Solving the Problem of Medical Device Poor Quality

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SUMMARY & CONCLUSIONS

Inadequate risk management by medical device providers is significantly impacting the safety of the customers they serve, the quality of their products and their profitability. Billions of dollars are being spent yearly in the medical device industry on the direct costs of poor quality. One would not expect this to be happening given that the medical device Industry is one of the most regulated industries in the world. The required steps and volume of paperwork required to obtain medical device approval is second to no other industry. The question that must be asked is if all this work is being done why are the direct costs of poor quality so high?

This paper will show that the current methods used by medical device providers being driven by standards such as ISO 13485:2016 "Medical devices — Quality management systems — Requirements for regulatory purposes" [2] and ISO 14971:2019 "Medical devices — Application of risk management to medical devices" [1] are ineffective at managing risk because they are ineffective at defining the root causes of risk exposure. The reader will learn how a medical device provider can consistently comply with these standards while creating medical devices that will fail to meet the users' needs.

The paper will introduce the reader to Risk Based Medical Device Lifecycle Management™ (Risk Based MDLM™). Risk Based MDLM™ is very effective in reducing/removing the root causes of medical device poor quality through the systematic management of risk over the medical device's entire life cycle from definition of user needs through to decommissioning and disposal of the medical device if applicable.

Risk Based MDLM™ uses tools many readers may have heard of such as Design FMEAs, Process FMEAs and Application FMEAs. Because of this some may come to the incorrect conclusion that there is nothing new in Risk Based MDLM™. Although they have the same names, the FMEAs used in Risk Based MDLM™ are fundamentally different than the FMEAs being used by 99% of the companies in the medical device industry. The paper will explain why the vast majority of FMEAs currently being performed by medical device companies are ineffective in managing risk and why the FMEAs used in Risk Based MDLM™ are the most effective risk management tools in existence. Existing medical device industry paradigms about the purpose of FMEAs and the steps required for their proper performance are the greatest barrier to the effective implementation of Risk Based MDLM™ and the significant benefits it can provide.

1 CURRENT MEDICAL DEVICE QUALITY COSTS

Based on 2017 McKinsey study [3], the estimated direct costs aof poor quality in the medical device industry in 2016 was between $18 billion and $22 billion. Included in the direct costs of poor quality were the labor cost of remediation, routine internal quality failures, external quality failures and non-routine external failures. According to the study, in 2016 between 11.6% and 16.3% of every sales dollar in the medical device Industry was spent on the direct costs of poor quality.

Any user need not met has the potential to lead to increased direct costs of poor quality. Since not meeting the user needs can occur at different frequencies and lead to different hazard exposures, one must use effective risk management tools to optimize the use of customer resources in their reduction.

2 MEDICAL DEVICE QMS TOOL: DESIGN MATRIX

Most medical device quality management systems (QMS) use two risk management tools as their foundation. They are the Design Matrix and the Hazard Traceability Matrix. The Hazard Traceability Matrix that will be discussed in the next section. A typical Design Matrix can be found in Figure 1 below.

User Needs	Design Inputs	Design Outputs	Design Verifications	Design Validations
UN-1:The Catheter shall be easy to manipulate.	**DI-1**: The Catheter shall have a torque ratio of 1:1.	**DO-1:** Polyurethane tubing material specification.	**VER-1:** Catheter torque testing per method TP-035-1.	**VAL-1:** End User Simulated Use Testing
		DO-2: 7-FR polyurethane triple lumen tubing drawing.		
		DO-3: Catheter torque inspection.		
		DO-4: 7-FR triple lumen catheter drawing.		

Figure 1: Design Matrix

The Design Matrix is an excellent tool for helping medical device companies pass quality audits. It provides the auditor with insight into the medical device design development process. The auditor can easily trace the medical device user needs to design inputs, design inputs to design outputs, design outputs to design verification and user needs to design validation

While the Design Matrix may great for audits, it is ineffective in managing risk. To effectively manage risk and ensure that user needs are met, one must be able to define and remove the root causes of the user needs not being met. Following are five reasons why the Design Matrix is ineffective at identifying the root causes of a user need not being met:

1. It is possible for a medical device to fail to meet a user need in more than one way. There is no place to document this.
2. It is possible for a medical device to fail to meet a user need because a design input is incorrectly specified in a specific way. There is no place to document this.
3. It is possible for a medical device to fail to meet a user need because a design output is incorrectly specified in a specific way. There is no place to document this.
4. It is possible for a medical device to fail to meet a user need because of a way the design is not used, maintained and/or disposed of as intended. There is no place to document this.
5. It is possible for a medical device to fail to meet a user need because the medical device is not manufactured to the design output specifications because of manufacturing process condition.

3 COMMON MEDICAL DEVICE QMS TOOLS – HAZARD TRACEABILITY MATRIX

Another commonly used tool by most medical device QMS is the Hazard Traceability Matrix. An example of the matrix and the information it contains can be found in Figure 2.

Risk Analysis									Risk Control				
Hazard	Reasonably Forseeable Sequence or Combination of Events	Hazardous situation	P 1	Harm	P 2	Sev	P (P1 x P2)	Residual Risk	Risk Control	Risk Control Verficiation	Severity	P	Residual Risk
Exposure to Testing Agents	Leakage of testing agents from Medical Device.	Exposure to Testing Agents due to Leakage of testing agents from Medical Device.	2	Patient death.	1	5	1	L					
				Injury requiring medical inter-vention.	2	4	1	L					
				Temporary injury requiring medical inter-vention.	3	3	2	M					

Figure 2: Hazard Traceability Matrix

The definitions for the Risk Analysis section of the Hazard Traceability Matrix are as follows:

1. Hazard: source of harm.
2. Reasonably Foreseeable Sequence or Combination of Events: sequence of events that can lead to hazardous situation.
3. Hazardous Situation: circumstance in which people, property or the environment is/are exposed to one or more hazards.
4. P1: probability of Hazardous Situation.
5. Harm: injury or damage to the health of people, or damage to property or the environment.
6. P2: probability of Hazardous Situation leading to Harm.
7. Sev: severity of Harm.
8. Residual Risk: current risk.

Users of the Hazard Traceability Matrix begin their risk analysis from the hazard level. Because of this, it is not uncommon to have "reasonably foreseeable sequence or combination of events" that that are very general and lack sufficient detail to define the many possible root causes of a single hazard exposure. The question of why the leakage of testing agents from the medical device occurred must be answers. Potential causes could include incorrect design inputs, incorrect design outputs, improper use of the medical device and improper manufacture of the medical device.

Figure 3 shows fourteen potential incorrect medical device design outputs and manufacturing sources of variation that can lead to leakage of testing agents from a hypothetical medical device and subsequent exposure of the user to testing agents. A proper risk analysis to prevent the exposure of users to testing agents would include many more.

Root Causes of Testing Agent Leaks	
Incorrect Design Outputs	**Manufacturing Sources of Variation**
Seal cross section is specified too small or too large.	Operator uses expired seal mold compound.
Seal internal diameter is specified too large or too small.	Contamination buildup in seal mold.
Seal cross section is specified too small.	Worn or damaged seal mold.
Seal ring groove width is specified too wide or too narrow.	Seal cure oven conveyor speed is set to fast.
Seal ring groove bottom diameter is specified too large or too small.	Seal cure oven temperature control system temperature setting is set too low.
Seal ring groove surface finish is specified too rough.	Out of calibration cure oven temperature control system.
Rotating Component Diameter is specified too small.	
Rotating Component Surface Finish is specified too rough.	

Figure 3: Possible Causes of Test Agent Leakage

There are multiple reasons for a lack of root causes in the typical Hazard Traceability Matrix. The primary reason is that exposure to a single hazard can have many different root causes that occur during different times in the medical device life cycle. The definition of the possible root causes and their prevention requires a systematic methodology with specific actions taken during specific times within the medical device product

development cycle. The Hazard Traceability Matrix cannot be used to support this task.

4 RISK BASED MDLM OVERVIEW™

Risk Based MDLM™ (Risk Based medical device Lifecycle Management™) is the systematic management of risk to improve patient and health care worker safety during the entire medical device lifecycle from definition of user needs to decommissioning and disposal of the medical device. It is both ISO 13485:2016 and ISO 14971:2019 compliant.

Risk Based MDLM™ identifies five core processes (see Figure 4) used during the product life cycle that are the major sources of all medical device risk. The first core process is definition of User Needs. The voice of the user is the key input into the first core process. The second core process is definition of Design Inputs. The second core process is driven by the user needs defined during the first core process step. The third core process is definition of design outputs. The third core process is driven by the design inputs defined during second process. The fourth core process is definition of usage controls to ensure proper use, maintenance and disposal (if applicable of the medical device). The primary driver of the fourth process step of the Risk Based MDLM™ process are the design outputs defined during the third process step. The fifth and final step of the Risk Based MDLM™ process is the manufacture of the medical device. The fifth process step of the Risk Based MDLM™ process is driven by design outputs defined during the third process step of Risk

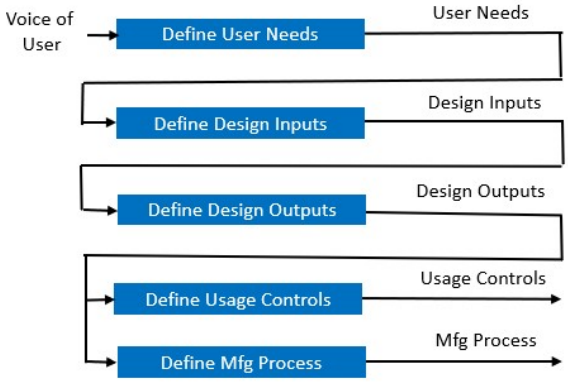

Figure 3: Possible Causes of Test Agent Leakage

In the following five sections we will examine each of these processes, the risks they create and the tools used to manage the risks.

5 STEP 1: DEFINE USER'S NEEDS

When defining user needs it is critical that all user needs be captured. While it is common for the designers to do a good job of capturing user needs related to the function of the product, it is not uncommon to find other types of user's needs not documented. One type of user's need often inadequately defined is the prevention of exposure to hazards when the medical device is functioning as intended. Risk Based MDLM considers eighteen different categories of user's needs, one of which is function.

User's needs can be competing, conflicting and beyond the current limits of technology. Competing user's needs are needs that require one or more design input specifications to be changed in opposite directions to meet the competing user's needs. Conflicting user needs that cannot be met simultaneously regardless of where the specifications for the design inputs are set. User's needs beyond the current limits of technology are self-explanatory.

Failure to meet any user's needs that are competing, conflicting or beyond the limits of technology expose the user to risk. The presence of user's needs that are competing, conflicting and beyond the limits of technology is quite common. They are a common source of residual risk in new medical device designs.

6 STEP 2: DEFINE DESIGN INPUTS

User's often do not speak in a language that medical device designers can design to. The improper translation of user's needs to design inputs is a common root cause of risk exposure. The longer an improper translation of a user's need to design inputs goes undetected, the greater the greater the cost to the company.

The Requirements Risk Assessment ® (RRA®) in combination with two different Design Validation plans is used to determine the residual risk that currently exists in the medical device due to the currently defined design inputs. When determining the residual risk due to the current design inputs, it is assumed that that the medical device designer will be capable of designing a medical device that will meet the design inputs.

The RRA® and supporting Design Validation Plans are shown in Figure 4 below.

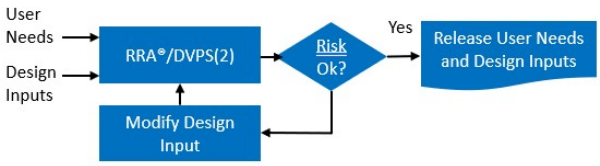

Figure 4: Use of RRA

When developing the user needs list based on intended use, eighteen different categories of user needs are examined. Two different Design Validation Plans are developed using information from the performance of the RRA®. The first Design Validation Plan "DVP-Design inputs" is created to determine the adequacy of the Design inputs before the medical device design creation process is started. The second Design Validation Plan "DVP-Product" is to validate that the final medical device defined by the Design outputs meets the user needs.

7 STEP 3: DEFINE DESIGN OUTPUTS

The next step in Risk Based MDLM™ is the definition of design outputs. Design outputs can be in the form of hardware specifications and/or software code. The Design FMEA and supporting Design Verification Plan shown in Figure 5 below are used to assess the risk of using the Design outputs as currently defined to meet the Design inputs defined during Step 2.

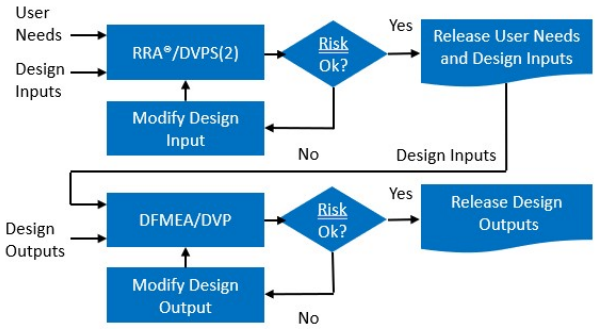

Figure 5: Use of Design FMEA

Although design for manufacturability is a key element of the Design FMEA for the medical device, it is assumed when performing the Design FMEAs that the manufactured medical device will meet the Design output specifications. If there are combinations of design output conditions that can lead to one or more design inputs not being met, Multiple Integrated Cause Analysis (MICA™) is used to capture these conditions during the Design FMEA.

8 STEP 4: DEFINE USAGE CONTROLS

Risk Based MDLM™ uses the Application FMEA (aka Usage FMEA) and supporting Usage Control Design Verification Plan shown in Figure 6 below to assess the risk due to usage.

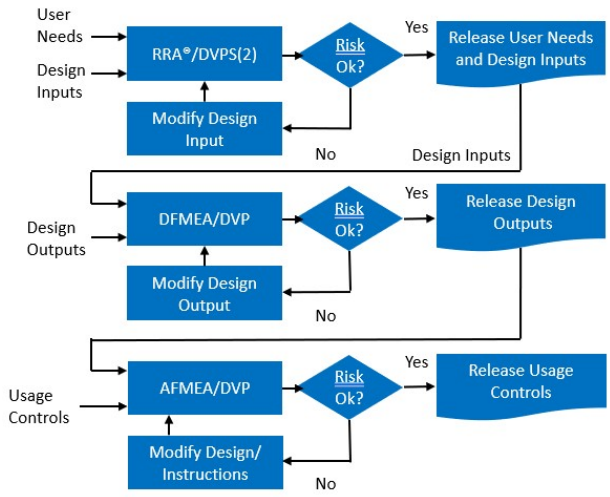

Figure 6: Use of Application FMEA

One can properly define the user needs, design inputs and design outputs but if the medical device is not installed, used, maintained and disposed of (if applicable) as intended one or more user needs will not be met. When designing usage controls, it is important to consider reasonably expected misuse and under certain circumstances unexpected misuse.

9 STEP 5: DEFINE MFG PROCESS

The Process FMEA and supporting Process Validation Plan shown in Figure 7 are used to capture the information defined above and to assess the risk of using the current Process (includes Process Equipment, Process Controls and Suppliers) in producing a medical device to meet the design output specification.

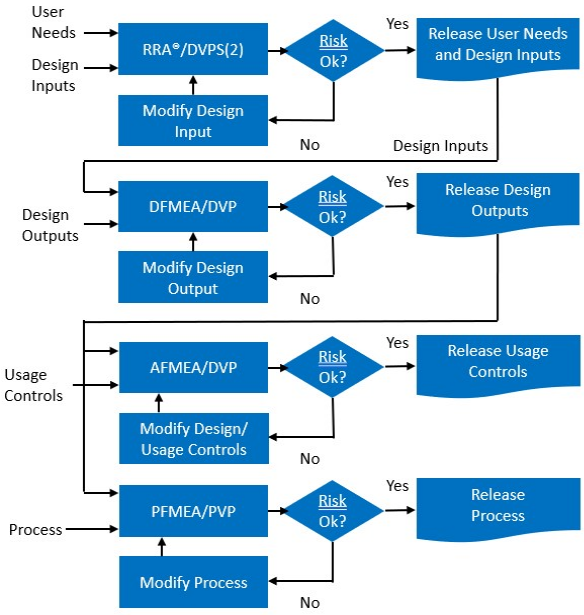

Figure 7: Use of Process FMEA

The Risk Based MDLM™ process uses the Design FMEA to educate manufacturing personnel on the importance of each design output and the user needs that may not be met if the manufactured medical device is not complaint with the design output specifications. Each step in the manufacturing process in investigated for ten sources of variation that can lead to the design output specifications not being met in the manufactured medical device. Process controls are defined to prevent the presence of the sources of variation and to detect and prevent the shipment of medical devices that are not compliant with design output specifications.

10SUMMARY AND FUTURE CHALLENGES

If the medical device industry is to make significant improvements in medical device quality and reduce the current billions of dollars per year in direct costs of poor

quality, new risk-based product development tools are needed to accurately identify the root causes of the medical device failures to meet user needs. It is critical that the new tools allow the root causes of the potential failures to be defined as quickly as possible after they are created. The longer a mistake in defining user needs, design inputs, design outputs, usage controls or process goes unnoticed and not resolved, the higher the direct costs of poor quality.

The greatest barrier to the implementation of Risk Based MDLM™ is the current paradigms that currently exist in the medical device industry that result in inaccurate information about the purpose and the proper implementation of FMEAs. In twenty-five years of reviewing FMEAs in the medical device industry, I have yet to find a company that prior to training who understood the purpose and implementation methodology of the Design FMEAs, Process FMEAs and Application FMEAs used in Risk Based MDLM™ process.

One of the largest reasons for this is that many in the medical device industry use the IEC 60812 "Analysis techniques for system reliability – Procedure for failure mode and effects analysis (FMEA)" [4] as their FMEA standard. Although the most recent version of IEC 60812 was published in 2018, the core FMEA methodology contained within the standard is very old and fundamentally flawed. Many of the core principals in the standard are traceable to **MIL-STD-1629A**, MILITARY STANDARD: PROCEDURES FOR PERFORMING A FAILURE MODE, EFFECTS, AND CRITICALITY ANALYSIS (24 NOV 1980) [5]. It is important to recognized that MIL-STD-1629a was cancelled in August of 1998 without replacement. Despite cancellation, the MIL-STD-1629A still remains in widespread use and continues to negatively influence the effective use of FMEAs for risk management and the creation of standards such as IEC 60812.

Following is the IEC 60812 definition of FMEA: "Failure modes and effects analysis (FMEA) is a systematic method of evaluating an item or process to identify the ways in which it might potentially fail, and the effects of the mode of failure upon the performance of the item or process and on the surrounding equipment and personnel." By comparison, Risk Based MDLM™ provides the following definition for a Design FMEA: FMEA: "The Design FMEA is a systematic risk assessment of the adequacy of the medical device design outputs in defining a medical device that will meet the design inputs."

Common misstatements made by medical device "FMEA experts" and "risk management experts" that are clear indications of a lack of understanding of Design FMEAs as used in Risk Based MDLM™ are:

1. "Design FMEAs are a bottom-up process."
2. "Design FMEAs are not a risk management tool."
3. "Design FMEAs can only be used to manage risk when a fault occurs."
4. "Design FMEAs are normally only used during new product development".

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Richard Harpster is president of Harpco Systems Inc. which he founded in 1987. Harpco Systems specializes in providing software, training and consulting for Risked Based Product Lifecycle Management (RBPLM™). Over the past 37 years Richard has helped numerous companies implement improved design and manufacturing systems on a wide variety of products from automotive components to molecular assays to detect diseases such as Prostate Cancer and HIV. He is a recognized expert in the application of Failure Mode and Effects Analysis and invented several new concepts including the linking of Design FMEAs to Process FMEAs which became an automotive industry standard in 2008, eighteen years after he first introduced the concept to Ford Motor Company Climate Control Division. His latest inventions in the field of RBPLM™ include Requirements Risk Assessment™ (RRA™), Multiple Integrated Cause Analysis (MICA™) and Rapid Integrated Problem Solving (RIPS®). He has published several papers on the topic of RBPLM™.

Prior to starting Harpco Systems, Richard spent 14 years at Ford Motor in a wide variety of positions including Senior Design Engineer, Superintendent of Plant Maintenance and Plant Manager. His education includes a B.S.E.E. from Penn State University, M.S.E.E from the University of Detroit and an M.B.A. from Eastern

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