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Project Highlights

Project Name : EU MDR REMEDIATION FOR NEONATAL HYDROGEL SENSOR AND POSITIONING STRIP
Team Size : 4
BU Mentor Name : Mr. Vaibhav Jadhav Mentor PS#: 20157065
GEA Mentor Name: Mr Sandeep Talya and Mr Bharath G
Team Members Details (Professional Stamp Size Photo with few lines of individual briefing

Gagan N
PS#: 99002610
GENESIS Track
Code: 2009BLRMED01
Education Details :
B.E. (ECE)
Professional Skills C, C++, Python

Puneeth Gowda SR
PS# 99002621
GENESIS Track
Code: 2009BLRMED01
Education Details
B.E. (EEE)
Professional Skills C, C++, Python

Shivam Kumar
PS# 99002712
2009BRDMEED02
B.tech in Mechanical Eng.
Professional Skills C, C++, Python

Gowthaman V
PS# 99002714
2009BRDMED02
B.E Mechanical Engg
Professional Skills
Solidworks, Creo

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EU MDR and Design History File

- EU MDR - **The European Medical Device Regulation (EU MDR)** ensures high standards of quality and safety for medical devices being produced in or supplied into Europe. It is to have a fundamental revision in 2017/745 to better identify medical devices products and improve transparency through standard data, technological advances and the establishment of an EU database (Eudamed).

- Design History File (DHF): The compilation of records which describes the design history of finished product. The DHF covers the design activities used to develop the device, accessories, major components, labeling, packaging and production processes.

Problem Statement

- Consult customer and obtain detailed user requirements.
- Neonatal Hydrogel Sensors and Positioning Strip documents are not meeting EU-MDR requirements.
- Need to update or create documents as per EU MDR compliance.
- All the QMS template and procedures updated as per the Eu MDR guidelines and provided by the customer.

Scope

- Prepare the EU MDR gaps for available legacy documents.
- For EU MDR Remediation follow up for EU MDR guidelines and customer QMS procedure and template.
- To learn design and development policy and good documentation practice.
- Understand the complete PDLC of a product development .

Overview

- The overview of this project is about the Neonatal Hydrogel Sensors and Positioning strips.

Product Description:

- **The Neonatal Hydrogel Sensors** are type of adhesive electrodes which are typically used as a non-invasive method of connecting EEG equipment to a patient, carrying the signals to and from the EEG equipment as required. In this instance, the hydrogel sensor is carrying a signal to the Olympic Brainz Monitoring System. This is a Class I type device.
- **The Olympic Brainz Monitor (OBM) positioning strips** is to assist with the alignment of disposable surface recording electrodes. This is a Class I type device.

Key Deliverables

- FDR 1
  - Design Planning Checklist
  - Product Requirements rev01 – Puneeth Gowda SR
  - Traceability Matrix
  - Usability Engineering File
  - Risk Management Plan
  - RAS File and RM Report
  - Risk Management Plan and Risk Analysis Spreadsheet
- FDR 2
  - Product Requirements rev02 – Puneeth Gowda SR
  - Packaging and Handling & Environmental Test Plan
  - Hardware Detailed Design Document
  - Design Verification Plan and Protocols – Puneeth Gowda SR

Product Requirements Document

Purpose:

- Product Requirements Document containing all the requirements of a particular product
- It includes purpose, feature, functionality and behavioral of the project
- Mainly it serve as a guide for business and technical team to help in build and launch the product

Reference

- QMS-000075- Corporate Design & Development Policy
- QMS-000081- Corporate labelling requirements
- DOC-040153- User Requirements
- DOC-XXXXXX- OBM Accessories Risk Assessment Spreadsheet

Requirements characteristics

- Electrical characteristics

Data and Signal characteristics, format, ranges, limits, defaults, presentation, polarity, noise

- Physical characteristics

Device material, size, weight, storage and shelf life

- Software characteristics

Software Data Inputs / Outputs, Data characteristics, format, ranges, limits, and defaults. Software Data definition and Database requirements

- Measurements and Tolerances

Consideration for requirements dealing with measurements and or tolerances

- Interface requirements between hardware, software and other systems

Exchange between electronic interfaces at device and system level.

Continued..

- Security

Authentication, Authorization, Integrity of communication, Audit Trail, Security/Sensitive/Confidential information. Cybersecurity, Product and Data Security.

- Labeling

QMS-000081 and associated labeling procedures for complete requirements

- Regulatory, Safety and Standard

Markets where the product will be sold define the regulatory requirements and standards that apply (e.g. IEC, WEEE, RoHS, and REACH)

- Manufacturing and Operation

Manufacturing process capabilities and needs, Purchasing - Supplier, capabilities and needs

- Maintenance and Service Installation

Installation and Service, Install process, Service process and tools

Design Verification Plan

Purpose:

- The verification plan will be used to conform that a product system meet its design specification and performance plan
- Normally a verification plan would consists of Functional requirements, Design requirements and Defining coverage goals

Reference

- QMS-003002 – statically technique for design verification producer
- DOC-038161 - Neonatal Hydrogel Sensor Integrated Design Plan
- DOC-039741 - OBM Accessories Product Requirements

Verification Plan includes

- Design Input Requirements

requirements to be tested are found in DOC-002676

- Design Outputs to be verified

1. OBM Accessories Requirements -- Verified with the execution of DOC-039741
2. OBM Accessories Labels -- Verified with the execution of DOC-039741
3. OBM Accessories User manual -- Verified with the execution of DOC-039741
4. REACH and ROHS Certification

Continued..

Resources

- Human Resources

Tester-Create Design Verification Protocols, Maintain Traceability Matrix, Execute Design Verification Protocols, Document results of executed Protocols and Report any potential defects

- Material Resources

1. Neonatal Hydrogel Sensor package
2. Olympic Brainz Monitor (OBM) positioning Strip
3. OBM User manual

Continued..

Sample Size Decision

- Non-Statistical Methods

1. Those requirements tested as part of design verification that are non-statistical in nature shall be clearly identified and a reason shall be given for considering them a non-statistical requirement
2. Non-statistical requirements require testing a **single unit**

- Statistical Methods

1. Statistical methods are only required when variability is involved, For design input requirements where variation can occur

- Determine Conformity Rating

1. The Conformity Rating depends on the potential of severity.
2. The Conformity Rating of 99%, 97%, and 95% shall be considered subsequently for severity levels of Major, Moderate, Minor and Negligible failures.

Continued..

- Verification Methods to be used
  Functional Test
  Measurement Test
  Inspection
  Lab Test
- Acceptance Criteria

1. All protocols shall be executed and deviations from plan justified in the verification summary
2. All test records/executed protocols are reviewed and approved in Agile

Design Verification Protocols

- The verification protocol defines how the verification activities are to be completed
- The protocol includes

1. Developing
2. Execution
3. Report

Process

- Developing

1. The test case development will done at this stage.
2. All design inputs or requirements must verified by using variety of test methods.

- Execution

1. The test procedures created during the development phase is executed in accordance with the test plan, strictly following them in verification activity
2. If any invalid results occur or if any procedures required modification, it is important to document the changes and get proper approval.
3. Tractability matrix is created to verify that all the design input identified in the verification test plan has been tested and determine the pass ratio.

- Report

- This activity is performed at the end of each phase of verification execution
- The design verification report gives the detailed summary of verification results which includes the configuration management, test results for each type of testing and issues found during the verification activity

Reference:

- DOC-039741 - OBM Accessories Product Requirements
- DOC-038031 - OBM Accessories Design Verification Plan

Test equipment

- Signal Generator
- DSO
- Vernier Caliper
- Measuring Tape
- OBM amplifier module

Challenges

- Identifying verification samples and verification method.
- To get familiar to different medical standards & regulation.

Learnings outcome

- Understanding DHF,IDP & URD .
- Understanding and preparing PRD and verification plan and protocol.
- Understanding other documents like DPC, PNH and Traceability Matrix.
- Role of requirement engineer.
- familiar with different Medical Device standards & regulation.

Conclusion

- This project gave an opportunity to understand different kind of regulation for medical device, class of medical device.
- The main purpose of this project is EU MDR Remediation of OBM accessories as per EU MDR guidelines.
- This project gave an opportunity to understand PDLC and TDLC of a medical product
- The project provides an opportunity to understand risk assessment process as Risk Manager which begins with risk analysis followed by risk evaluation, risk control measures, Benefit-Risk analysis (B-RA)’s, for all post-mitigation residual risks.

Thank You !

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