Quality Assurance and Regulatory process for Orthopedics

A

Dissertation Report

Submitted in Partial Fulfillment of the Requirements

for the Award of the Degree

Master of Technology in

Biotechnology

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Declaration

I hereby declare that the work being presented in the dissertation report entitled " Quality Assurance and Regulatory process for Orthopedics submitted by me for the award of the degree of Master of Technology in Department of Biotechnology, TIET University, Patiala is true and original record of my own independent and original research work carried out under the joint supervision of Dr. Siddharth Sharma, Yogesh Girdhar Manmeet Chawla and Jyoti Dhaniyasth. Further, I declare that no part of this dissertation has been submitted to any other University/Institute for the award of any degree in India or abroad.

Dated: 25.09.2019

(Shivani Mathur)

CERTIFICATE

This is to certify that the dissertation work entitled "Quality Assurance and Regulatory process for Orthopedics" submitted by Shivani Mathur (Roll No. 601704007) in partial fulfillment for the award of degree of Master of Technology in Biotechnology from Thapar Institute of Engineering and Technology, Patiala Punjab is the record of the candidates own independent and original research work carried out under our supervision and guidance. The matter embodied in this dissertation has not been submitted in part to any other University/Institute for the award of any degree or diploma in India or Abroad.

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(Shivani Mathur)

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Abbreviations

SGTC	Stryker Global Technology Centre
R&D	Research and Development
RAQA	Regulatory affairs and Quality Assurance
JR	Joint Replacement
QMS	Quality Management System
ISO	International standard of organization
US	United States
MDR	Medical Device Report
NPS	Net Promoter Score
SPS	SGTC Partnership Score
B2B	Business to Business
VOC	Voice of customer
PLM	Product Lifecycle Management
CSI	Customer Satisfaction Index
QPR	Quality Procedure

QWI	Quality Work Instruction
QFM	Quality Form
MGT	Management
PMS	Post Market Surveillance
CAPA	Correction Action and Preventive Action
NC	Nonconformance
GPRD	Global Product Registration Database
DD	Design Dossier
TF	Technical File
LCC	Life Cycle Code
GIM	Global Item Master
EU	European Union
EUMDR	European Union Medical Device Regulation
FDA	Food & Drug Administration
CHS	Complaint Handling System
CIC	Complaint Intake Centre

CMC	Complaint Management Centre
PAC	Product Assessment Centre
PR	Project Record
PI	Product Inquiry
CQR	Clinical Quality Regulation
INFO	Information

Terminologies

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.

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

Becomes Aware: Any Stryker employee or agent of Stryker has become aware of a MDR reportable event that is required to be reported to FDA within 30 calendar days or an event that is required to be reported within 5 working days pursuant to an FDA written request, or - Any Stryker employee, who manages or supervises persons with regulatory, scientific, or technical responsibilities, or whose duties relate to the collection and reporting of adverse events, has become aware of an MDR reportable event from any information, including any trend analysis, and the event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health

Business Day: A 24 hr week day which excludes weekends and holidays

Complainant: Person notifying Stryker of the complaint

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: Action taken to eliminate 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): The purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures.

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: Manner in which 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 single repository for

information about items. And it used to identify the item owner, investigation and manufacturing sites in Trackwise

Health Care Professional (HCP): Those individuals and entities that purchase, lease, recommend, use, arrange for the purchase or lease of or prescribe medical device or drug. HCP includes non-physician practitioner, medical fellow, resident or student, or any employee or agent of any educational or health care organization retained for any personal or professional services or compensated or remunerated in any way, directly or indirectly, for or in anticipation of personal or professional services. This includes both clinical and nonclinical people who make product-related decisions of the shortlisted. It also includes decision-makers within group purchasing organizations. It is a broad definition, intended to encompass anyone with material influence over purchasing decisions

Initial Reporter: The person who initially reported the event to the manufacturer or company representative.

Labeling: Written, printed, eMedia, or graphic matter. a. affixed to a medical device or any of its containers or wrappers, or b. accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents

Non-Adverse Trend: A trend that has not exceeded the predicted occurrence in risk documents for a failure mode or hazard/harm combination

Nonconformance: An event that is contrary to a standard or requirement whether intended or specified

Nonconformance Report (NCR): A form and procedure initiated to investigate product/process non-conformances to identify root cause and corrective action

Occurrence Date: The date a problem, or nonconformance, took place

Original Equipment Manufacturer (OEM): A third party that provides a product or service that is part of the final product, or a Finished Medical Device, that is considered to be commercially available to any medical device manufacturer or distributor. Specifically, the intellectual property is not owned or dictated by Stryker

Originator: The originator is responsible for entering all new Product Inquiries into the System

PER (Product Experience Report) File: The customer complaint, and its associated investigation, and any associated adverse incident reports to regulatory authorities(such as MDR or MDV reports) and miscellaneous supporting documents

Potential Nonconformance: A Nonconformance which has likelihood to occur, but has not occurred yet.

Preventive Action: Action taken to eliminate the cause of a potential nonconformance to prevent or reduce its potential occurrence

Preventive Maintenance: where an action occurs that identifies device deterioration, which may compromise function and ensures that the device is suitable for its intended purposes. Consequently, the resultant action indicates that no patient was involved and no actual or potential patient harm existed for the alleged device

Product: Components, in-process, finished and returned devices or substances manufactured by Stryker or a subcontractor that must meet regulatory standards.

Record: Document or electronic media stating results achieved or providing evidence of activities performed

Reporter: Any person who initially reports an event potentially meeting the criteria of a customer complaint to a Stryker representative

.**Risk:** Combination of the probability of occurrence of harm and the severity of that harm

.**Risk Assessment:** Overall process comprising a risk analysis and a risk evaluation.

Risk Management: Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.

Root Cause: The original or fundamental reason for a nonconformance.

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)

Complaint Intake Center (CIC): CIC is the Stryker entity or location that intakes event information into CHS

Complaint Management Center (CMC): CMC is the Division or Business Unit associated with the product reported in the event

CMC Regulatory Representative: the person responsible for conducting the reportability decision in the PI record

Complaint Project Record: A CHS record that contains the complaint evaluation and the information required to determine if the complaint is a reportable event.

Family: The parent-child navigation tree. This hierarchical tree allows the user to see a current PR in relation to its PR family (root, parent, children PRs) to allow easy navigation and editing

Field: Fundamental Component of a Trackwise Record. Fields are used to record data.

Investigation Owner: The person responsible for conducting the complaint investigation and entering all of the details into the Complaint Project Record

Product Assessment Center (PAC): PAC is the site that performed the investigation regardless of the Stryker entity type it is (Division, Business Unit, etc.)

Product Inquiry (PI): The CHS record that contains the initial event information and is the root parent record

Project Record: CHS project records include Product Inquiry, Complaint, eMDR,eMDV, Country Submission, and Product Return

Query: One of the two Components used to determine which Records are displayed in Trackwise. Query determines the search criteria based on any data field in the system

Approver: A person responsible for verifying all requirements have been met before moving a Trackwise record to the next state

Scope: One of the two Components used to determine which Records are displayed in Trackwise. Scope determines which Record types are displayed

Post-market surveillance: Systematic process to collect and analyze experience gained from medical devices that have been placed on the market

Customer: Anyone who is affected by the product, process or by the services performed by SGTC.Customers may be external or internal, however internal customers (or divisional partners) are defined as contracting Stryker divisions using resources for R&D Projects/Services. External customers are defined as health professionals who are the end users of Stryker's product in the field

Customer Feedback: Formal and informal communication from the customer relating to performance

Formal: Feedback solicited and obtained via online tool

Informal: Unsolicited feedback obtained via informal means such as Email in person or telephone conversations

Customer dissatisfaction: A state of affairs in which deficiencies (in goods or services) result in customer annoyance, complaints, claims, and so on.

Customer satisfaction: A state of affairs in which customers feel that their expectations have been met by the product features or services provided

SGTC Partnership Score (SPS): Scores provided by customer during the formal feedback process obtained via online tool.

Validation: Validation is the process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in testing and then production maintains the desired level of compliance at all stages.
Verification: It is the act of reviewing, inspecting or testing, in order to establish and document that a product, service or system meets regulatory or technical standards.

Global Product Registration Database(GPRD): A System used by Stryker to request and exchange regulatory documentation between Design Division RA and commercial organization across globe

Design Dossier (DD): The collection of files submitted for review by 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.

Design History File (DHF): Contains all original project documents including test reports which may not be available through the library.

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.

Lifecycle code (LCC): Indicates the current production status and can be found in Global Item Master (GIM).

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)

Abstract

The present study is based on application of tools for quality assurance, validation and regulatory processes. The tools used are Trackwise: Complaint Handling System, SPS (SGTC Partnership Score) and GPRD (Global Product Registration database). These tools have been developed for effective handling, monitoring and registering Joint Replacement products manufactured by Stryker Corporation, a multinational firm with headquarters at Kalamazoo, Michigan (USA)

Here, Trackwise Complaint Handling System is the depository for all complaints and related documentation. Product complaints are managed by different roles within complaint handling team i.e CIC (Complaint Intake Centre), CMC(Complaint Management Centre) and PAC(Product Assessment Centre).This project deals with CIC(Complaint Intake Centre) and CMC(Complaint Management Centre).

SPS stands for SGTC Partnership Score. It is a feedback Management tool that is used to gauge the strength of customer relationships. It has a scale range of 1-5, 1 being the lowest and 5 being the highest score. Additionally, customers can also provide their comments along with the score. Based on score, customers are categorized into promoters (>3), Passives (=3) and detractors (<3). SPS score is calculated using the below mentioned formula:

SPS Score = %Promoters - %Detractors

GPRD stands for Global Product Registration Database. It is a system used by Stryker to request and exchange regulatory documentation between design division RA and distribution division RA for registration purposes.

The study involved hundred case studies for complaint handling (Annexure I), SPS validation and two GPRD requests. The validation of SPS tool was done successfully by preparing list of users along with the expected responses. Then the survey was initiated to all the users mentioned in the list. Users were instructed to fill the responses as per the sheet and then cross verifying the responses and thus validating the tool (Annexure II)

GPRD request 1 is from Latin America region and it is initiated for risk management documents like FMEA risk analysis of simplex with tobramycin and also its biocompatibility reports (Annexure III)

GPRD request 2 is from Canada region and it is initiated for retrieval of 210 labels for different part numbers

Introduction

This project “Quality Assurance and Regulatory Process for Orthopedics” is under the aegis of Stryker Global Technology Centre (SGTC), India Gurugram with practical application. Stryker Corporation is a medical technologies firm.Stryker's products include implants used in joint replacement and trauma surgeries, surgical equipment and surgical navigation systems, endoscopic and communications systems, patient handling and emergency medical equipment; neurosurgical, neurovascular and spinal devices as well as other medical device products used in a variety of medical specialties.

Stryker segregates their reporting into different business segments: Orthopedics, Medical, Surgical, Neurotechnology and Spine.

Orthopedics deals with means to treat musculoskeletal trauma, spine diseases, sports injuries, degenerative diseases, infections, tumors and congenital disorders. This project is based on Joint Replacement which is undertaken by the Orthopedic Section of Stryker Corporation.

Joint replacement offers a combination of implants for hips and knees, along with Mako Robotic-Arm Assisted Technology for the orthopedic service line.

Hip joint replacement is intended for use in individuals with joint disease resulting from degenerative and rheumatoid arthritis, avascular necrosis, fracture of the neck of the femur or functional deformity of the hip and knee joint replacement is intended for use in individuals with joint disease resulting from degenerative, rheumatoid and post-traumatic arthritis, and moderate deformity of the knee.

Joint Replacement also called as joint arthroplasty involves the complete removal of the damaged joint and tissues to be replaced with artificial prosthesis or implants are medical devices manufactured to replace a missing biological component, support and enhance an existing biological component

The various implants manufactured by the team of Joint Replacement are following

Hip and Knee Implants includes:

Accolade

Accolade Morphometric Wedge is designed to address modern demands with novel technology by evolving conventional tapered wedge femoral stem design with size specific medial curvature to more closely fit a broad range of bone sizes and shapes of today’s patient population. Accolade has been shown to allow for enhance stability, decreased intraoperative femoral fractures, as well as survivorship and functional outcomes which may lead to satisfied patients.

Clinically, Accolade has shown significantly better overall canal fit than conventional tapered

wedge design with five times less intraoperative fractures observed compared to conventional tapered wedges and less than 0.1mm subsidence pursuant to a 2-year RSA study. Additionally, Accolade has shown 99.2% survivorship pursuant to a 3.5-year mean study.

Fig 1: Accolade

Anato

Anato is an evolution of past clinically successful anatomic femoral stem iterations, offering the confidence of clinical history based on the heritage of Porous Coated Anatomic (PCA), ABG and Citation. Published studies demonstrate over 11 years of clinical performance and survivorship with predecessor stems. Anato features an optimized stem length and low-profile lateral shoulder suitable for a variety of surgical approaches, including muscle-sparing techniques. In addition to the standard Anato instrumentation, the system is compatible with Stryker's Direct Anterior and Direct Superior instrument sets.

Fig 2: Anato

Exeter

The Exeter cemented femoral hip system is designed for surgeons who are looking to utilize a single system for all hip indications, primary, fracture and revision, with a single proven system. Exeter accommodates primary, revision and hip fracture cases with one implant and instrument system. The streamlined system helps promote operating room efficiencies by simplifying the training required for OR staff. The wide range of stem sizes, offsets and length options in the

Exeter system allows surgeons to intra-operatively restore a wide variety of patient anatomies with one hip system.

Fig 3: Exeter

Mako Total Hip

It facilitates the surgical approach of choice: direct anterior, posterolateral or anterolateral. The outcomes achieved have the potential to create the future of the orthopedic service line

It enables surgeons to more accurately plan and place components, potentially reducing variability within the THA procedure and allowing for enhanced functional and clinical outcomes. It has demonstrated greater accuracy in achieving planned leg length compared with manual total hip replacements in a cadaveric model.

Fig 4: Mako Total Hip

Triathlon

The Triathlon Total Knee System is a primary total knee replacement system designed to work with the body. Triathlon has been implanted in over 2 million patients worldwide. Triathlon Total Knee is now available for use with the Mako System for Mako Total Knee.

Fig 5: Triathlon

Trident

Acetabular Shell Systems

The needs of each patient with the versatility of the Trident Acetabular Shell offerings, all of which can be used with Stryker's advanced bearing options, like MDM X3, X3 Polyethylene, and Trident Constrained Liners.

Fig 6: Trident

The present study is aimed on the development of an efficient protocol for the Quality Assurance and Regulatory Process for Orthopedics. This study aimed at handling Customer Complaints associated with Stryker Joint Replacement division and operations sites in Mahwah,Cork, Limerick that are involved in the manufacture anddesign of medical devices.
The present study is also aimed to validate the application of SPS (SGTC Partnership Score) tool used for collecting the feedbacks from contracting Stryker divisions

SPS stands for SGTC Partnership Score. It is a feedback Management tool that is used to gauge the strength of customer relationships. It has a scale range of 1-5, 1 being the lowest and 5 being the highest score. Additionally, customers can also provide their comments along with the score. Based on score, customers are categorized into promoters (>3), Passives (=3) and detractors (<3). SPS score is calculated using the below mentioned formula:

SPS Score = %Promoters - %Detractors

This study also aimed at registering Stryker Joint Replacement products through a database called Global Product Registration Database (GPRD). It is a system used by Stryker to request and exchange regulatory documentation between design division RA and distribution division RA for registration purposes.

Review of literature

Complaint handling system is an essential practice in all goods manufacturing industries because all complaints are about defective products that must be paid attention to and completely evaluated to prevent recurrence (Nirmal Kumar et.al, 2015). European Commission has published chapter 8 EU guidelines for GMP (Complaints, Quality defects and product recalls,2014) in their regulatory guidance papers. Nirmal Kumar et.al in their research paper have stated that the critical outcome of the investigation can lead to a withdrawal of the product from the market. If the product or a batch of products is fatal for the consumers or shows regulatory violations or high risk to patient's health, it can be withdrawn from the market. There are risk management tools and /or internal standard operating procedures which is provided by USFDA.Some of the tools are basic risk management facilitation methods (flowcharts, check sheets etc.), Failure Mode Effects Analysis (FMEA), Failure Mode Effects and Criticality Analysis (FMECA), Fault Tree Analysis (FTA), Hazard Analysis and Critical Control Points (HACCP), Hazard Operability Analysis (HAZOP),Preliminary Hazard Analysis, Risk ranking and filtering and supporting statistical tools.

The complaint from patient is one of the major concerns of exercising patient's rights in the health care system. Such complaints are alarm for patients' safety and efficacy which has to be taken seriously. This paper is about different types of patient complaints received by a medical care organization and the responses given by organization's personnel (Sanna Pauliina Ryyanen et.al,2018). The data and responses of patient's complaints were collected from personnel of medical care organization from 2012 to the end of January 2014.These data were analyzed through qualitative data analysis.
The results showed many unwanted complaints but also helped in the improvement of health care processes. The results were related to patient's care experiences, provision of information, personnel's professional skills and the approach to patient complaint's handling. The main idea of these results was to protect public health by improvising and maintaining safety and efficacy of the products used by medical care organizations.

Single question from customers have become widespread and popular tool to measure customer loyalty and satisfaction(Wiesel,Verhoef and de Haan 2012).Net promoter score(NPS) is often used in many organizations to predict company's financial growth and performance(Reichheld 2003.The question is framed as "How likely is it that you would recommend company X to a friend or colleague?", a firm or organization is able to predict customer loyalty with this survey and this NPS tool is used as a loyalty indicator. It is not used to find causes of low score, root cause or any kind of explanation for the low scores provided by the customers. Depending on single question is risky and dangerous for a company to rely upon so organizations are encouraging to implement multidimensional approach to better predict customer behavior (Keiningham, et al. 2007; Wiesel, Verhoef, and de Haan 2012). NPS is based on customers attitude rather than his or her actual behavior.

This paper is about understanding and managing customer loyalty measurement in four ways.

First, the study is about unreliability of the NPS or overall satisfaction as a loyalty measure in B2B complex service organizations. Second, the background study helps in collecting customer data from multiple sources by including demographic, behavioral and attitudinal customer data when evaluating customer loyalty. A lot of criticism faced by the organization who were using a single loyalty metric (Aksoy 2013; Keiningham et al.2007; Kristensen and Eskildsen2011; Pollack and Alexandrov 2013). Creation of judgement on loyalty of customers without giving any attention to behavioral data is deceptive. Third,predictive analytics model uses big data techniques to identify and predict loyalty of customers and identifies customers who are no longer conducting business with the organization. In this study big data approach is used to capture and analyze customers data from various other sources. Fourth approach is about linguistic text mining determined by Villarroel Ordenes et al. (2014). This approach was used to determine the complaint status and emotions of each complaint. By using this technique customers are classified into three different categories complainers, neutral and satisfied.

Customer loyalty measurement is based on survey metrics and overall satisfaction of customers (Bolton and Drew 1991; Parasuraman 2006). NPS is used as a stand-alone metrics for determining and calculating customer loyalty. Customers are categorized into promoters, passives and detractors. The scale is in the range of 0-10. 0 means not at all likely and 10 means extremely likely. Promoters are the happy customers who give ratings as 9 or 10. Passives are neutral customers with ratings of 7 or 8 and detractors are the unhappy customers ranging from 0 to 6 on the scale of NPS (Reichheld 2006). Financial growth of company is determined by NPS.

For example, Keiningham et al. (2007) simulated the studies used in NPS research and compared the findings of Reichheld (2003) with Customer Satisfaction Index (CSI). The research showed rejection for the Net Promoter Score as the most reliable indicator to determine company's financial growth. They further researched and concluded that the customers loyalty-based behaviors are multidimensional and therefore a better tool is needed for measurement.

In these studies, RFM model was used to determine customers purchasing behavior based on historical transactional data. The RFM analysis is important because it converts customer transactional data into profitability scores. RFM analysis is performed by observing customers purchasing patterns over a period.

In this study customers are divided into 11 groups created with the help of RFM scores. This was done by K-means segmentation algorithm. K-means cluster has an average RFM score. Total 11 groups were selected for 11 -point scale of NPS that classified the customers based on promoter, passive and detractor categories. These groups were then organized based on their average RFM score. For example, customers who had highest average RFM score of 555, their NPS score is received as 10 and customers with an average RFM of 111, their NPS score is received as 0. This process was repeated for 11 customer groups.

NPS categories were then expressed according to the classification as promoters with score 9 or 10, passives with score 6,7,8 and detractors with score 0 to 5.

Table 2: The New RFM_NPS Categories Using RFM and K-means Clustering Model

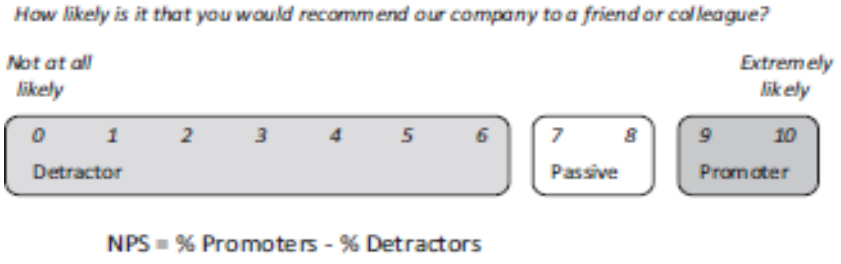
Cluster Number	Average RFM	Corresponding NPS scale	New RFM NPS Categories
5	111	0	Detractors
9	112	1	
8	221	2	
4	222	3	
10	223	4	
11	332	5	
3	333	6	Passives
7	334	7	
6	343	8	
2	344	9	Promoters
1	555	10	

The Net Promoter Score – an asset to patient experience surveys (Maarten W. Krol, Dolf de Boer, Diana M. Delnoij et.al)

The objective of this paper was to estimate patient experience surveys using NPS tool. To summarize patient experiences and satisfaction NPS was evaluated against three constructs that are global ratings, recommendation questions and overall scores calculated from patient experiences. The methodology involved the relationship between the NPS and the three other constructs were evaluated and their distributions were compared and also relationship between NPS and patient surveys were evaluated.

The analysis of the results indicates that NPS was moderately to strongly associate with the three constructs. However, their distribution proved evidently different. The patient experiences from the survey showed weaker relationship with NPS than with global rating and the overall score.

The conclusion of this study indicates minimum extent to which the NPS reflects the survey results. It is still not very clear what the NPS specifically adds to patient experience surveys.



Objectives

1. Handling Customer Complaints associated with Stryker Joint Replacement Implants and Instruments.

2. Validation of SPS Tool and development of its validation protocol and report.

3. Supporting product registration of Joint Replacement products by preparing submission documents as per International Regulations.

Tools and Methods

Trackwise

Trackwise Complaint Handling System is the depository for all complaints and related documentation. It is software and a web-based system that governs compliance, diminishes product safety risk. This system helps to receive, respond and resolve customer's complaints. The customers get in touch through different modes on a regular basis. So, to solve customer complaints requires a system with multichannel abilities.

SPS

SPS stands for SGTC Partnership Score. It is a feedback Management tool that is used to gauge the strength of customer relationships. It has a scale range of 1-5, 1 being the lowest and 5 being the highest score. Additionally, customers can also provide their comments along with the score. Based on score, customers are categorized into promoters (>3), Passives (=3) and detractors (<3). SPS score is calculated using the below mentioned formula:

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GPRD

GPRD stands for Global Product Registration Database. It is software or a system used by Stryker to request and exchange regulatory documentation between Design Division RA and commercial organization across globe.

Complaint Handling System:

Trackwise Complaint Handling System is the depository for all complaints and related documentation. Product complaints are managed by different roles within complaint handling team i.e. CIC(Complaint Intake Centre),CMC(Complaint Management Centre) and PAC(Product Assessment Centre).This project deals with CIC(Complaint Intake Centre) and CMC(Complaint Management Centre).

Complaint Intake Handling
The CIC Originator enters Complaints into the trackwise complaint handling system as per Complaint Intake Center Procedure. The Inputs for the origination of a customer complaint includes web-portal, mobile application, fax, email, phone, mail and other various sources. If the complaint originates from phone, the Originator uses the CIC form to document details of the reported event for Joint Replacement-Implant Instruments devices. After reporter contacted the Originator, the Originator logged into trackwise,

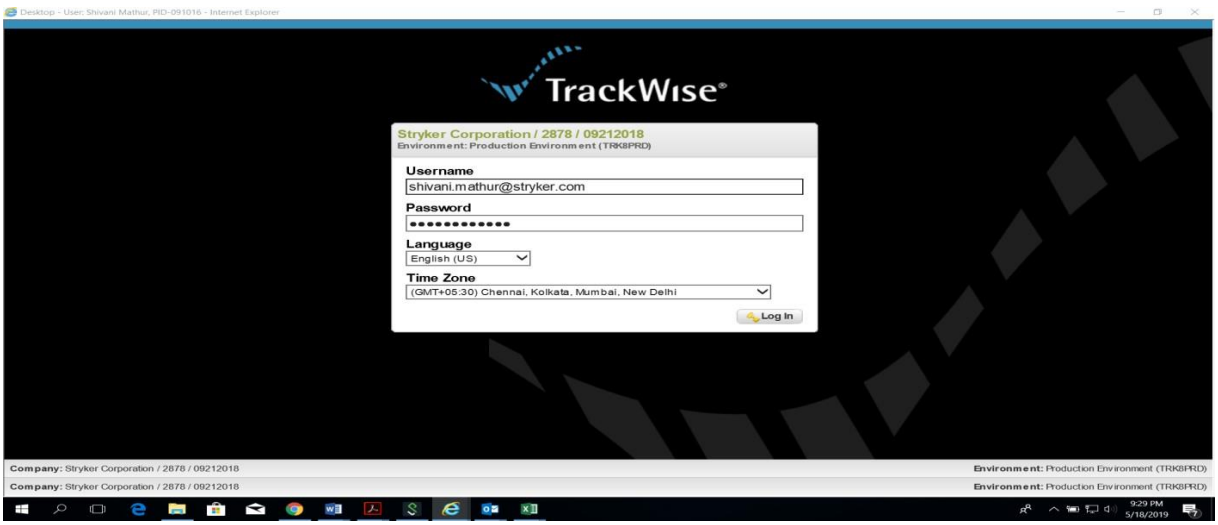


Fig 7: Trackwise Login Page

and navigate to the Desktop and press the "New PR" button to initiate a new Project Record (PR).

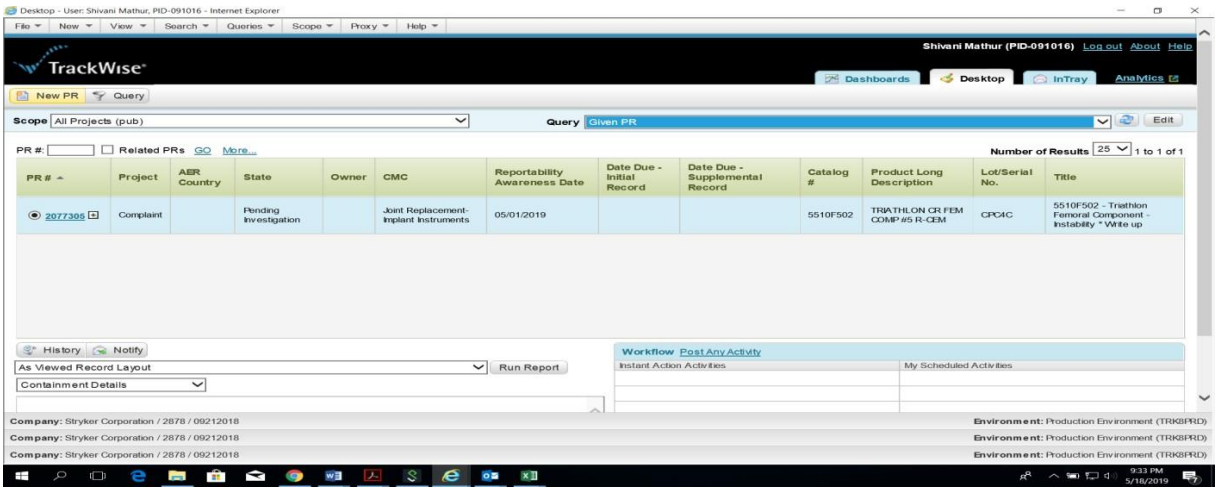


Fig 8: Desktop view

The Originator gathered and enter the information to complete the required fields within the Product Inquiry Record. This includes the Intake, Event Details, Contact Information, Product Details, Patient/Physician Info, Communication Log and Intake (Native Language) tabs within the system.

Table 3: Intake Tab

Date Opened	system generated field
Originator	system generated field
Country of Event	field to indicate the country in which the event occurred
CIC	field to indicate the Complaint Intake Center responsible for the reported event.
Intake Source	field to indicate how the event was reported
Intake Source – Other	field to be completed when “Intake Source” selection is “Other
Awareness Date	field to indicate the date that the first Stryker employee or person acting on behalf of Stryker Becomes Aware of an event
Reason for Delay	field to indicate the responsible party for a delay in reporting an event later than one (1) Business Day
Attachment – Intake	field to allow attachment of supporting documentation
Duplicate PI Search	field to allow the Originator to search for duplicate Product Inquiry Records
Communication Log	If additional information is provided in a subsequent report, the userinclude it as a additional information

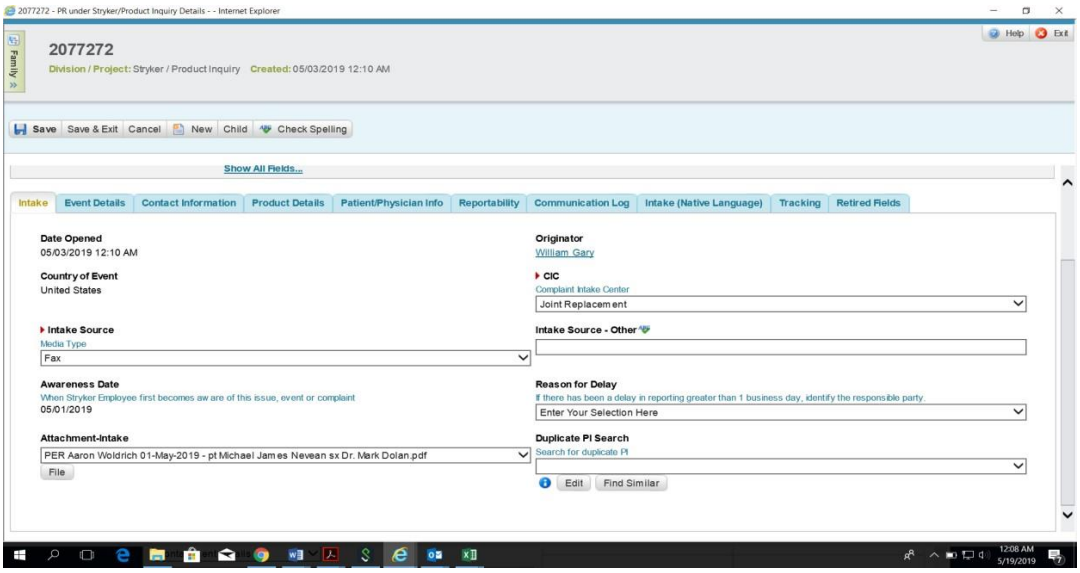


Fig 9: Intake Tab

Table 4: Event Details Tab

Event Date	field to indicate the date of the reported event
Approx	choose “Yes” if the Event Date is unknown
Event Description	field to indicate a description of the event. Obtaindetailed and factual information to describe what occurred. Avoid subjective language
How was issue noticed	field to include when the event was identified
Procedure Completed Successfully	field to indicate if the associated procedure was successfully completed
Patient Involvement	field to indicate if a patient was affected or impacted as a result of the event
Medical Intervention	field to indicate if unanticipated medical procedures, treatments or therapies were administered as a result of the alleged device malfunction
Surgical Delay	field to indicate if there was an unanticipated delay or prolongation to a medical procedure, treatment or therapy
Adverse Consequences	field to indicate if there was patient or user impact
Adverse Consequences Details	field to indicate information concerning medical intervention, surgical delay or adverse consequences. Provide detailed information such as amount of additional time associated with delay/prolongation, type of unanticipated medical intervention performed and the impact to the patient/user
Death Date	field to indicate the date of an associated death if applicable
Notify Legal	field to indicate if legal will be or has been notified
User/Distribution Reported	field to indicate when the user facility, user or distribution site has notified regulatory authorities of the same event
Reg Authority/Notified Body	field to indicate which Regulatory Authorities have been alerted

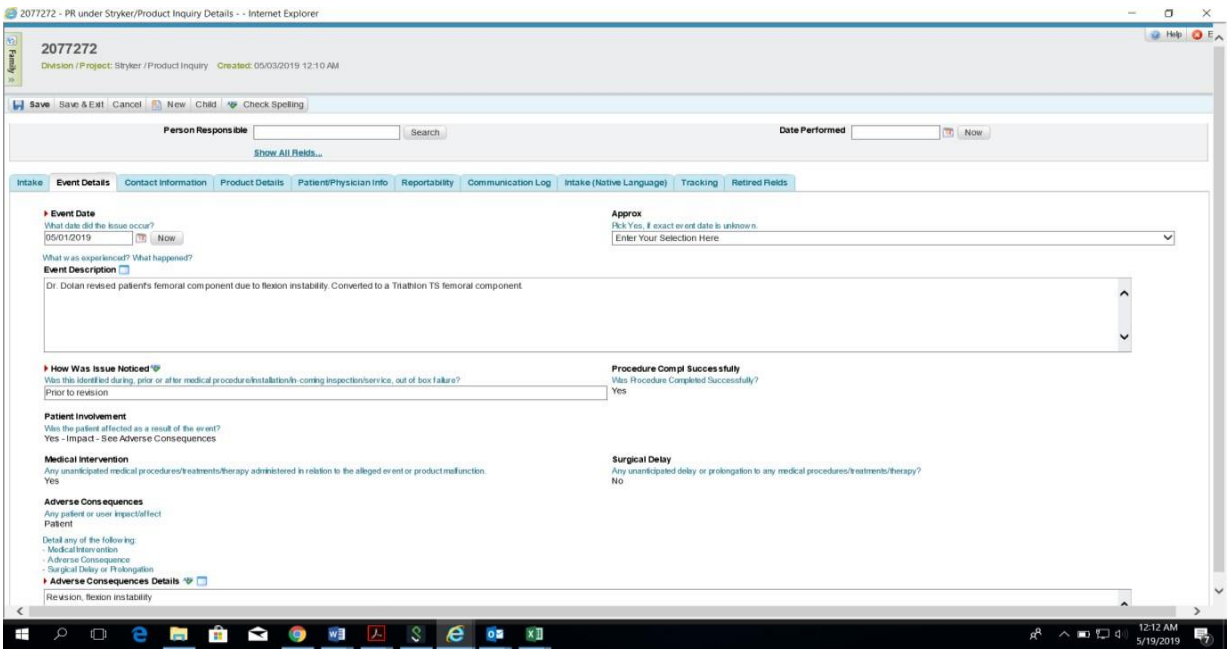


Fig 10: Event Details Tab

Table 5: Contact Information Tab

Initial Reporter Name and Address	fields that indicate the contact information for the person who initially reported the event to Stryker and who can be contacted to provide information on the event if follow-up is needed
Initial Reporter Country	indicates the country where the initial reporter is located
Initial Reporter Phone	format for the phone number should be in the following format: +1(Area Code) Phone Number Extension.
Initial Reporter Type – Other	field to indicate via text a value other than those available
Health Professional Occupation	field to indicate the type of Health Care Professional
HP Occupation – Other	field to indicate the appropriate specialty
Sales Rep	a field to enter the company representative name
Sales Rep as Reported	a searchable field to allow entry of a Stryker Sales Rep
Distribution Direct	field to indicate the Stryker distribution site such as a sales branch or International Distribution Divisions

Contacts	field to include contact information for additional people who may have relevant information. Choose “Open”, click “Add Row” and complete the “Contacts” grid

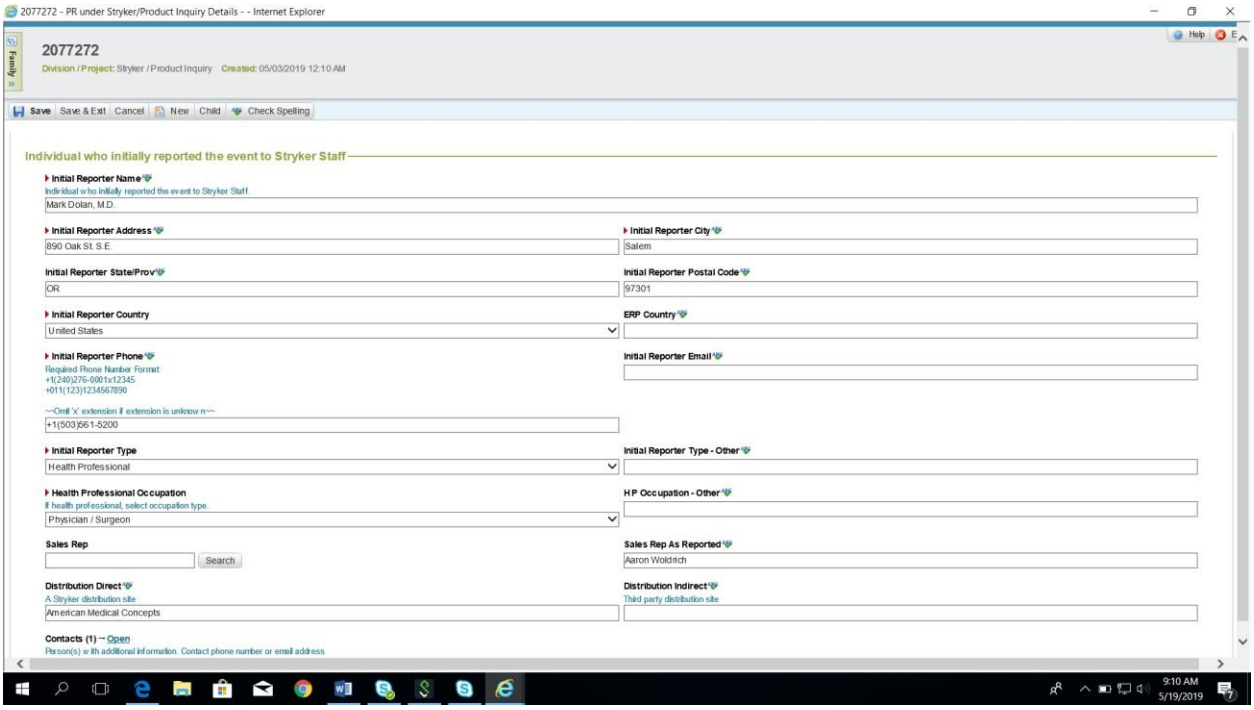


Fig 11: Contact Information Tab:

Table 6: Product Details Tab

Product Grid	grid to indicate the Product involved in the event
Complainant Acknowledgment Required	field to indicate if the Complainant has requested notification the event was received
Acknowledgement Type	field to indicate the type of Complainant acknowledgment requested
Complainant Require Results	field to indicate if the Complainant requests results of the investigation.
Complainant Result Type	field to note the format of the investigation results requested by the Complainant
Product Available to Stryker	field to indicate if and how the Product is available for investigation
Product Not Available, Why Not	field to document why the Product is not available for return to Stryker

Medical Records Available	note if medical records are available
Items Shipped	field to indicate items to be shipped to Stryker
Product to be Returned	field to indicate if the customer would like the Product(s) returned after the investigation is complete
Products to be Returned List	field to indicate the Product(s) requested to be returned to the customer. Enter the catalog number and choose “Add “Choose “Edit” to update, remove or add catalog number(s)
Other Event Cross References	field to indicate any associated references applicable to the event such as related project records, additional patient/customer information, and past Regulatory Action reference numbers
Reprocessed Products	field to indicate Product(s) that may have been identified as Reprocessed

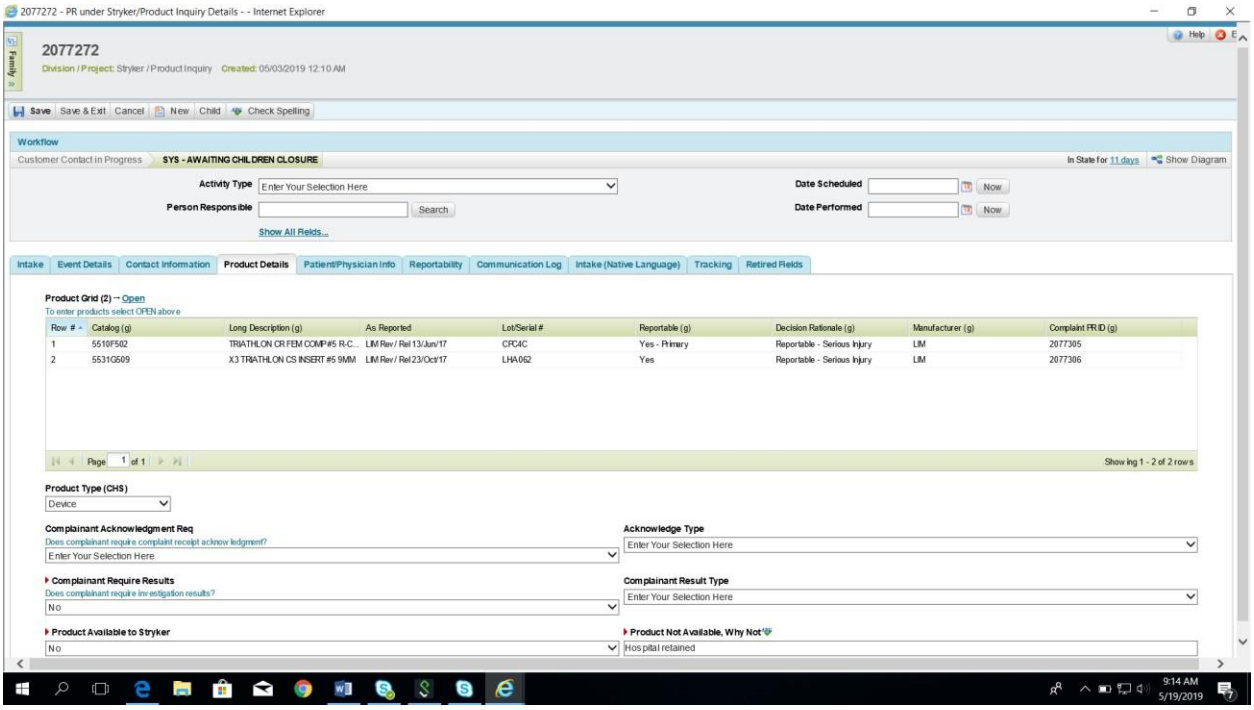


Fig 12: Product Details Tab

Table 7: Patient/Physician Info Tab

Patient Identifier	field allowing for identification of the patient. Data should not be the patient's name
Anatomy Position	field to indicate the body part affected by the event. Originator may use field to indicate the area in which reported Product(s) is used
Patient Information	Gender, Age at Time of Event, Age Units (Patient), Height, Height Units, Weight, Weight Units, Date of Birth
Activity Post Implant	-
Revision	field to indicate if the event was associated with a primary surgery or with a revision surgery, and, if known, the applicable revision number
Clinical Study Type	field to indicate the type of clinical study if applicable
Clinical Study Description	field to indicate an associated clinical study reference
Physician Name	-
Physician Contact Information	-

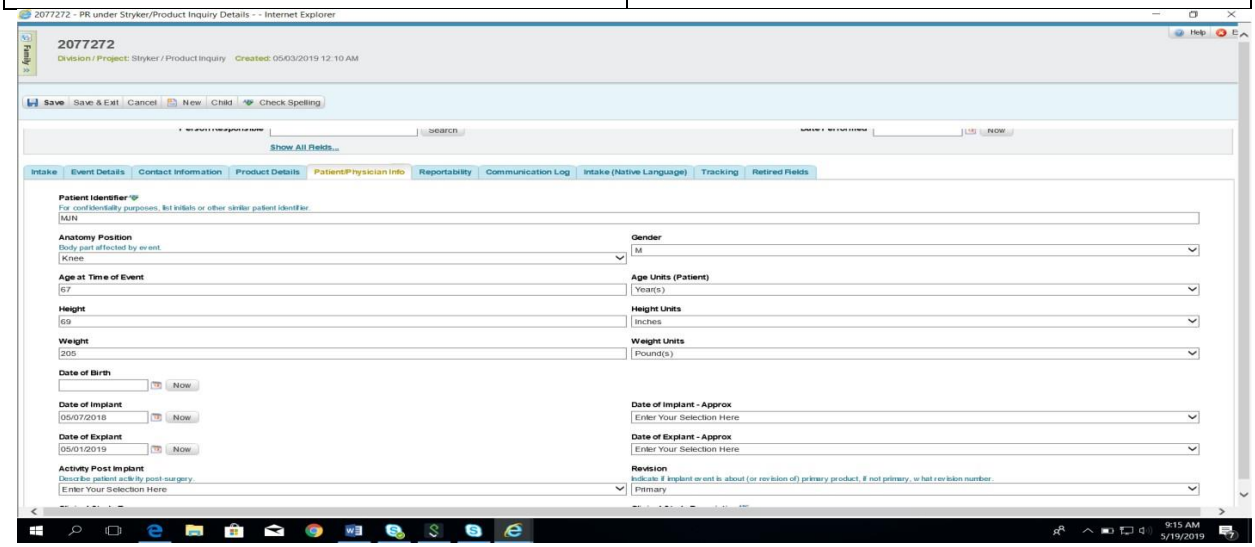


Fig 13: Patient/Physician Info Tab

Table 8: Communication Log Tab

Customer Contact 1, 2 and 3	indicates when the customer was contacted
Customer Contact Method 1, 2 and 3	field to indicate the method by which the customer was contacted. Once this information is saved, it cannot be edited
Communication Details	field utilized to document any external communication regarding the event such as requests for additional information from customer, sales rep, or other Stryker sites
Attachment – Communication	field to allow attachment of documentation associated with any communications, investigational material, or patient/customer information, such as medical records. Choose "File, "browse to select applicable file and choose "OK.
Customer Response Date	field to indicate when the investigation results were provided to the Complainant
Assigned To	field to indicate the person primarily responsible for customer communications
Customer Contact Status	field to indicate which contact number is pending
Other Communication	field utilized to document other communication regarding the processing of the event such as updates from additionaL requests or information found through the process of investigation

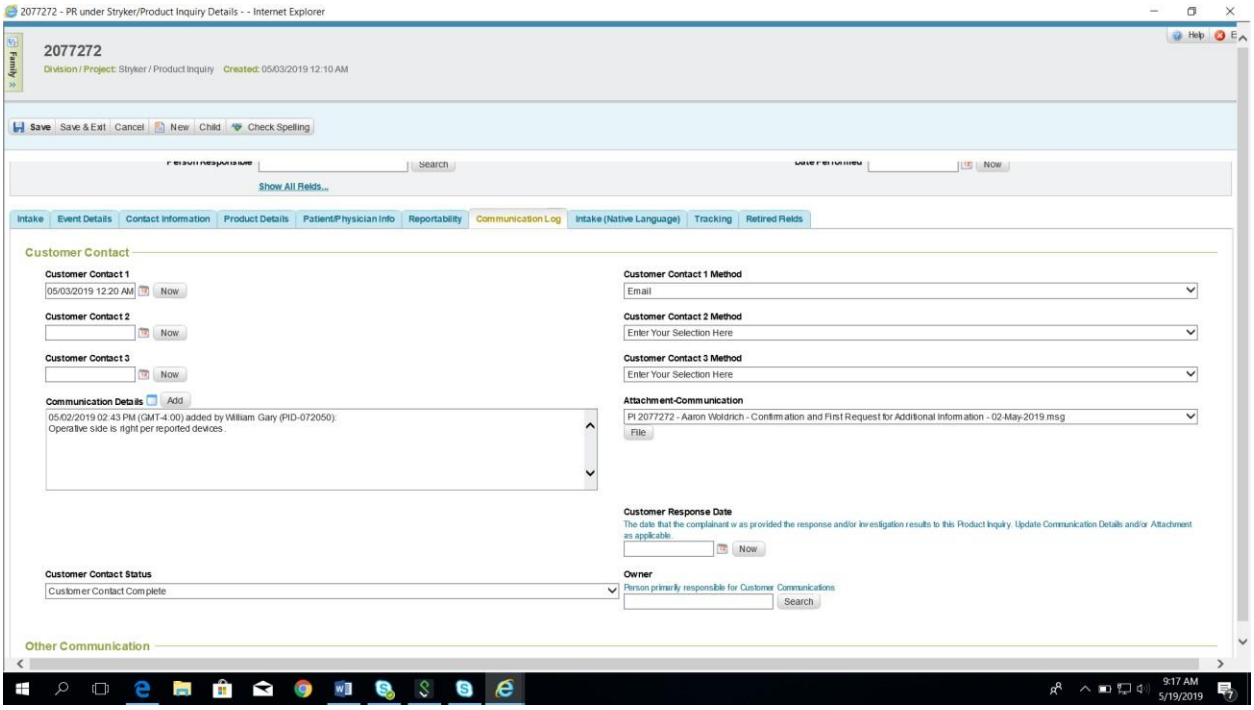


Fig 14: Communication Log

The Originator shall save the Product Inquiry Record after the required fields are completed. This ensures that a Project Record is assigned to the entered information

CIC Product Inquiry Closure

Once the associated Product Inquiry child records have been closed and/or approved, the Reviewer shall review the Product Inquiry Record to determine if customer feedback and/or Product return was requested. The Reviewer shall then close the Product Inquiry. The Reviewer monitored to ensure that all PI's at 'Final Approval' are submitted for closure.

Complaint Management Centre

Once an Originator submits a Product Inquiry Record, a Complaint Project Record for each Line item in the Product Grid is system generated. The CMC logged into CHS and choose a Complaint Project Record in the "Opened" state assigned to their CMC. The CMC shall review the Complaint Project Record and Product Inquiry to ensure the correct CMC was assigned. If the incorrect CMC is identified, the Coordinator shall choose the correct CMC. The CMC is automatically assigned on the Product Inquiry based upon the first Line item in the Product Grid

Table 9: Complaint Details Tab

CMC	field to indicate the assigned CMC
PAC	field to allow assignment of the Product Assessment Center
CMC Coordinator	field to indicate the owner of the record at the CMC. This field should reflect the name of the person who performs complaint submission for that particular PR
Investigation Owner	required field to indicate the owner of the complaint investigation

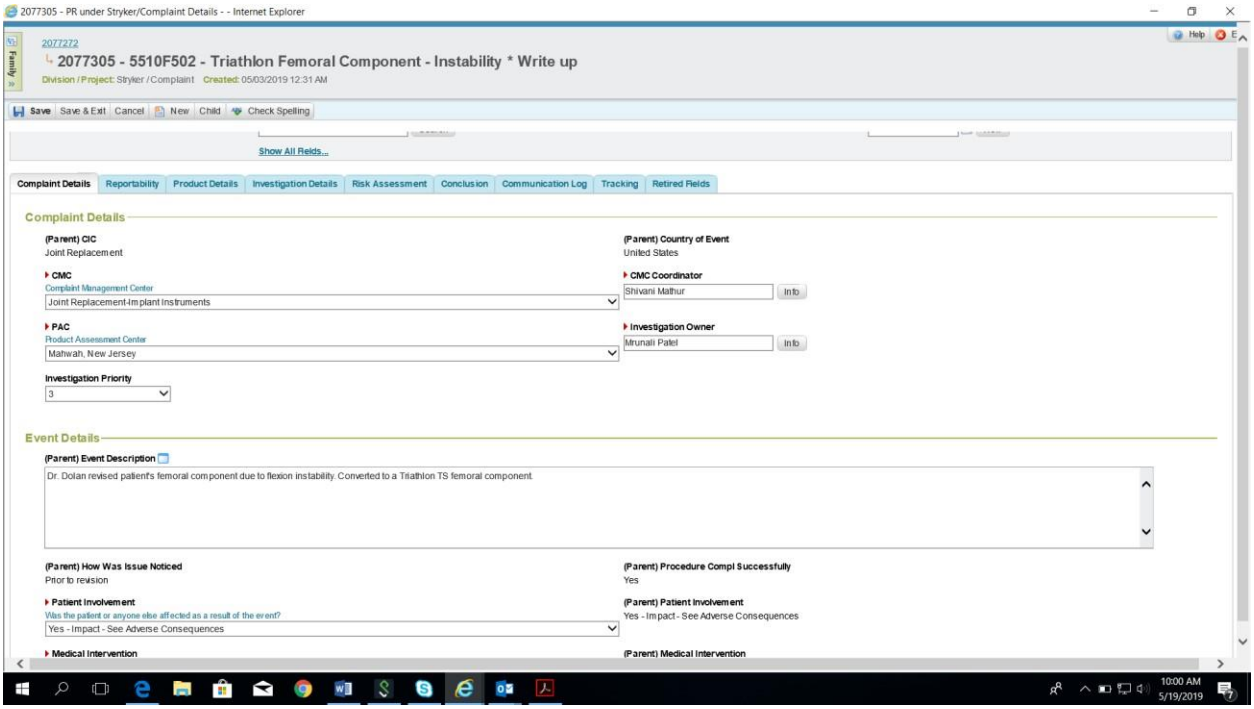


Fig 15: Complaint Details Tab

Table 10: Event Details

Patient Involvement	field to indicate if a patient was affected or impacted as a result of the event for this specific product
Medical Intervention	field to indicate if unanticipated medical procedures, treatments or therapies were administered because of the alleged product malfunction for this specific product
Surgical Delay	field to indicate if there was an unanticipated delay or prolongation to a medical procedure, treatment or therapy for this specific product

Adverse Consequences	field to indicate if there was patient or user impact from this specific product
Adverse Consequences Details	field to indicate information concerning medical intervention, surgical delay or adverse consequences
Adverse Consequence Event Code	conditional field that is required when Adverse Consequences are reported
Initial Assessment	The CMC shall make an initial assessment which represents a first classification of the reported event for the associated product
Experience Report Type	field to indicate the type of classification assigned to the reported event for the associated product
AR – Product Problem Code	grid to indicate associated Product Problem Code based on the as reported details for the event
Manufacturing Date	enter the manufacturing date of the reported product within the Product Details Tab
Other Product Cross References	field to indicate any associated references applicable to the product, such as related project records
Product Family	enter the product family name by starting with "JR -"

Then submit the complaint in the workflow station and the record will progress to the "Pending Investigation" state. A complaint record may undergo a technical approval if requested by management.

Validation of SPS tool

The survey was initiated, and feedback participants were identified. The notification was provided from RAQA, department head – R&D and lab manager identified and shared list of participants for SPS initiation with RAQA. The survey and feedback were developed. The online tool had issued the standard feedback survey to the divisional partners with a request to receive the response to the survey within 15 days of issue. The feedback was further collected and followed up. The system had initiated reminders and were sent to survey participants. The frequency of reminder was decided based on the responses received. Survey was not closed until 80% response at SGTC level were received. The timeline was extended as per the request by divisional manager /SGTC stakeholder to RAQA Team for the surveys which were not responded.

Feedback Analysis

RAQA had consolidated and generated report for the formal responses. They communicated the survey results and trends to department head R&D and RAQA head. Department head/lab manager identified and analyzed the feedback results and prepared the action plan. The results of feedback were presented to management as required by management review procedure. Department head had discussed the status of action plan in management review meeting. Any non-conformance on notification of customer dissatisfaction were handled through nonconforming product handling and CAPA procedure.

Test Steps

The lists of users were prepared along with the expected responses. Then the survey was initiated to all the users mentioned in the list. Users were instructed to fill the response as per the sheet. The response in SPS tool was cross verified with the sheet of expected results. Results were 100% exact thus justifying the validation of the tool

Table 11: Test Case and Expected Outcome

Test Case	Expected Outcome
Survey initiation to all users	100% users shall receive a mail with feedback link
Capturing Ratings & Feedbacks of users	All the ratings and feedbacks shall be 100% accurate
Score less than 3 mandates all the fields	Scores less than 3 shall mandate all the questions For score 3 or more, only the comment field shall be mandatory
Triggering Reminders to users with no response	Reminders shall be triggered to only those users who have not submitted their response

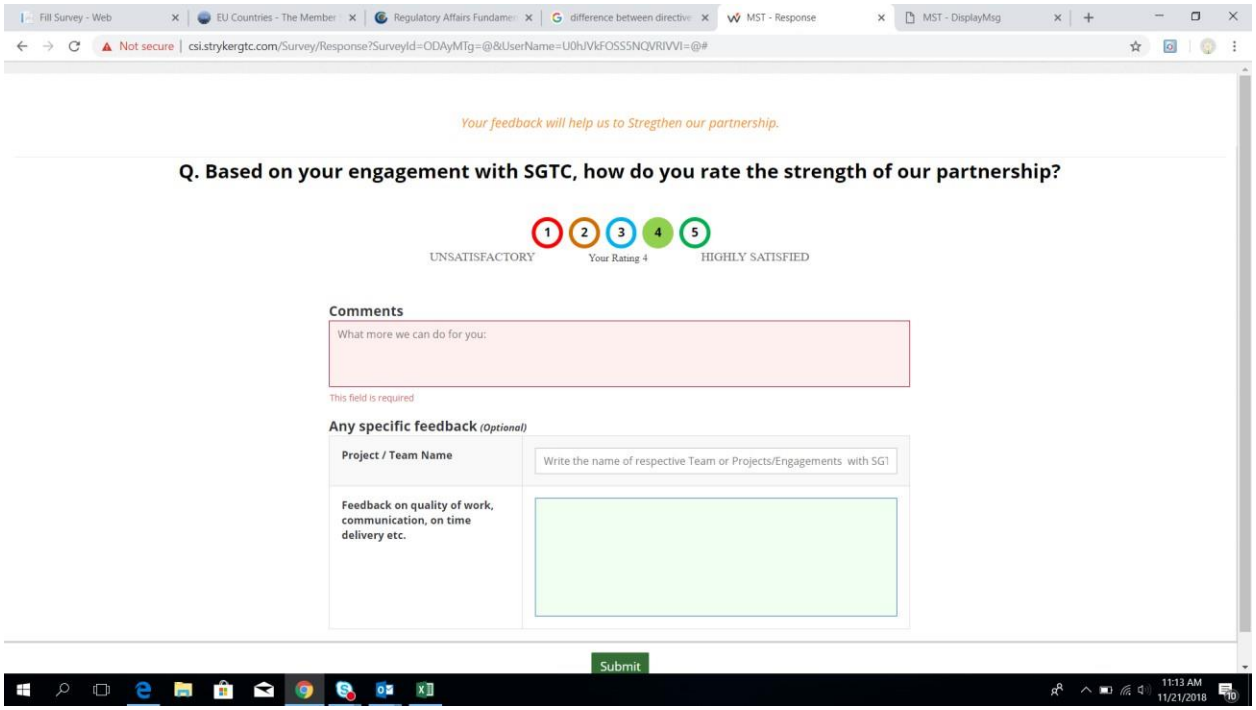


Fig 16: SPS Tool

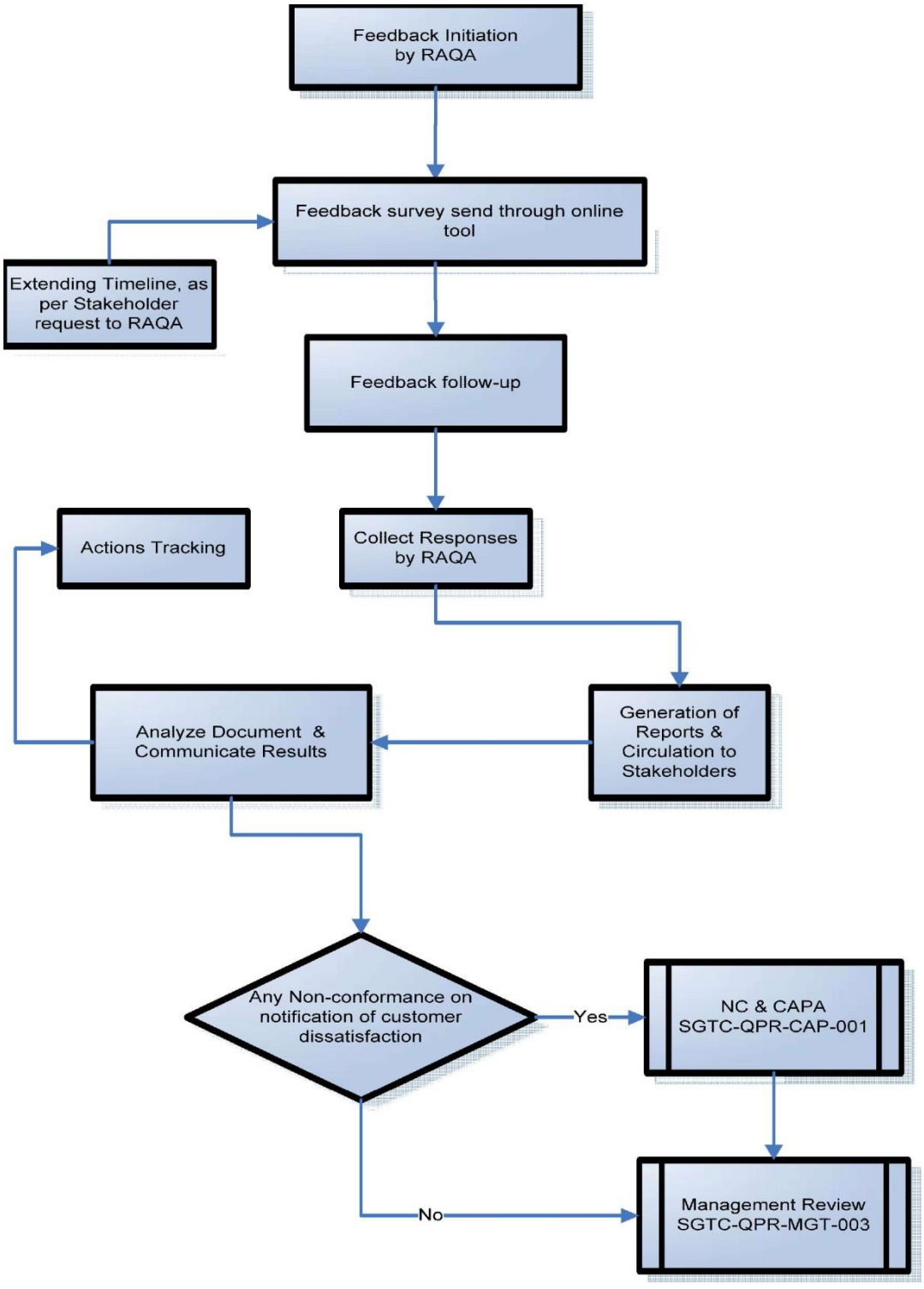


Fig 17: Process Flow Chart

Product Registration Database

Stryker Joint Replacement used GPRD to complete their product submissions. Firstly, logged on to GPRD portal and entered the site address (https://intranet.strykercorp.com/GPRD) then type in user ID and password and click on the "GO" button. Then clicked on the request number to View the detail of the request. Requests can also be searched using the "Find a Request "option".

If information is needed for specific products then confirm that the requestor has provided a GIM checked item list; if not, request one (marketing collaterals such as brochures and surgical protocols are not adequate). This item list should only contain items that are in GIM life cycle code 200 to 400.Documents that were requested via GPRD are uploaded by clicking on the "Upload" button. JR/ RA uploaded a digital copy of all requested documents. Once documents are uploaded they are available for International RA to download. JR/RA will ship out a physical document only when indicated on the request. Once all requested documents are uploaded and/or shipped, the status of the item is changed to "shipped". To do so, click on the "ship" button in request detail page. Once the documents are uploaded then they are available for download. If needed, messages to the requestor are sent by clicking on the "Reply" button under the Message History section

Table 12: GPRD Status

Status	Description	Responsible Party
Pending	Once the request is created, the status will be set as Pending and it will wait for local manager approval.	Requestor
Approved	The request has been approved by the requestor and his/her manager.	Requestor
Shipping	RA has started to ship (send) documents.	JR RA
Received	All documents were received by the requestor	Requestor
Submitted	The request/documents have been submitted to local regulatory body	Requestor
Completed	The request was approved by local regulatory body	Requestor
Deleted	The request is deleted from the system (for errors)	Requestor

Prerequisites to work on GPRD:

1. Item number
2. Life cycle code
3. TF/DD
4. Manufacturing site

To get item numbers copy and paste the link in browser and enter User ID and password.

https://intranet.strykercorp.com/GPRD

Fig 18: GPRD Login Page

After login you will be directed to homepage screen where all the GPRD requests are seen.

Open the particular request, download the excel file containing item number and LCC.

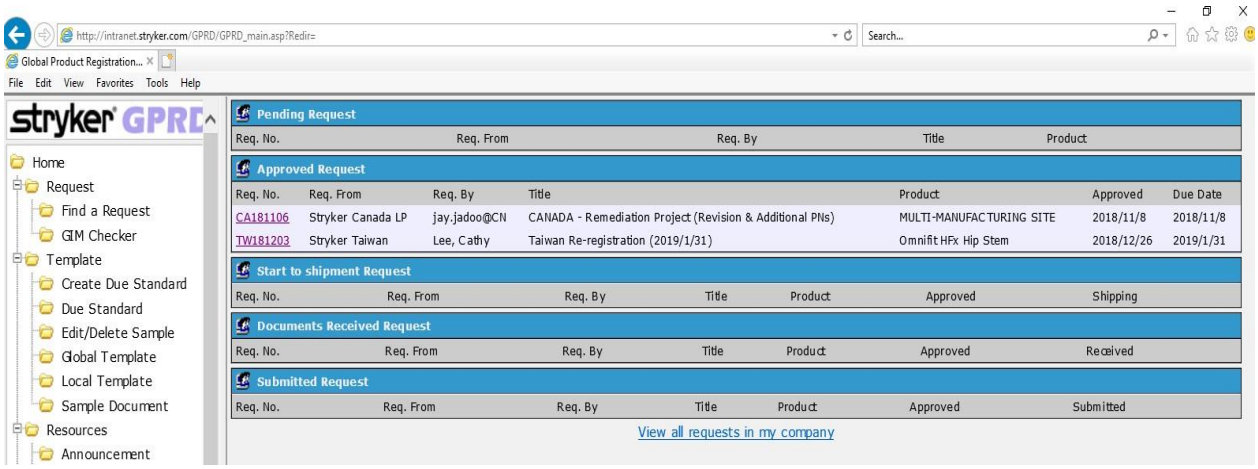


Fig 19: GPRD Homepage Screen

For cross checking copy the part numbers and save them in notepad to upload in GIM.

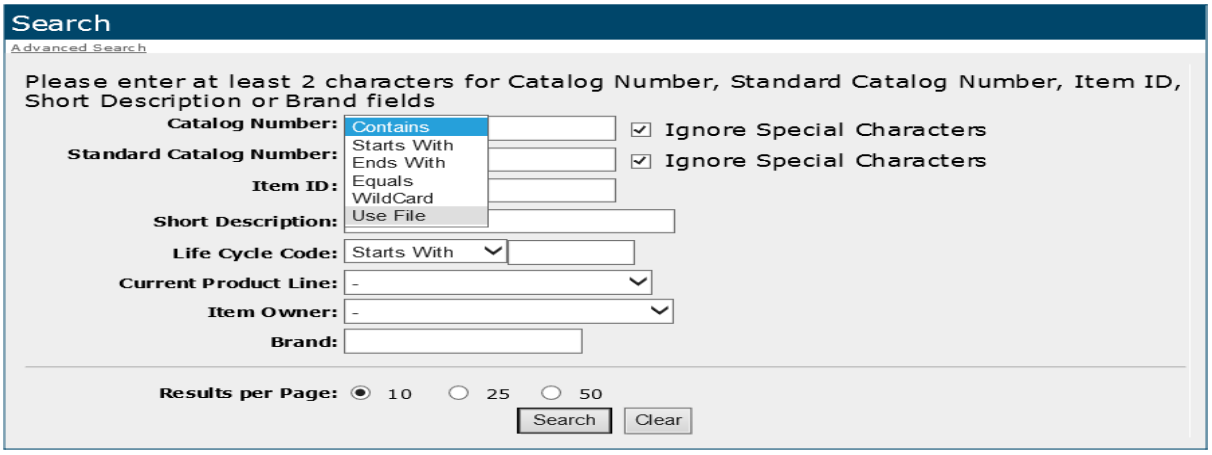
Open GIM to get LCC http://gim.stryker.com/search.do and enter email ID and password

Fig 20: GIM Login Page

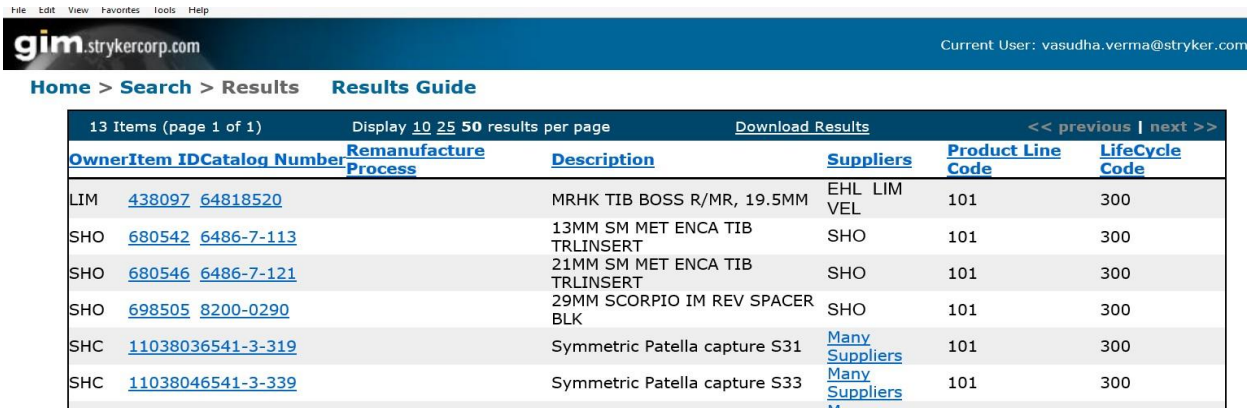
Then click on search additional fields

Choose contains option in catalog number

- Click on use file option
- Browse and choose your notepad file
- Choose 50 in results per page
- Click on search



Click on download results



Choose CSV for excel and unzipped and click on download, open the excel file and crosscheck the LCC mentioned in GPRD request with the LCC available in GIM excel file for further use.

Open Regaffand find the TF or DD of the item number to know the manufacturing site

\\mydata\Regaff

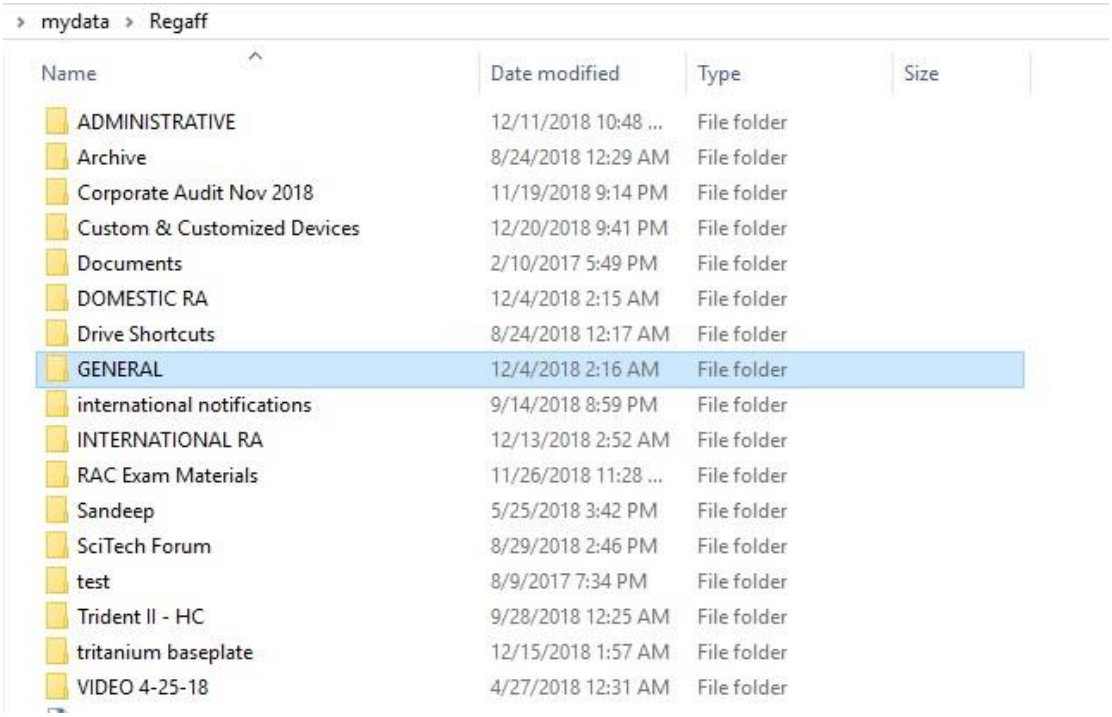


Fig 21: Regaff Drive

Click on oracle reports

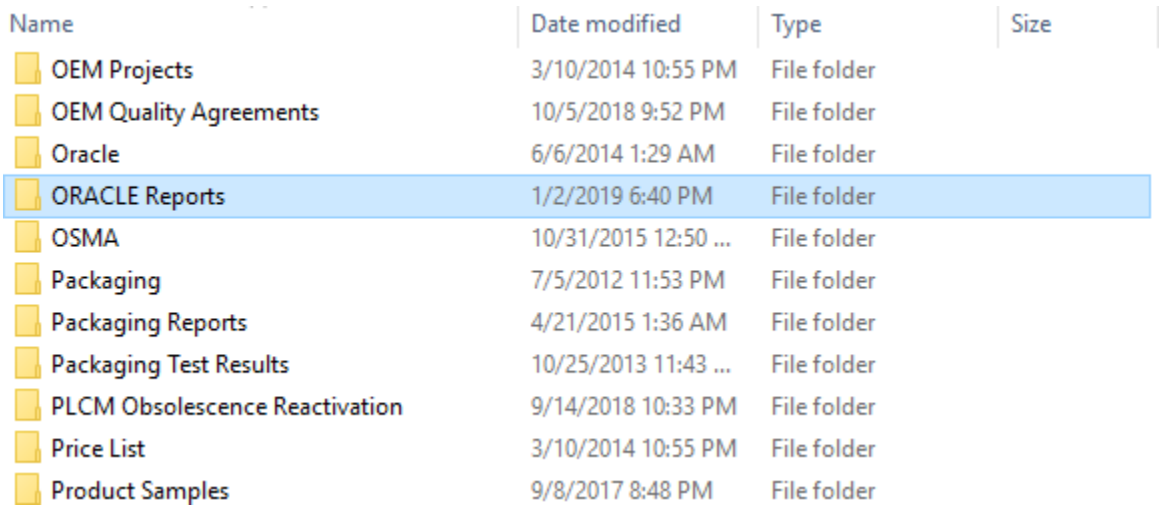
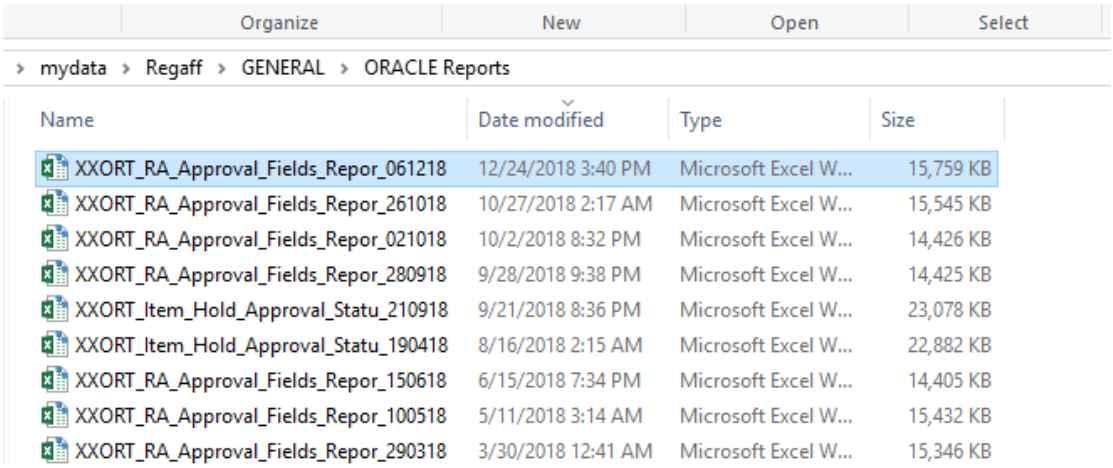
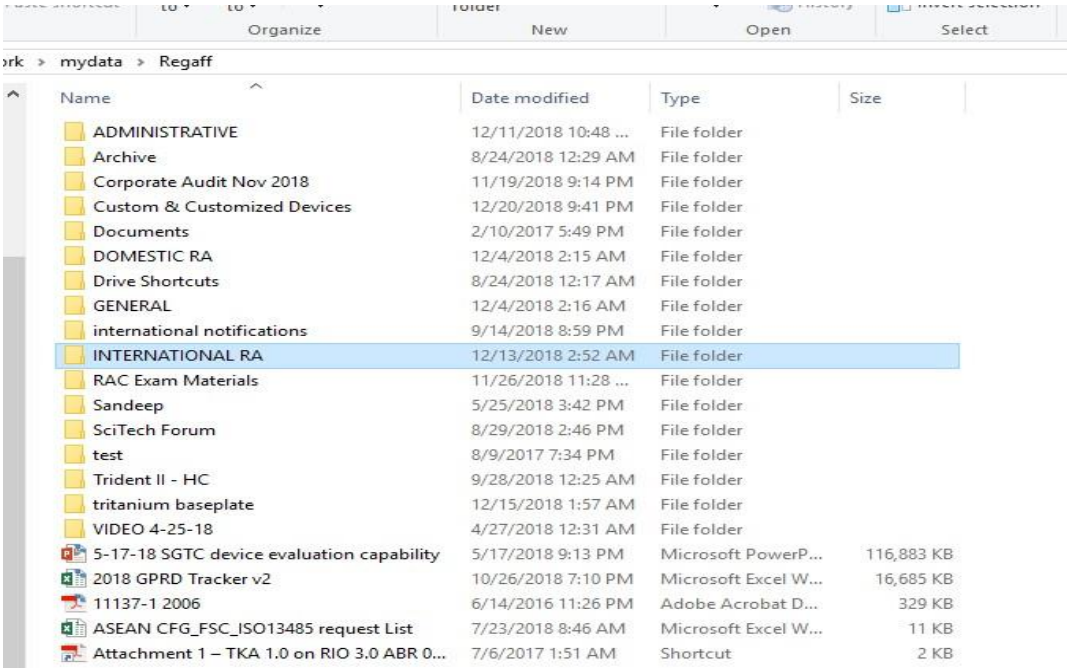


Fig 22: Oracle

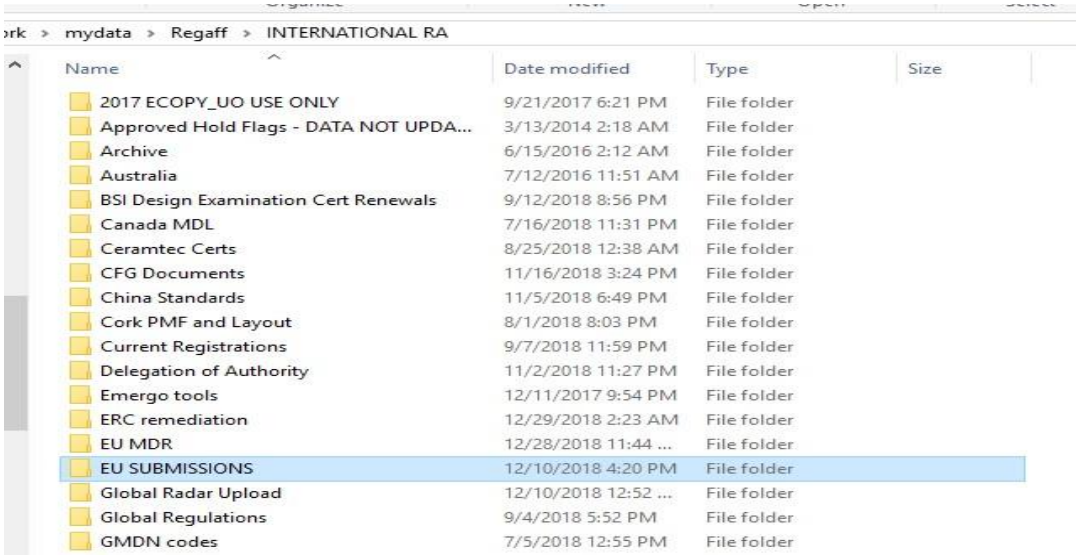
Click on latest excel sheet and copy technical file number or design dossier for the particular item number from oracle excel sheet.



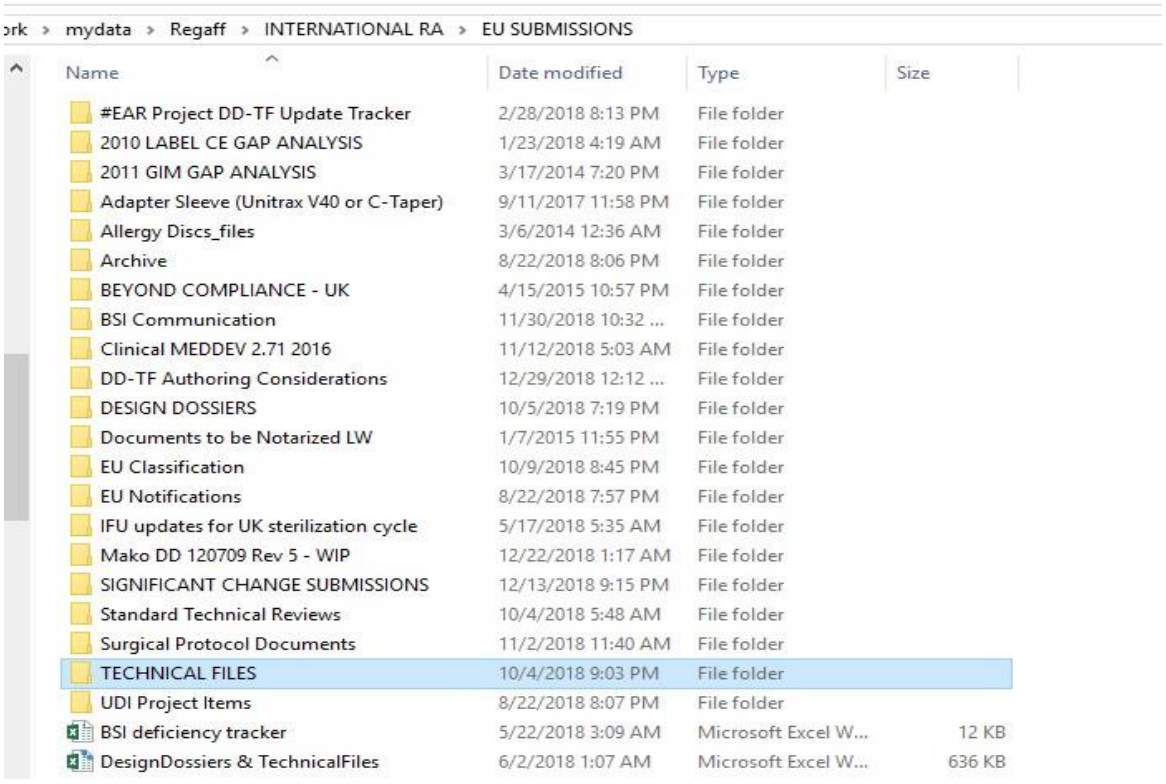
Open Regaff to get manufacturing site from the TF or DD [\\mydata\Regaff](\\mydata\Regaff) then click on International RA



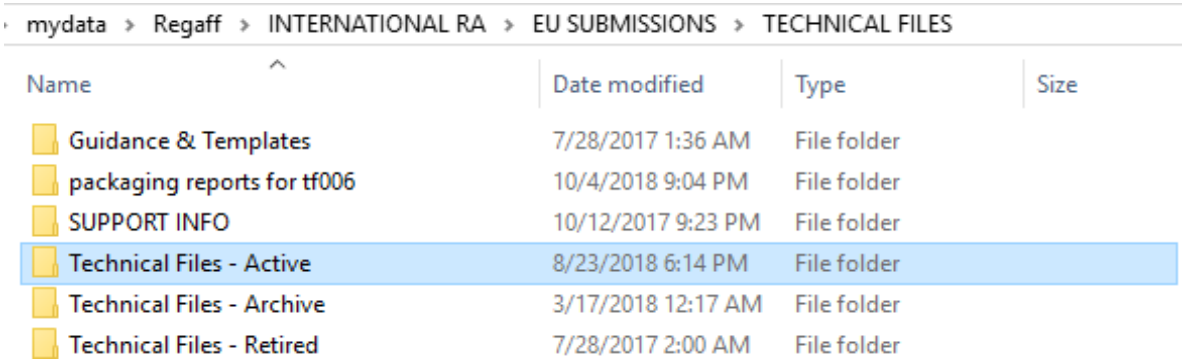
After that Click on EU submissions



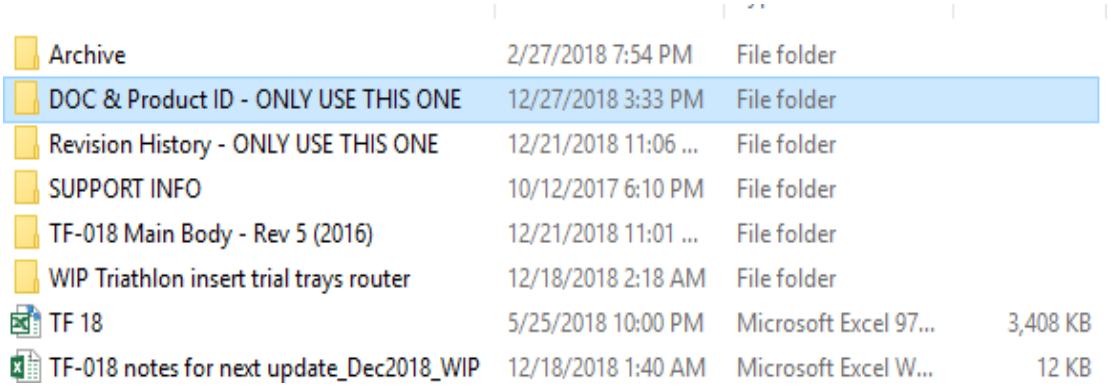
Click on Technical files



Click on active technical file



Choose the TF you are looking for and click on DOC and product ID



Results and Discussion

Table 13: Types of Complaints

S.NO.	Event details	Product details	Failure Mode	Priority	Hazard (Product)	Harm (Product)	Harm (Patient)	Hazard (Patient)
1	Dr. Dolan revised patient's femoral component due to flexion instability. Converted to a Triathlon TS femoral component	Triathlon Femoral component	Joint Instability	3	Mechanical issue-Unintended movement	Unstable	Joint Instability	Insufficient range of motion
2	Dr. Dolan revised patient's femoral component due to flexion instability. Converted to a Triathlon TS femoral component.	Triathlon Insert	Joint Instability	3	Mechanical issue-Unintended movement	Unstable	Joint Instability	Insufficient range of motion
3	Rep reported revision due to instability. Surgeon did a poly exchange and removed a 3x9 PS tibia insert and put in a 3x13 TS tibia insert. Rep reported that no further information will be provided by	Other Knee	Joint Instability	3	Mechanical issue-Unintended movement	Unstable	Joint Instability	Insufficient Constraint

	the hospital or surgeon.							
4	Trunnion failure. Appeared on x-ray. Update 06/May/2019 WG: As reported in the Patient/ Physician info tab, revision was performed on May 2, 2019	Femoral Heads	Revision Surgery	2	No - Info	No-Info	Revision Surgery	Hazard not Reported
5	Trunnion failure. Appeared on x-ray. Update 06/May/2019 WG: As reported in the Patient/ Physician info tab, revision was performed on May 2, 2019	Accolade	Revision Surgery	2	No - Info	No- Info	Revision Surgery	Hazard not Reported
6	On incoming inspection, item was visibly worn. Device delivered to Decon Lab. No further information is available	Accolade Tray	Wear	3	Material Integrity Issue-Degraded/ Disintegrated	Degraded	None, S0	Excessive visual degradation
7	The slap hammer is NOT gliding as expected. Instrument will be	Triathlon slap hammer	Seizing	2	Mechanical issue	Mechanical issue	User annoyance	Excessive locking strength between devices

	returned when customer has got a replacement							
8	MDM and head removed, replaced with constrained liner	Modular dual mobility Liner	Revision Surgery	3	No information	No information	Revision Surgery	Hazard not reported
9	The customer reported that the plastic was bent on both stems which resulted in them being unable to attached it to the stem.	Exeter Stem	Damage	3	Material integrity issue-Deformed/ Degraded	Material deformation	None	Incorrect or inappropriate output or functionality
10	It was reported that the patient's left hip was revised due to pain. The patient's bipolar component and femoral head were revised to a competitor shell and liner with a Biolox ceramic head. The stem was well-fixed and was not revised. Rep	Unknown Implant	Revision Surgery	3	No information	No information	Revision Surgery	Hazard not reported

	reported that no further information is available from the hospital or surgeon.							
11	It was reported that the patient's right hip was revised due to the distal portion of the distal stem breaking inside the patient's femur. No possible cause or contributor was reported to the rep. Patient's Restoration Modular stem and a femoral head were revised to competitor devices. Rep provided pre-revision x-rays and reported that no further information will be released by the hospital or surgeon.	Restoration modular hip system	Fracture	3	Material integrity-Breakage issue	Break	Revision Surgery	Fractured device
12	It was reported that the patient's right hip was	Accolade Stem	Fretting	3	Material integrity-Degraded/ Disintegrat	Material erosion	Revision Surgery	Excessive fretting debris

	revised due to trunnionosis. Pre-op x-rays show the head disassociated from the stem. Intra-operatively, black tissue was noted in the patient. No liner wear or discoloration were reported. The stem, head and liner were revised to a Stryker liner with a competitor stem and head. Rep provided a pre-revision x-ray and reported that no further information will be released by the hospital or surgeon.				ed			
13	It was reported that the patient's right hip was revised due to trunnionosis. Pre-op x-rays show the head	Accolade Stem	Fretting	3	Material integrity-Degraded/ Disintegrated	Material erosion	Revision Surgery	Excessive fretting debris

	disassociated from the stem. Intra-operatively, black tissue was noted in the patient. No liner wear or discoloration were reported. The stem, head and liner were revised to a Stryker liner with a competitor stem and head. Rep provided a pre-revision x-ray and reported that no further information will be released by the hospital or surgeon.							
14	Cement filled with Exeter use BHA, decreased heart beats after stem insertion, and it was occurred temporary cardiac arrest treated by cardiac massage, then recovered.	Simplex Cement	Patient Factors	3	No Information	No Information	Arrhythmias	Incorrect or inappropriate output or functionality

	After that, went to ICU							
15	Found liner trial broken	Trident Insert Trial	Crack	3	Material integrity issue-Breakage	Break	None	Excessive visual degradation
16	Found offset reamer broken in SPD	Offset Reamer Handle	Crack	3	Material integrity issue-Breakage	Break	None	Fractured device
17	Found offset reamer broken in SPD	Trial Head						
18	Pin will not slide through cutting block							
19	Pin won't slide in block		Cleaning Issue	3	Distribution position-Cleaning/ Disinfection/ Sterilization	Product cleaning issue	None	Failure to assemble
20	As reported: "Surgeon use mallet to insert T-Handle rod. The mallet split the rubber on the T-Handle". Update: "Discovery of damage to t-handle was post-surgery. While turning over instruments the next day. Patient information is	Triathlon handle driver	Damage	3	Material integrity issue-Degraded/ Disintegrated	Degraded	Complications associated with extended surgery	Excessive visual degradation

	unavailable."							
21	In Navigation THA surgery, the connecting parts to the handle of the cup positioner was broken when the surgeon was impacted the cup. All the fragments was retrieved	Navigation Cup positioner	Crack/Fracture	2	Material integrity issue-Breakages/Fractures/Cracks	Break	Complications associated with extended surgery	Fractured device
22	Lid of the tray is broken / color flakes off. No pictures available	GMRS Case Tray	Crack/Fracture	3	Material integrity issue-Breakages/Fractures/Cracks	Break	None	Fractured device
23	It was reported that the patient's left knee was revised due to a broken MRS femoral stem. The surgeon reported that the most likely cause or contributor was that the patient was moving furniture at the time. Rep provided pre- and post-	MRS stem	Crack/Fracture	3	Material integrity issue-Breakages/Fractures/Cracks	Break	Revision Surgery	Fractured device

	revision x-rays and explant pictures, and reported that no further information will be released by the hospital or surgeon							
24	It was reported that the patient's right hip was revised due to a femoral periprosthetic fracture sustained in an unspecified incident at a nursing home. An Accolade II stem and 36 -5 ceramic head were revised to a Restoration Modular stem construct with another 36 -5 ceramic head and 4 sets cabled devices. Rep provided implant sheets from current and prior surgeries as	Accolade Stem	Periprosthetic Fracture	3	No - Info	No - Info	Periprosthetic Fracture	Excessive stress in the bone

	well as a pre-revision x-ray and reported that no further information will be released by the hospital or surgeon							
25	Before the surgeon was ready to cement in the baseplate he recognized two distinct lines on the bottom surface of the baseplate	Triathlon Baseplate	Damage	1	Material Integrity – Degraded/ Disintegrated	Degraded	Complications associated with extended surgery	Incorrect or inappropriate output or functionality
26	The customer reported that the patient who had had a primary THR (left hip) on 4.4.2008 with a MITCH cup / head and an Accolade stem underwent revision surgery. The customer further reported that his was due to a loose trunnion, corrosion, fretting and metallosis	Accolade Stem	Fretting	2	Material Integrity – Degraded/ Disintegrated	Corrosion	Inflammatory response to inert particles	Excessive fretting debris

	The patient was asymptomatic, but had heard a clunking noise recently							
27	The customer reported that the patient who had had a primary THR (left hip) on 4.4.2008 with a MITCH cup / head and an Accolade stem underwent revision surgery. The customer further reported that his was due to a loose trunnion, corrosion, fretting and metallosis The patient was asymptomatic, but had heard a clunking noise recently	Mitch Cup	Fretting	4	Not applicable	Not applicable	Inflammatory response to inert particles	Excessive fretting debris
29	6.5mm x 25mm Torx Screw threads stripped.	Other Hip screw	Thread Damage	3	Material Integrity – Degraded/ Disintegrated	Degraded	Complications associated with extended	Incorrect or inappropriate output or functionality

	Screw removed. Inserted new screw. No complications.						surgery	
30	It was reported that the patient's right hip was revised. A poly and head exchange was performed.	Unknown Implant Liner	Revision Surgery	3	No Information	No Information	Revision Surgery	Hazard not reported
31	The patient underwent a revision of ahemiarthroplasty, on the right hip, following progression of his disease. He presented with groin pain believed to be due to acetabular wear. There was also some subsidence of the femoral stem. The stem and Bi polar head were removed, and the acetabulum was revised, and a short stem	Metal Head	Revision surgery	3	No Information	No Information	Revision Surgery	Hazard not reported

	cemented into the remaining cement mantle							
32	SukranUzunlar reported that "We're having difficulties to perform the hip cases because of the worn Trident reamers, drills. When i checked the situation with our ex-dealer, current direct sales team they told me they had regularly sharpen the Trident reamers to have better results. But, it clearly changes the reamer sizes."	Cutting Edge Reamer	Wear	2	Material Integrity – Degraded/ Disintegrated	Degraded	User annoyance	Excessive visual degradation

Effect of CMC – Complaint Submission

Table 14: Effect of Complaint submission by CMC coordinator

Week	Total	Submitted by CMC Coordinator	Contribution
6th - 10th May'19	260	18	7%
13th - 17th May'19	265	25	9%
20th - 24th May'19	258	25	10%
27th - 31st May'19	260	23	9%

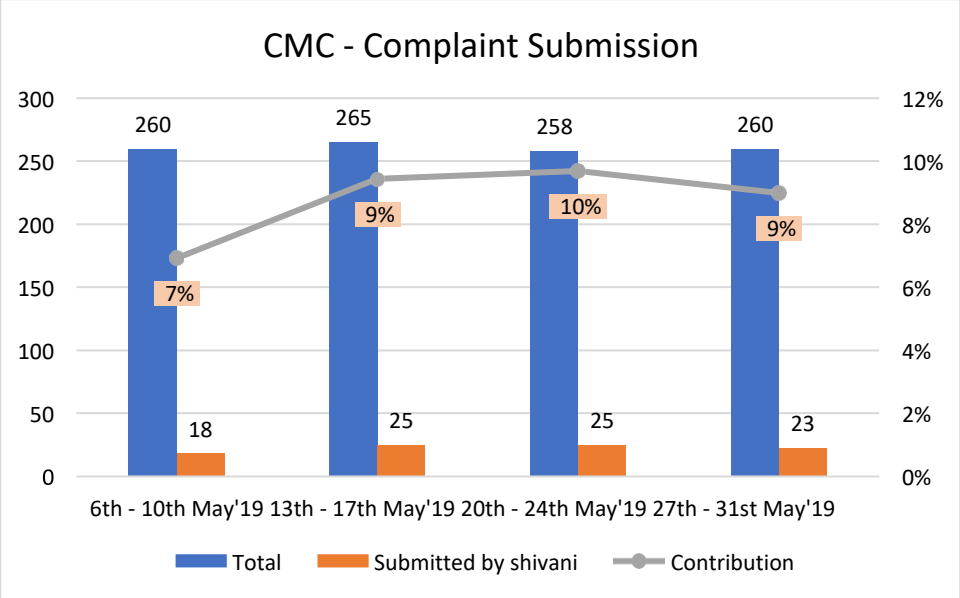


Fig 23: Effect of Complaint submission by CMC coordinator

Inference: Data recorded for 4 weeks, for first week total of 260 complaints were submitted by the complaint handling team out of which 18 complaints were submitted by me as a CMC coordinator and the contribution for the first week was recorded to be 7%. In the second week complaint submission by the team increased to 265 in which 25 complaints were submitted by me. The contribution in the second week was also increased to 9%. For third week the total of 258 complaints were submitted by the complaint handling team out of which 25 complaints were submitted by me and gradually the contribution also increased to 10%.In the last week the total of 268 complaints were submitted by the team out of which 23 complaints were submitted by me and contribution in the last week was 9%. Hence complaint submission was done successfully.

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Effect of Complaint Submission Rejection

Table: 15 Effect of Complaint submission rejection by CMC Coordinator

Week	Total	Rejection	% Rejection
6th - 10th May'19	18	0	0%
13th - 17th May'19	25	0	0%
20th - 24th May'19	25	0	0%
27th - 31st May'19	23	0	0%

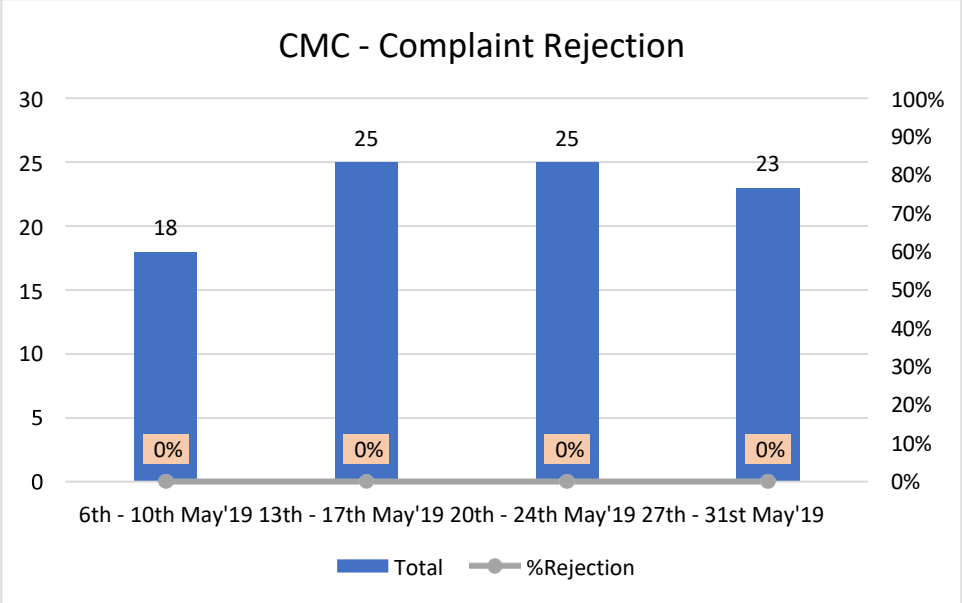

Fig 24: Effect of complaint rejection

Inference: - Data recorded for 4 weeks, for first week 18 complaints were submitted with 0% rejection. In the second week 25 % complaints were submitted with 0 % rejection. For third week 25 complaints were submitted with 0% rejection and for the last week 23 complaints were

submitted with 0% rejection. Hence no rejections were observed for the complaint submission and thus complaints were handled effectively.

Effect of PI Intake by CIC

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	4	10	1

Table: 16 Effect of PI Intake by CIC

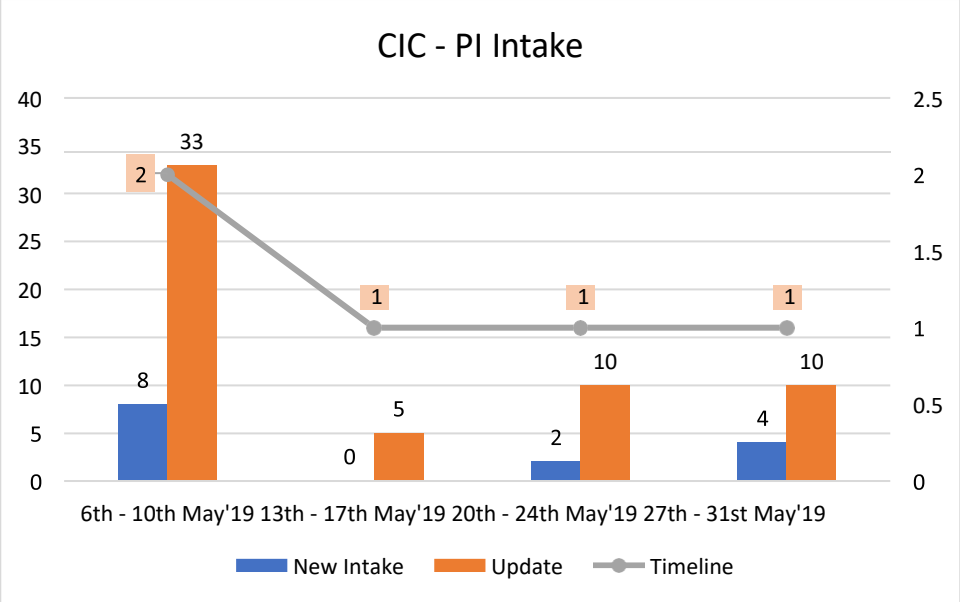

Fig 25: Effect of PI Intake by CIC

Inference: - Data recorded for 4 weeks. For the first week 8 new PI were created, and 33 duplicate PIs were found within two business days. In the second week no new PI were created, and 5 duplicate PIs were found within a day. For the third week 2 new PI were created and 10 duplicate PIs were found within a day and for the last week 4 new PIs were created and 10

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duplicate PIs were found in a day. Hence CIC- PI intake was done successfully within the timeline provided.

Effect of PI Closure

Week	Total PIs closed
6th - 10th May'19	12
13th - 17th May'19	18
20th - 24th May'19	25
27th - 31st May'19	30

Table: 16 Effect of PI closure

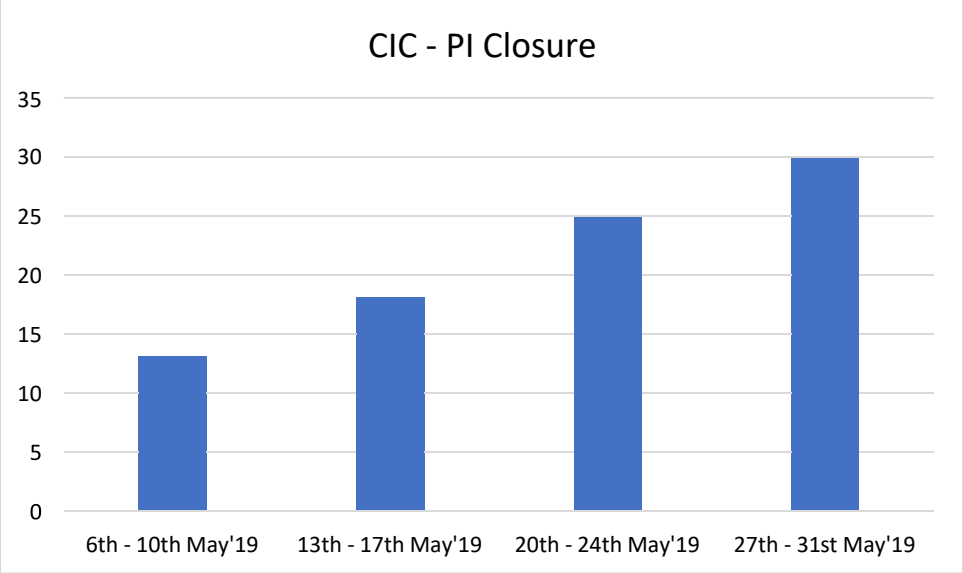

Fig 26: Effect of PI Closure

Inference: - Data recorded for 4 weeks. In the first week total of 12 product inquiries were closed. For second week 18 PIs were closed, third week 25 PIs were closed and for the fourth week 30 PIs were closed. So total of 85 PI closures were closed in four weeks.

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Validation of SPS tool

Sample Size Calculation:

Sample Size= $z^2 * p (1-p)/e^2 / 1 + (z^2 * p(1-p)/e^2 N$

Where, confidence level =90%

P=50%

Z score=1.65

e=10%

N=100

Sample size= 41

Where N = population size e = Margin of error (percentage in decimal form) z = z-score. The z-score is the number of standard deviations a given proportion is away from the mean.

Here N=100, e=10, confidence interval=90%

From the above formula sample size calculated is 41.

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Table: 17 Test Inputs

E-MAIL	Score	Comments	Project Name	Feedback	Date of response
yogesh.girdhar@stryker.com	2	Needs improvement	NC CAPA remediation	Received numerous complaints about the quality of work	19.11.18
Rishabh.Mathur@stryker.com	2	Needs improvement	Risk Management	Lessen the risk as much as possible to avoid its negative impact on project	19.11.18
harleen.01@stryker.com	1	Scope of Revision	Document control	Sharepoint may be good for handling documents	19.11.18
Dhruv.Grover@stryker.com	2	Needs improvement	Complaint Handling (Endoscopy)	Received numerous complaints about the quality of work	19.11.18
naina.gupta07@stryker.com	1	Correction is needed	design quality assurance	The processes used to asssure the quality of product can be improved	19.11.18
shailesh.kumar01@stryker.com	2	Needs rectification	Complaint Handling (T&E)	Received numerous complaints about the quality of work	19.11.18
yogeshgirdhar1@gmail.com	1	Advancement is required	EU MDR	MDR is more advanced then compared to MDD	19.11.18
rish.mathur10@gmail.com	2	Revision is required	Complaint Handling (medical)	Received numerous complaints about the quality of work	19.11.18
harleen521@gmail.com	1	Further analysis is needed	Validation	Different validation protocol needs to be analysed	19.11.18
shivanimathur16@gmail.com	1	Correction is required	GPRD(spine)	Document retrieval process can be simplified	19.11.18
naina.7jan@gmail.com	1	Needs correction	Record Control	Records can be controlled in a better manner	19.11.18
shaileshsliet2k5@gmail.com	2	Rectification is required	International QA project	Continuous updation is required	20.11.18
Rajesh.Purang@stryker.com	1	Revision is required	GPRD(JR)	Document retrieval process can be simplified	20.11.18
vasudha.verma@stryker.com	2	Modification is required	Inrernational RA project	Continuous updation is required	20.11.18
jessica.01@stryker.com	2	Needs improvement	Gap analysis (mdd vs eu mdr)	Difficult to handle predicate devices which is already in the market	20.11.18
gargi.sharma@stryker.com	1	Needs improvement	EU Importer determination	Time consuming data	20.11.18
navodit.singh@stryker.com	3	Communication can be improved	-	Regular check-ins,meetings or even email communications can be improved	20.11.18
shubham.srivastav@stryker.com	3	Performance of work can be improved	-	Gathering about proper information can be improved	20.11.18
gaurishankhdhar@gmail.com	3	Slow performance	-	Performance rate can be made rapid	20.11.19
sugat.sravasti@stryker.com	3	Not responsive to emails	-	Regular check-ins,meetings or even email communications can be improved	20.11.20
akhilesh.yadav@stryker.com	3	Not recommended	-	Time consuming data	20.11.21
satyajit.bhat@stryker.com	3	Performance rate is very slow	-	Performance rate can be made rapid	20.11.22
sandeep.malakar@stryker.com	3	Unsatisfatory results	-	Results can be made satisfactory	20.11.23
sneha.ranjan@stryker.com	4	Correction is needed	-	Data needs to be corrected	20.11.24
ragasudha.veerabathiran@stryker.com	4	Performance rate can be improved	-	Performance rate can be made rapid	20.11.25
harinder.singh1@stryker.com	4	Communication can be improved	-	Regular check-ins,meetings or even email communications can be improved	20.11.26
manmeet.chawala@stryker.com	5	Unsatisfactory performance	-	satisfactory performance can be delivered	20.11.27
navjyoti.gorai@stryker.com	4	Excellent	-	Slight improvement is required	21.11.18
saurabh.dubey@stryker.com	4	Satisfactory results	-	Marginal scope of improvement is required	21.11.18
kamal.soloman@stryker.com	5	Nothing	-	Consistently delivers beyond expectations	21.11.18

deepnita.singh@stryker.com	5	Nothing	-	Consistently delivers beyond expectations	21.11.18
shilpi.shukla@stryker.com	4	Excellent performace	-	Slight improvement is required	21.11.18
abhay.kumar@stryker.com	4	Good work	-	Marginal scope of improvement is required	21.11.18
shivani.mathur@stryker.com	4	Great work	-	Minute improvisation is required	21.11.18
shilpa.dhariwal@stryker.com	4	Slight scope of improvement is needed	-	Slight improvement is required	21.11.18
sanjay.ranga@stryker.com	5	Nothing	-	Consistently delivers beyond expectations	21.11.18
sachin.yadav@stryker.com	4	Outstanding performance	-	Minute improvisation is required	21.11.18
afaque.khan@stryker.com	5	Nothing	-	Consistently delivers beyond expectations	21.11.18
mayank.sharma@stryker.com	5	Nothing	-	Consistently delivers beyond expectations	21.11.18
navjot.sidhu@stryker.com	5	Nothing	-	Consistently delivers beyond expectations	21.11.18
supratim.sarkar@stryker.com	5	Nothing	-	Consistently delivers beyond expectations	21.11.18

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Table 18: Test Cases and Outcomes

Test Case	Outcomes
Survey initiation to all users	100% users received a mail with feedback link
Capturing Ratings & Feedbacks of users	All the ratings and feedbacks shall be 100% accurate test inputs
Score less than 3 mandates all the fields	Scores less than 3 were mandated all the questions and the outcome were as per the test inputs For score 3 or more, only the comment field was mandatory
Triggering Reminders to users with no response	Reminders were triggered to only those users who have not submitted their response

The outcomes were predefined in test inputs. Customers were asked to provide the response as per the test inputs. Verification Report was exported from the tool by Webmysystems team after completion of survey, it was found that the report exported from the tool was exact similar to the test inputs of validation and the tool met all the evaluation criteria. Thus SPS tool was validated successfully

Table: 19 Test Cases: Verification Report

Test Case Id	Module	Test Description	Step	Expected Result	Test Case Created On	Result
TC_01	Survey > Create Survey	Verify that Create survey link is working.	1. Go to Survey tab. 2. Click on Create Survey link.	User should redirect on Create survey screen.	10/1/2018	Pass
TC_02	Survey > Create Survey	Verify that Create New survey button.	1. Go to Survey tab. 2. Click on Create Survey link. 3. Click on New Survey button.	Survey Name field should be enable.	10/1/2018	Pass
TC_03	Survey > Create Survey	Verify that New survey Record.	1. Go to Survey tab. 2. Click on Create Survey link. 3. Click on New Survey button. 4. Enter Survey Name in text field. 5. Click on Next button.	Survey should be generate with new survey name, not on duplicate name.	10/1/2018	Pass
TC_04	Survey > Configure Survey	Verify Is SPS Survey? Check box is check with right (√) sign.	1. Go to Configure Survey section. 2. Check Is SPS Survey? Check-box is true.	User should able to check Is SPS Survey check-box.	10/1/2018	Pass
TC_05	Survey > Configure Survey	Verify Is SPS Survey? Check box is Uncheck with (X) sign.	1. Go to Configure Survey section. 2. Un-Check Is SPS Survey? Check-box is false.	User should able to Un-check Is SPS Survey check-box.	10/1/2018	Pass

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TC_06	Survey > Create Survey	Verify that user should select Start date and End date.	1. Click on Start date. 2. Select appropriate date. 3. Click on End date. 4. Select appropriate date.	User should be able to select start date and end date.	10/1/2018	Pass
TC_07	Survey > Create Survey	Verify that Dates format as per requirement i.e. mm-dd-yy	1. Click on Start/End date. 2. Select appropriate date. 3. observe format of date.	Start/End Date format should be in appropriate format.	10/1/2018	Pass
TC_08	Survey > Create Survey	Verify that Cannot accept characters in the date function	1. Click on Start/End date. 2. Enter characters in date field.	User should not able to enter characters in date fields.	10/1/2018	Pass
TC_09	Survey > Create Survey	Verify that Date field should accept 29 days of february in the leap year.	1. Click on Start/End date. 2. select feb month of Leap year.	Date field should be display 29 days in feb in the leap year.	10/1/2018	Pass
TC_10	Survey > Create Survey	Verify that should not accept 000000 as a date.	1. Click on Start/End date. 2. Enter 000000 value in date fields.	Date field should not be accept 000000 value is date field.	10/2/2018	Pass
TC_11	Survey > Create Survey	Verify that End date should not be less than the start date.	1. Enter Start date for example 01-01-2016. 2. Enter End date for example 01-01-2015.	Validation message should display for invalid date range.	10/2/2018	Pass
TC_12	Survey > Create Survey	Verify that Start date should not be more than end date.	1. Enter Start date for example 01-01-2016. 2. Enter End date for example 01-01-2015.	Validation message should display for invalid date range.	10/2/2018	Pass
TC_13	Survey > Create Survey	Verify that Enter Completion Message text area.	1. Click in Enter Completion Message field. 2. Enter a Completion	User should able to enter message.	10/2/2018	Pass

			message.			
TC_14	Survey > Create Survey	Verify that, Save button is working.	1. Enter all required detail of Configure Survey. 2. Click on Save button.	Configure Survey should be saved successfully.	10/2/2018	Pass
TC_15	Survey > Edit Survey	Verify that, User should not able to change value of "Is SPS Survey?" Field.	1. Go to View Survey screen. 2. Click on Configure Survey link. 3. Click on "Is SPS Survey? "Check box to Un-check this field.	User should not able to change "Is SPS survey?" Check box.	10/2/2018	Pass
TC_16	Survey > Add Question	verify that add questions functionality.	1. Go to recently added Survey. 2. Click on Question symbol from Add Question column.	Question is added by all authorized person	10/2/2018	Pass
TC_17	Survey > Add Question	verify that add questions functionality.	1. Go to recently added Survey. 2. Click on Question symbol from Add Question column.	User should redirect on Add Question screen.	10/2/2018	Pass
TC_18	Survey > Add Question	Verify that If SPS survey is false then All Question types should display except "Scalar Number".	1. Go to recently added Survey. 2. Click on Question symbol from Add Question column. 3.Click on Select Question Type field.	If SPS survey is false then All Question types should display except "Scalar Number".	10/2/2018	Pass

TC_19	Survey > Add Question	Verify Select Question Type if SPS True	Click on Select Question Type field.	Only one value should display "Scalar Number".	10/2/2018	Pass
TC_20	Survey > Add Question	Verify that in SPS survey added question should be required by default	1. Click on Select Question Type field. 2. Select "Scalar Number" Question type.	In SPS survey added question should be required by default	10/2/2018	Pass
TC_21	Survey > Add Question	Verify Enter Question Text field.	1. Click on Enter Question text area. 2. write a Question in text area.	User should able to write question in text area.	10/2/2018	Pass
TC_22	Survey > Add Question	Verify Enter Question Description field.	1. Click on Enter Description text area. 2. write a description in text area.	User should able to write question description in text area.	10/2/2018	Pass
TC_23	Survey > Add Question	Verify that user should not able to add more then one question for SPS Survey.	1. Go to Add Questions screen. 2. Select Question Type. 3. Click on Next button. 4. On Question detail screen Add question button is not display.	If User selected SPS survey then Add question button should not display on question detail screen.	10/2/2018	Pass
TC_24	Survey > Add Question	Verify Save button.	1. Fill all required data in add question form. 2. Click on Save button.	Question list should be add in Survey list.	10/2/2018	Pass
TC_25	Survey > Deploy	Verify Deploy survey functionality	1. select one valid survey from survey list. 2. Click on deploy link from deploy link.	User should redirect on deploy survey screen.	10/2/2018	Pass

TC_26	Survey > Deploy	Verify select Email ID functionality.	1. Fill all required data in deploy survey. 2. collapse categoriy to select email. 3. Click on Check all email id.	User should select all email ids from particular categories.	10/2/2018	Pass
TC_27	Survey > Deploy	Verify Next button.	1. Fill all required data in deploy screen. 2. select email ids from selected categories. 3. Click on Next button.	User should redirect on Select Templete screen.	10/2/2018	Pass
TC_28	Survey > Deploy	Verify Select Template drop down.	1. Click on Select Templete drop-down. 2. Drop-down collapase and select template from drop-down.	user should able to select template.	10/2/2018	Pass
TC_29	Survey > Deploy	Verify SelectedTemplate text area.	1. Select template from drop down. 2. template appear on screen. 3. Display same Template body .	User should able to receive same text.	10/2/2018	Pass
TC_30	Survey > Deploy	verify Send email button.	Click on send email button to send a survey email.	User should able to send an email to selected users.	10/2/2018	Pass
TC_31	Survey > Email	Verify Survey email format in enduser email.	1. Login in register email id. 2. Open survey email. 3. Notice email format.	Email format should same as selected by an survey creater.	10/2/2018	Pass
TC_32	Survey > Email	Verify Survey email Click Here button.	1. Open Survey email in inbox. 2. Click on Click Here button.	user should be redirect on Survey screen.	10/3/2018	Pass

TC_33	Survey	verify Survey form	1. Pre-added question displayed. 2. Select answer for question.	User should able to select appropriate answer for question.	10/3/2018	Pass
TC_34	Survey(SPS)	Verify that, Survey form rating is required.	Without selecting rating click on submit button.	Rating is required message should display.	10/3/2018	Pass
TC_35	Survey	Verify that Project Name & Feedback fields should be requried if rating less then 3.	select rating less then 3.	Project Name & Feedback fields should be requried if rating less then 3.	10/3/2018	Pass
TC_36	Survey	Verify that Project Name & Feedback fields should be not requried if rating 3, 4 or 5.	select rating 3,4 or 5.	Project Name & Feedback fields should be not requried if rating 3, 4 or 5.	10/3/2018	Pass
TC_37	Survey	Verify that comment is always mandatory in scalar question	Click on Submit button	Comment is always mandatory in scalar question	10/3/2018	Pass
TC_38	Survey	Verify Submit survey form functionality.	1. Fill all required data in survey. 2. Click on Submit button.	Survey submitted to Admin or survey creater and Pre-typed message should display like Thank you.	10/3/2018	Pass
TC_39	Survey	Verify that, Survey report successfully submit.	Click on Submit button,	Thank you screen should display to user.	10/3/2018	Pass
TC_40	Survey > Report	Verify Survey individual report.	1. Go to Report section. 2. Click on individual report. 3. Select Survey from drop down. 4. Observe servey response.	User should see survey response in detail.	10/3/2018	Pass

TC_41	Survey > Report	Verify Survey individual report.	1. Go to Report section. 2. Click on individual report. 3. Select Survey from drop down. 4. Click on View response for particular user.	User should be see user answer and commnet on response.	10/3/2018	Pass
TC_42	Survey > report	Verify that, survey response data should export in PDF.	1. Go to Report section. 2. Click on SPS Report and go to analysis report. 3. Select Survey from drop down. 4. Click on View response for particular user. 5. Click on Save button.	Selected survey response data should export successfully in PDF file.	10/3/2018	Pass
TC_43	Survey > report	Verify that, survey response data should export in Excel.	1. Go to Report section. 2. Click on SPS Report and go to analysis report. 3. Select Survey from drop down. 4. Click on View response for particular user. 5. Click on Save button.	Selected survey response data should export successfully in Excel file.	10/3/2018	Pass

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Table: 20 Global Product Registration Database

Request No.	Type of request	Documents Provided	Outputs	Timeline
US190326	Renewal	Risk Analysis (FMEA) and Biocompatibility Report	Renewal Certificate is provided	Within 3 business days
US230541	Remediation	Labels	259 labels were provided,23 submissions were completed and submitted to health authority	Within 2 business day

GPRD request 1 is from Latin America region and it is initiated for risk management documents like FMEA risk analysis of simplex with tobramycin and its biocompatibility reports

GPRD request 2 is from Canada region and it is initiated for retrieval of 210 labels for different part numbers

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CONCLUSIONS

Complaint handling system is an important part of quality system. Any complaint received on a medical device should be evaluated, investigated and analyzed and if necessary, corrective and preventive actions are taken. The complaints are thoroughly investigated and helped Stryker to take remedial or corrective action. The present study paves a new path for the development of quality assurance and regulatory process for orthopedics.

- The total of 68 complaints were submitted in four weeks and overall 26% contribution was made by me as a CMC coordinator
- 0 % rejections were found while submitting complaints
- 48 PIs were updated, and 10 new PI intakes were done.
- 85 PIs were closed in four weeks.

A test survey was initiated to 41 users (90% confidence interval) considering approximately 100 users as sample population for this survey. The purpose of this survey was to validate the SPS tool used for collecting feedback from contracting Stryker divisions. To validate the tool, survey was initiated for 41 users. The expected outcome was pre-defined in Test inputs. Users were asked to provide the response as per the test inputs. Report was exported from the tool by Webmysystems team after the completion of survey. It was found that the report exported from the tool was exact like the test input. Hence the tool met all the evaluation criteria and thus validation was successful.

Product registration is an important part of regulatory system as it provides assurance to customers that the product will be safe and effective for use and this study contributes two types of registration requests

- **GPRD request 1** is from Latin America region and it is initiated for risk management documents like FMEA risk analysis of simplex with tobramycin and its biocompatibility reports
- **GPRD request 2** is from Canada region and it is initiated for retrieval of 210 labels for different part numbers

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