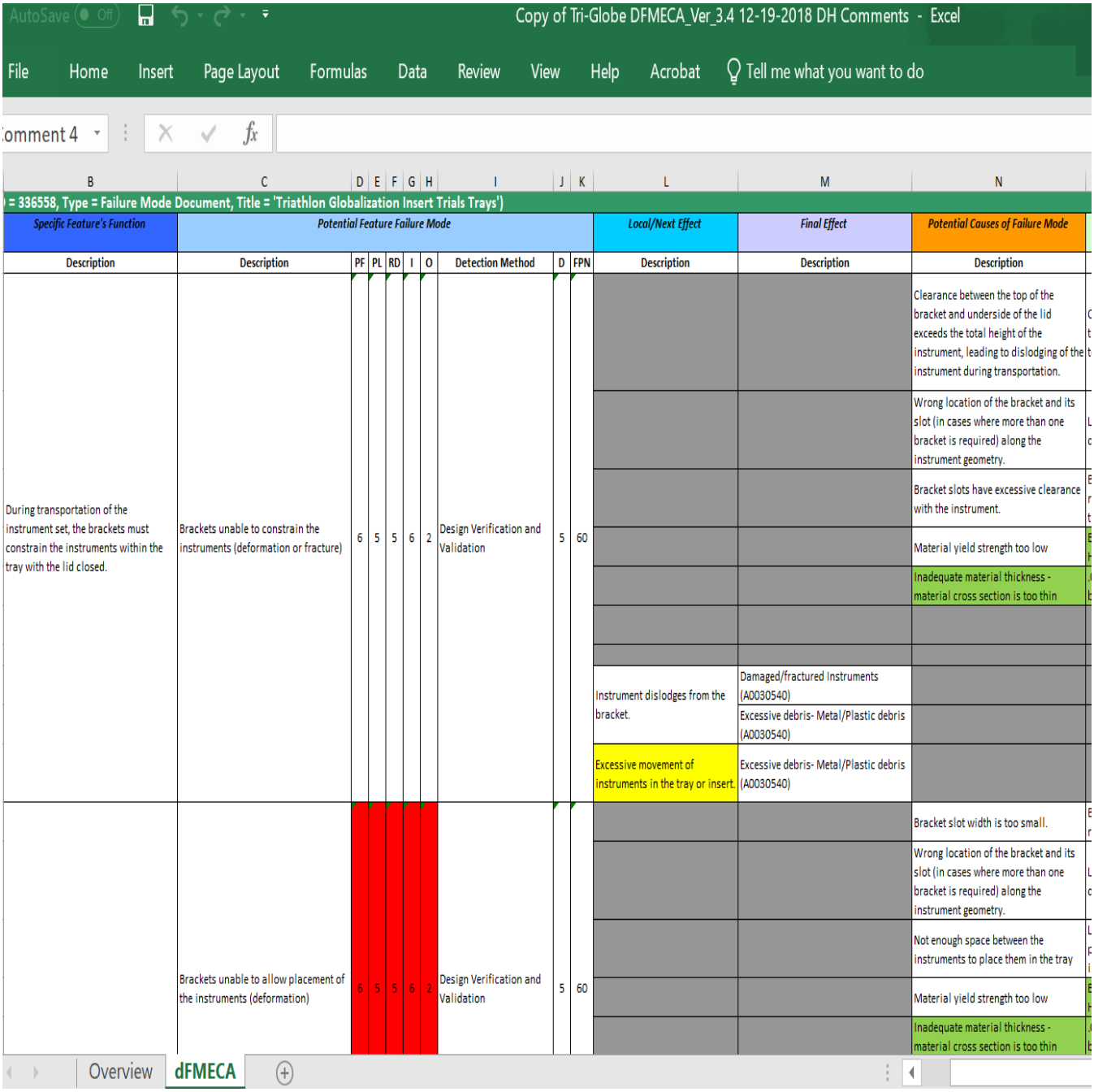


Figure 25: Template (dFMECA)

This is the template that is created in the end as a result of all the tracing performed. This is the combination of two documents *i.e.* Failure Mode Document and Failure effect document

Project – Complaints Handling System

Introduction

This procedure applies to all complaints associated with Stryker Joint Replacement Division and associated Global Quality and Operations sites in Mahwah, Tullagreen, Limerick and Fort Lauderdale that are involved in the manufacture and/or design of medical devices. All information and documents pertaining to product complaints are to be treated as confidential information and handled accordingly.

*Note: This procedure does not apply to customer-service related complaints such as shipping or billing errors; or to investigational medical device products when separately addressed in study specific protocols in accordance with regulatory requirements and guidelines.

Definitions

Adverse Event: Any event where the use of a medical device is suspected to have resulted in an adverse outcome for a patient.

Adverse Event Report (AER): Reports include eMDR, eMDV and Country Submissions.

Adverse Trend: A trend in an unfavorable direction. If an adverse trend is not resolved, it could result in a health, compliance, or business risk.

Awareness Date: The date that the first person in Stryker becomes aware of an event.

Complainant: Person notifying Stryker of the complaint.

Complaint: Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a Stryker device after it is released for distribution by a manufacturing site.

Complaint Handling Team: People under the following the Division or Business Unit (Complaint Intake Center, Complaint Management Center, Product Assessment Center and CMC Regulatory Representative) in charge of the complaint process.

Corrective Action: Steps taken to eradicate the cause of a nonconformance which has occurred to prevent its recurrence or reduce the occurrence to an acceptable

threshold.

Corrective and Preventive Action (CAPA): Steps taken to correct or prevent the occurrence of any problem is called CAPA. The steps are:

- Information collection
- Analyzation of information
- Identification of quality problem
- Further investigation of the problem
- Appropriate corrective actions taken to prevent its recurrence

Evaluation: The process to determine the level of investigation performed on a complaint that will assess if the reported event has undergone a previous investigation that led to a definitive root cause, is a contraindication in the labeling of the reported device, or if insufficient information was provided to confirm the reported event and/ or determine root cause.

Failure Mode: Way an item fails.

Global Item Master (GIM): The Global Item Master is a system which contains information about the items that Stryker manufactures and sells. The GIM provides a single repository for information about items. And it used to identify the item owner, investigation and manufacturing sites in Trackwise.

Medical Device Reporting (MDR) Reportable Event: An event about which Stryker has received or become aware of information reasonably suggesting that:

A Stryker device may have caused or contributed to death or serious injury,
Or;

A Stryker device has malfunctioned, and the device or a similar Stryker device would be likely to cause or contribute to a death or serious injury if the malfunction was to happen again.

*Note: Food & Drug Administration (FDA) assumes that all malfunctions will

happen again.

Medical Device Vigilance (MDV): A report submitted to a competent authority in Europe when an incident occurs in Europe. Two reports comprise an MDV – the initial report and the final report.

Trackwise: The validated database used by Stryker to manage complaints ("Product Inquiries"), Medical Vigilance Reports ("MDVs"), and Medical Device Reports ("MDRs") entered on or after January 1, 2013 (January 5, 2015 for Recon Robotics).

Procedure

- Stryker Sites shall use the network-based Complaint Handling System (CHS) as the Complaint handling process workflow management system and data repository. Complaint records should be retrievable within 1 Business Day of request.

- Any Stryker employee or employee acting on behalf of Stryker who becomes aware (via e-mail, phone, fax, mail, verbally, etc.) of a possible Complaint shall forward Complaint information to the Complaint Intake Center (CIC) immediately. The targeted time frame is 1 Business Day.

- English is the language of record and shall be used for Complaint handling. Pertinent information that supports the Complaint investigation shall be provided in English. Documents that are received pertinent to the processing of the Complaint shall be communicated or directly translated by the CIC in the electronic record to expedite the Complaint process.

- Dates provided should be verified for chronological consistency (e.g. a surgery date prior to date of complications). If partial dates are provided, the date shall be interpreted as the first possible date of the time period. For instance, if the partial date provided is 2012, then enter 01-Jan-2012. If the partial date provided is April 2012, then enter 01-Apr-2012. If the exact date is unknown, indicate that the date is approximate, where possible.

- Supporting documents that are not a controlled quality record shall be attached to the record in CHS and named descriptively. Supporting documents that are a controlled quality record may be referenced within the record in CHS. In case information collected cannot be converted to a media that can be included in the file, the individual site may decide that paper or other media files are also necessary to ensure appropriate information is available for inspections or audits. If paper or other media files are used, they are part of the "official" Complaint file and shall be referenced in CHS.

- In case information collected cannot be converted to a media that can be included in the file, the individual site may decide that paper or other media files are also necessary to ensure appropriate information is available for inspections or audits. If paper or other media files are used, they are part of the "official" Complaint file and shall be referenced in CHS.

- Documents shall be attached upon receipt. Documents may be attached in groups if appropriate, *i.e*. medical records. Attachments should be written in English or have a translation provided. Attachments should be in .pdf or .jpg format.

Complaint intake

A separate product inquiry record shall be opened to document each event. For events with multiple products, each product shall be documented.

A For events with multiple serialized products, each shall be listed.

B For events with multiple lot numbered products, each lot number shall be listed.

* Note: An event refers to a single procedure, installation, service visit, service action, inspection, treatment, or therapy session which may include multiple problems, issues and/or products.

Product return

The originator or applicable person shall request return of the product for evaluation. These requests may occur at any point and shall be documented. This request may also include documentation such as patient records and x-rays. If available, the product shipment should include the associated reference number (e.g., PI, complaint and or product return record).

If the CIC receives the product from the complainant, the CIC shall coordinate with the CMC and/or the applicable PAC to return product to for evaluation.

Receipt and any transfer of product(s) shall be documented within the product return record by the person responsible for the product, as applicable.

If the product is noted as available within the record, the investigation(s) shall not be closed until a minimum of three (3) attempts to obtain the product from the individual who indicates the product is available or an individual who can retrieve the product have been conducted and documented. If the complainant indicates that the product will not be returned, this shall be documented in the product return record and no additional attempts are required.

The handling of complaint related product should be defined per local procedures.

Complaint record and regulatory reporting review

MDR reportability is done

Steps for review of reportability outside the United States shall be performed per local procedures. This included but is not limited to, assessment for reportability in Europe, Canada, Japan, Brazil, Korea, Hong Kong, Singapore, Columbia, China, Australia, and Saudi Arabia.

The regulatory representative shall review the product inquiry record for reportability and document the reporting decision and rationale

Regulatory reporting review

The regulatory representative shall review the product inquiry record for reportability and document the reporting decision and rationale.

Complaint investigation

If any complaint is not investigated, justification shall be documented.

If an investigation determines activities outside the organization contributed to the complaint, relevant information shall be exchanged between Stryker and the external party.

Reopening a record

A PI, complaint, product return, action required, or AER shall be re-opened when any of the following occur:

A. New information is received (e.g., medical records, device return).

B. An error is identified.
C. Clarification is needed.
D. Upon request from a regulatory agency
E. Clerical updates

Data monitoring, analysis and evaluation

Complaint thresholds shall be defined, established and monitored by each design division to support all input**s.**

Stryker sites managing complaints shall maintain metrics and monitor for trends.

A nonconformance shall be initiated, if risk occurrence and/or severity is higher than previously estimated (*i.e*. a threshold has been exceeded).

Key performance indicators for complaints shall be monitored

Any Stryker employee or person acting on behalf of Stryker who becomes aware by e mail, phone, fax, mail, verbally, or other means of a possible complaint shall submit/forward complaint information to a CIC immediately. The targeted time frame is one (1) business day.

A user may fulfill multiple responsibilities within CHS. Roles and responsibilities listed below are an overview of major roles and responsibilities and may be fulfilled by multiple Centers. CHS uses several user roles to complete the complaint handling process. Stryker entities

shall identify staff to fulfill roles and responsibilities.

`

Table 5: Complaint Management System – Roles & Responsibilities

Center	Roles	Major responsibilities
Complaint Intake Center (CIC)	Originator Reviewer	The Stryker entity or location that enters event information into CHS.
	Regulatory Representative	Receives information, enters data into CHS, asks quality screening questions, and obtains as much information as possible on first contact. Supports CMC and PAC to gather additional complaint information.
	Approver	Reviews newly released Product Inquiries (PIs) generated from web/mobile applications for completeness. Coordinates and escalates requests for additional information.
Complaint Management Center (CMC)	Reviewer Coordinator	Manages the complaint handling process from complaint receipt to closure, maintains complaint related files, evaluates complaints, ensures appropriate action is taken for designated products/product families, and reviews issues for adverse event reporting.
	Regulatory Representative	Coordinates initial activities necessary for the investigation of a complaint and escalates requests for information and ensures request acknowledged by the originator.
	Approver	Evaluates the complaint for reportability and/or generates the required regulatory submission forms.
		Evaluates investigations and entire complaint records for completeness, consistency, and compliance.
		Coordinates closure of the record family to ensure PI is ready for final approval by the CIC.
		Approves or rejects investigations and **may** re-open complaint records. Approves reportability decision, content of completed regulatory forms and submission. Flags complaint records with investigation results requiring re-evaluation of regulatory reporting

Results

CIC

- Reviewed each incoming PI for accurate content and possible multiple events being indicated (*i.e*. multiple revisions, etc.) and generate separate PI(s) as needed.

- Reviewed for possible duplicates for cancellation.
- Coordinated and escalated requests for additional information.
- Reviewed and submitted the Product Inquiry for final closure, for US based events, and coordinate required customer feedback and/or required product return
- Reviewed the Product Inquiry for final closure, for OUS based events, and coordinate required product return. The country representative will then complete required customer feedback and PI Closure.
- Verified any new information received is updated within the appropriate record and coordinate new information to the appropriate CMC. If needed request reopening of Product Inquiry and/or Complaint.

Table 6: Total CIC - PI Intake

CIC - PI Intake			
Week	**New Intake**	**Update**	**Timeline**
6th - 10th May'19	8	33	2
13th - 17th May'19	0	5	1
20th - 24th May'19	2	10	1
27th - 31st May'19	0	11	1

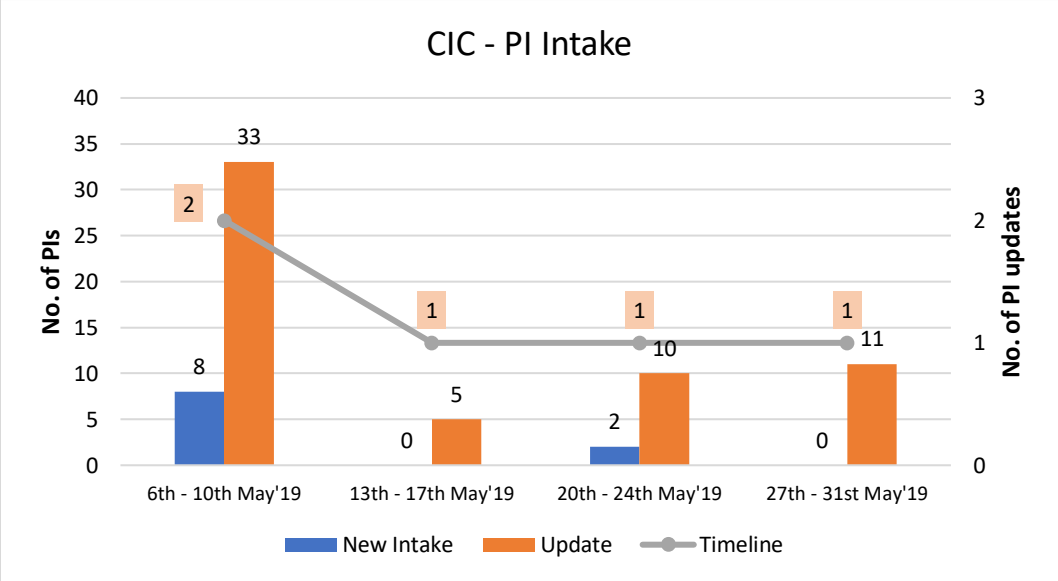


Figure 26: CIC – PI Intake

Blue ones are the new Intakes while orange ones are the new PI updates done in a given timeline in grey color.

Table 7: Total PI Closure

PI Closure	
Week	**Total**
6th - 10th May'19	12
13th - 17th May'19	15
20th - 24th May'19	26
27th - 31st May'19	30

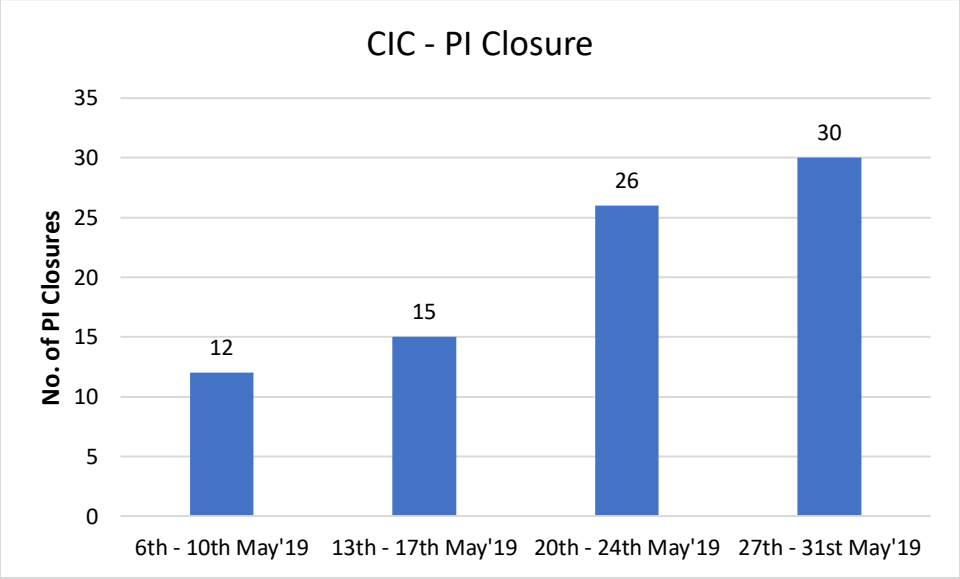


Figure 27: Total CIC – PI Closure done in the given timeframe

CMC:

- Coordinated initial activities necessary for the investigation of a complaint.
- Review the Complaint Project Record for completeness and determine the appropriate PAC. Managed the complaint handling process from complaint receipt to closure, maintained complaint related files, evaluates complaints, ensures appropriate action is taken for designated products/product families, and reviewed issues for adverse event reporting.

Table 8: CMC – Complaint Submission

CMC -Complaint Submission			
Week	**Total**	**Submitted by Deepnita**	**Contribution**
6th - 10th May'19	260	18	7%
13th - 17th May'19	265	24	9%
20th - 24th May'19	258	36	14%
27th - 31st May'19	260	40	15%

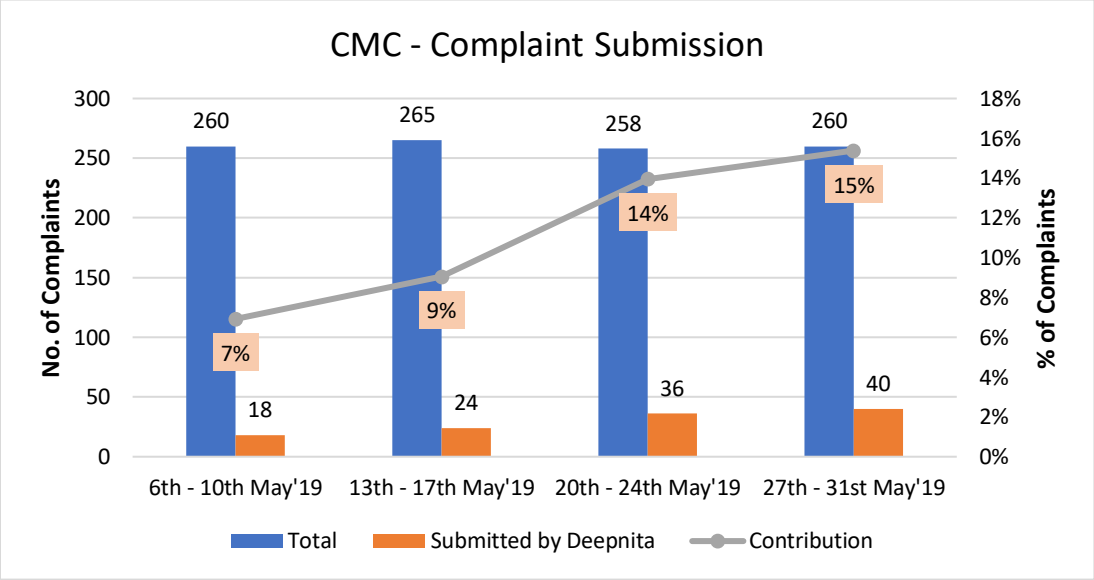


Figure 28: CMC – Complaint Submission in the given timeframe

Blue ones are the total submitted complaints. While orange ones are the complaints submitted individually by me and my contribution percentage is in grey color.

Table 9: Complaint Submission Rejection

Complaint Submission Rejection			
Week	**Total**	**Rejection**	**%Rejection**
6th - 10th May'19	18	0	0%
13th - 17th May'19	24	0	0%
20th - 24th May'19	36	0	0%
27th - 31st May'19	40	0	0%

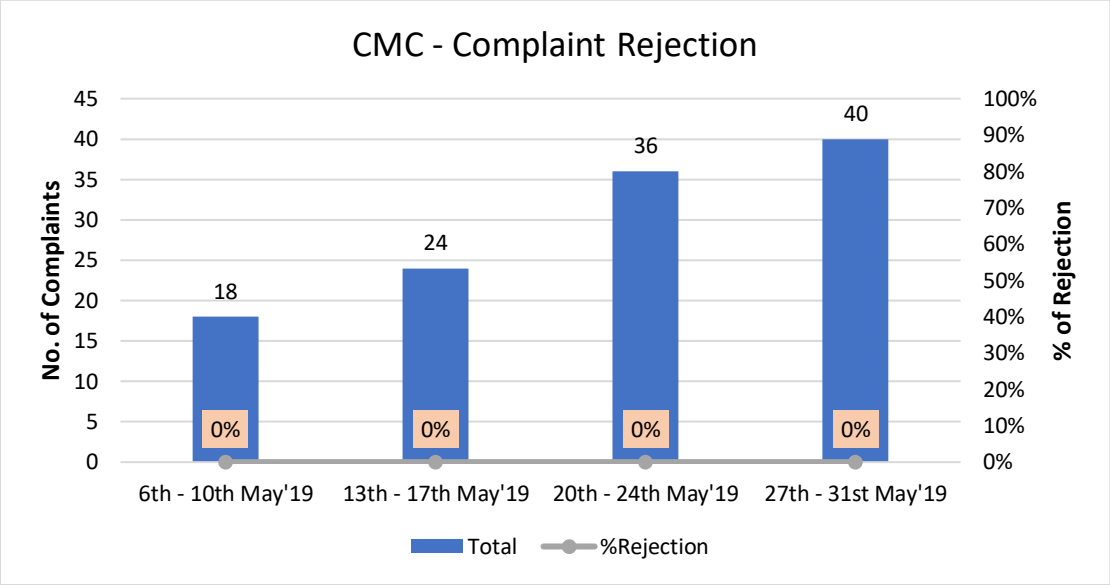


Figure 29: CMC – Complaint Rejection

Thus, reports of corrections and removals (complaints) initiated by me are submitted as a written report to FDA for any correction or removal of a device.

Correction or removal of device is done after FDA approval. The main purpose of this initiation is:

(1) To ensure the safety of users by minimizing the risk of device; or

(2) To provide compensation to the users who is going through the symptoms of risk of health because of the wrong device insertion into their body

This helps in delivering safe and effective medical products to the customer.

Also, helps in efficient New Product Development by the company.

Conclusion

CIC and CMC were handled and reviewed properly with zero rejections of complaints.

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22. Trackwise; Version – 17.6

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by Deepnita Deepnita

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