Understanding the Risk based Approach in a QMS

This template is to be used in process or product risk management, ultimately resulting in risk reduction of the finished product. Risk management at the process level safeguards product safety at every production stage, offers the benefit of real-time risk monitoring, and reduces rework. The requirements and expectations are suggested based on practical experiences learned from various manufacturing set-ups globally.

Sl. No.	Requirement	Expected activities	What are we doing to implement 'risk-based approach'?
1.	**Building processes or systems with risk reduction goals as one of the core objectives**	Process design begins with determining process objectives. Product technical specifications are a primary part of process objectives. At this stage, risk specifications should be included in the process objectives as well. This way, the criteria and methods to accomplish or maintain risk reduction will get incorporated into the process.	
2.	**Perform risk-based analysis**	A risk-based gap analysis should be exercised by comparing the current medical device risk levels associated with an existing process with the desired risk levels an organization aims to achieve.	
		Risk-based thinking enables an organization to proactively find ways for risk reduction and control even in situations of conformity or normalcy.	
3.	**Outsourced processes risk management**	The controls on outsourced processes shall be proportionate to the risk involved and the ability of the external party or supplier to meet the requirements. The controls shall include written quality agreements with defined roles and responsibilities.	
		The manufacturer is overall responsible for outsourced risk control activities and compliance to regulatory norms.	
4.	**Product realization risk management**	Manufacturing organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained.	
		Risk identification during the product realization should be input to risk mitigation for other related processes. These records shall be part of Risk management file and DHF.	
5.	**Design and development risk management**	Design and development input risk management related to product requirements must be determined, recorded and maintained. These inputs shall include applicable output(s) of risk management.	

		Design and development output risk management shall specify the characteristics of the product that are essential for its safe and proper use. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.	
6.	**Purchasing process or Suppliers' risk management**	Organization must establish criteria for selection of suppliers and evaluation proportionate to the risk associated with the finished product.	
		Non-fulfilment of purchasing requirements must be informed to the supplier proportionate to the risk associated with the purchased product and compliances with applicable regulatory requirements.	
		The extent of verification activities should be based on the supplier evaluation results and proportionate to the risk associated with the purchased product.	
7.	**Validation of processes for production and service provision risk management**	Process validation should be performed taking into consideration all of the conditions and environments of use.	
		A risk-based approach to process validation will require the inclusion of all reasonably foreseeable conditions of use or misuse, in line with the ISO 14971 standard requirements.	
		This will include evaluating the existing practices or deficiencies in clinical procedures and environments of various healthcare facilities that may impact medical device performance.	
		Process validation should cover parameters that result in device performance specifica-tions that can withstand a range of use scenarios.	
8.	**Using risk-based thinking to determine process data points for verification and the verification frequency**	It should address: a) When to initiate process verification? b) What sort of data should be collected? c) And, at what frequency should data be collected? The monitoring and measurement of processes shall demonstrate the ability of a process to achieve planned results.	

		Since risk specifications shall be introduced into the process objectives, the process components or parameters that result in a particular risk reduction shall also be verified.	
9.	**The frequency of testing may be intensified in higher risk situation**	a) When a new process has been implemented. b) There is a significant process change, c) There has been a repeated non-conformity related to the process, d) There is a corrective action related to the process in response to a non-conformity, e) A new medical device is produced using the process f) Re-starting a temporarily decommissioned process (for example restoration after complete shut-down), g) Repair and replacement work has been done related to the process. In the above situations, verification may be performed more frequently and more samples must be taken for necessary testing.	
		These data points will help manufacturers to establish trend reports that promote understanding and troubleshooting of the process performance. In some cases, the frequency of verification, type of data points and number of samples may be reduced over a period of time with the appropriate justification. For example, when performance or risk levels fall consistently within acceptable limits.	
10.	**Software risk management**	The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software, including the effect on the ability of the product to conform to specifications.	
11.	**Monitoring and measuring equipment risk management**	Risk management for monitoring and measuring equipment should be able to identify the calibration status, be protected from damages, unauthorised adjustments, mishandling and improper storage.	
		The measuring equipment should be calibrated at a fixed frequency to avert risk in the process.	
12.	**Implement a risk-based CAPA process**	CAPA and investigation procedures that apply root-cause analysis methodology must be in line with the ISO 14971 risk-based response to non-conformities.	

		An appropriate tool recommended by the standard to evaluate initiating circumstances is the Fault-Tree Analysis (FTA). The FTA involves tracking of failures by back-tracing the processes to identify the initiating events. It is an effective aid in the investigation of complaints and enables a CAPA plan that is better targeted to eliminate risks.	
13.	**Feedback as risk management input**	The information gathered from feedback process should be potential input to risk management for monitoring and maintaining the product requirements or process improvement.	

Reference:
ISO 13485:2016 (E) – Medical Devices – Quality Management systems – requirements for regulatory purposes; Clause 4.1.2 (b), Clause 4.1.5, Clause 4.1.6 – QMS; Clause 7.1 – Planning of product realization; Clause 7.3.3, 7.3.4, 7.3.9 – Design and Developments; Clause 7.4, 7.4.1(d), 7.4.3 – Purchasing; Clause 7.5.6 – Validation of processes for production and service provision; Clause 7.6 – Control o monitoring and measuring equipment; Clause 8.2.1 – Feedback.

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