

	MICRO LABS LIMITED, BANGALORE	No.: QAP/MLCM/0043-016
	QUALITY ASSURANCE PROCEDURE	Effective Date: 23/03/2024
		Next Review Date: 22/03/2026
Title:	QUALITY RISK MANAGEMENT	Supersedes No.: QAP/MLCM/0043-015 Dated: 31/07/2023

1.0 PURPOSE:

This procedure provides a systematic approach for assessment and management of quality risk in order to provide safe drug products to patients throughout the product life cycle.

2.0 SCOPE:

This procedure is applicable to quality risk assessments which shall be carried out for all the activities and systems having direct or indirect impact on product quality including data integrity.

3.0 RESPONSIBILITY:

3.1 Originating Department:

- 3.1.1 To identify the risk system / operation / area and initiation of risk assessment.
- 3.1.2 To summarize the risk assessment.
- 3.1.3 To carryout periodic review of risk assessment.
- 3.1.4 To monitor completion of proposed additional control measures and CAPA.
- 3.1.5 Initiation of Brain Storming session in coordination with site QA

3.2 Originating Department Head:

- 3.2.1 Identification and review of risk system / operation / area.
- 3.2.2 Selection of risk assessment team in coordination with Head of Site QA.
- 3.2.3 Implementing the outcome of evaluated risk.
- 3.2.4 To monitor implementation of additional control measures.
- 3.2.5 To monitor completion of periodic review of risk assessment.

3.3 Risk Assessment Team:

- 3.3.1 To identify and evaluate the possible risks involved in the risk system / operation / area.
- 3.3.1 To coordinate with originating department for risk evaluation, risk re - evaluation and periodic review of the risk assessment.

3.4 Head of Site QA:

- 3.4.1 Review and approval of identified risks.
- 3.4.2 Training of risk assessment team.
- 3.4.3 Selection of Risk Assessment Team in coordination with Originating Department Head.
- 3.4.4 Final review and approval of risk assessment and risk assessment summary.
- 3.4.5 Final review & approval of Periodic review of risk assessment report.

3.5 Site QA:

- 3.5.1 Monitoring completion of initial evaluation of risk and re - evaluation of risk.

3.6 Unit Head:

- 3.6.1 Final Review and approval of risk assessment.

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4.0 DEFINITIONS:

- 4.1 **Risk:** The combination of probability of occurrence of harm and severity of that harm.
- 4.2 **Hazard:** The potential source of harm
- 4.3 **Harm:** Damage to health, including the damage that can occur from loss of product quality or availability.
- 4.4 **Risk Assessment:** A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.
- 4.5 **Risk Identification:** The systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description.
- 4.6 **Risk Analysis:** The estimation of the risk associated with the identified hazards.
- 4.7 **Severity:** A measure of the possible consequences of a hazard.
- 4.8 **Detectability:** The ability to discover or determine the experience, presence, or fact of a Hazard.
- 4.9 **Risk Priority Number (RPN):** A numeric assessment of risk assigned to a process, or steps in a process, as part of failure mode effects analysis (FMEA). Each failure mode gets a numeric score that quantifies likelihood of occurrence, likelihood of detection and severity of impact. The product of these three scores is the RPN for that failure mode.
 RPN = Severity Rating X Occurrence Rating X Detection Rating
- 4.10 **Risk Evaluation:** The comparison of the estimated risk to given risk criteria to determine the significance of the risk.
- 4.11 **Risk Control:** Actions implementing risk management decisions.
- 4.12 **Risk Reduction:** Actions taken to lessen the probability of occurrence of harm and the severity of that harm.
- 4.13 **Risk Acceptance:** The decision to accept risk.
- 4.14 **Risk Communication:** The sharing of information about risk and risk management between the decision maker and other stakeholders.
- 4.15 **Risk Review:** Review or monitoring of output / results of the risk management process considering (if appropriate) new knowledge and experience about the risk.

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- 4.16 Quality:** The degree to which a set of inherent properties of a product, system or process fulfils requirements.
- 4.17 Risk Management:** The systematic application of quality management policies, procedures, and practices to the tasks of assessing, controlling, communicating and reviewing risk.
- 4.18 Quality Risk Management:** Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of drug product across product lifecycle.
- 4.19 Product Lifecycle:** All phases in the life of the product from the initial development through marketing until the product's discontinuation.
- 4.20 Proactive Risk Assessment:** An assessment that is conducted in advance of an activity, either before any work is conducted or before further work is conducted. This enables quality to be built into activities and risk to be reduced.
- 4.21 Reactive Risk Assessment:** An assessment that is conducted to assess the impact of a situation that has already occurred, e.g. impact of a deviation from normal ways of working.
- 4.22 Raw Risk:** Risk exists in the absence of controls or before any controls measures are implemented.
- 4.23 Failure mode:** Different ways that a process or sub process can fail to provide the anticipated result.
- 4.24 Failure Mode Effects Analysis (FMEA):** A systematic method of identifying and preventing product and process problems.

5.0 PROCEDURE:

- 5.1** The risk management process shall focus on potential risk to product quality, GMP compliance and patient safety and product availability.
- 5.2** Quality Risk Management (QRM) shall be integrated into existing activities or operations in the areas of:
- Quality System
 - Facility and Equipment System
 - Production System
 - Laboratory Control System
 - Materials System
 - Packaging and Labelling System
- 5.3** The activities or areas or operations affecting the GMP and product quality are detailed in, "List of Activities or Operations or Areas for Quality Risk Assessment, QAP/MLCM/0043/ANX/0001" and serves as a guidance. The list is not exhaustive and Risk Assessment Team shall consider activities beyond

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this list and identify checkpoints during review of each operation or activity based on experience, non-conformities observed and audit / inspection reports.

Note: For list of activities related to Risk assessment of Computerized systems, "Validation of Computerized System, QAP/MLCM/0095" and relevant site specific procedures shall be referred.

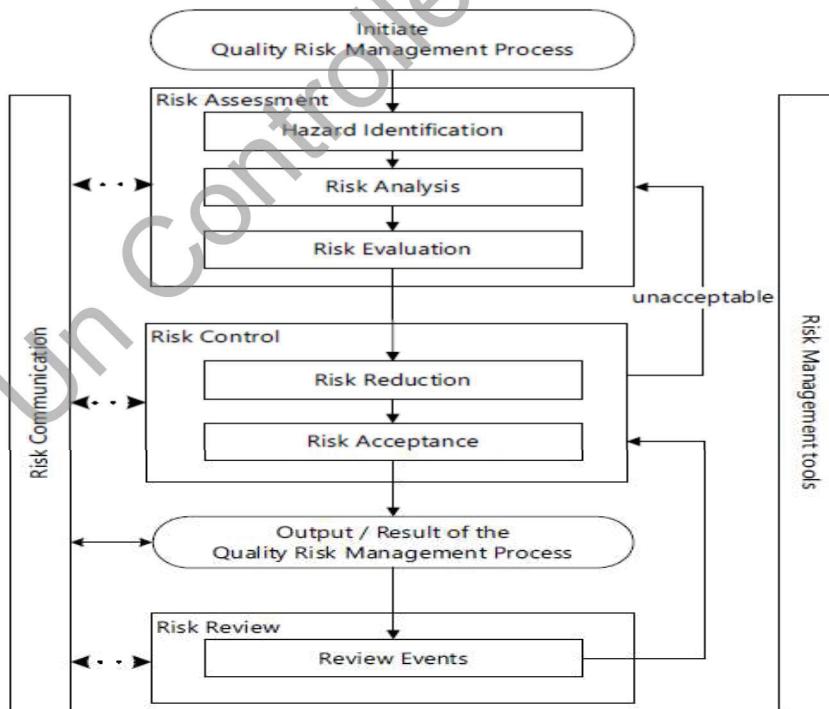
5.4 An independent risk assessment study shall be carried out for repeated discrepancies, deviations or non-conformances even though the risk assessment study had been conducted earlier for such non-conformances.

5.5 The Quality Risk Management process shall comprise following steps:

- Risk Assessment: Risk/Hazard Identification, Risk Analysis and Risk Evaluation
- Risk Control: Risk Reduction and Risk Acceptance
- Risk Communication
- Risk Review

5.6 The model of Quality Risk Management specified in ICH Q9 document shall be followed. The same is depicted below,

QUALITY RISK MANAGEMENT PROCESS



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5.7	Steps for quality risk management shall include
5.7.1	Initiation of Risk Assessment
5.7.2	Selection of Risk Assessment Team.
5.7.3	Conducting Brain Storming Session / Meeting and documenting the outcome.
5.7.4	Proposing additional control measures based on initial evaluation and re-evaluation of the risk.
5.7.5	Compilation, review, evaluation and approval of Risk Assessment.
5.7.6	Closeout of Risk Assessment.
5.7.7	Periodic Review of risk Assessment
5.8	Risk Assessment for Data Integrity
5.8.1	While designing new systems or implementation of new software or upgradation of software, Risk Assessment for Data Integrity shall be performed either as part of overall risk assessment or as a standalone exercise.
5.8.2	Risk assessment for data integrity shall be performed for all systems where data is generated manually or through software or through hybrid system and stored. This assessment shall cover the data integrity elements for compliance of data generated, with ALCOA+ principles.
5.8.3	While performing risk assessment for data generation the following elements of data life cycle shall be considered, <ul style="list-style-type: none"> ➤ Data generation and Capture ➤ Data transmission ➤ Data processing ➤ Data review ➤ Data reporting including handling of invalid and atypical data ➤ Data retention and retrieval ➤ Data disposal
5.8.4	Based on the evaluation of the risks associated with the data life cycle appropriate control measures shall be defined to mitigate the risk.
5.9	Initiation of Risk Assessment:
5.9.1	Risk Assessment shall be initiated as an outcome of identified activity/operation either Proactively/Reactively/and also as per Annual Risk Assessment Planner through the form, "Quality Risk Assessment Initiation Form, QAP/MLCM/0043/FMT/0006".

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- 5.9.2 Reactive risk assessment shall be carried out as and when Risk is identified by any individual or as part of Change controls, Deviations, Market Complaints, Audit compliance etc.
- 5.9.3 Proactive risk assessment shall be carried out before initiating any changes / modifications/ new introduction of procedure / system / facility / equipment / software etc.
- 5.9.4 Annual Risk Assessment Planner shall be prepared as per the requirement of procedure and in accordance with the form, "Annual Risk Assessment Planner, QAP/MLCM/0043/FMT/0005" including the risk assessment due for periodic review during the review period. The topics mentioned below shall be a part of annual risk assessment planner. All the activities shall be considered at least once in three years.
- Vendor Management
 - Cleaning Validation
 - Complaint Management
 - Material Management (Receipt, storage, handling and dispensing of materials)
 - Production (Manufacturing and Packing process)
 - Facility
 - Document storage, retrieval and destruction
 - Preventive Maintenance
 - Training and Education
 - Laboratory Control and Stability Testing
 - Sampling and Testing
 - Sanitization and Hygiene
 - Computerized System
 - Risks identified from periodic review.
 - Contamination and Cross Contamination
- 5.9.5 Annual Risk Assessment Planner shall be prepared by Site QA in consultation with other Department Heads before the start of the subsequent year.
- 5.9.6 The Annual Risk Assessment Planner shall be identified by an unique numbering system such as QRM:MLXX:YY:001
- Where,
- QRM : Quality Risk Management
- MLXX : Micro Labs site code
- YY : as 24 for Year 2024
- 001 : is sequential serial number.
- e.g. The annual risk assessment planner of Micro Labs, ML14 for year 2024 shall be QRM:ML14:24:001.

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- 5.9.7 Risk Assessments, which are planned as a part of Annual Risk Assessment planner / Periodic risk assessment shall be completed within 3 months of the scheduled month.
- 5.9.8 In case of addition of new activity which is not specified in Annual Risk Assessment Planner of the year and/or inclusion of any risk assessment as part of periodic review, Site QA shall prepare the addendum as per format "Annual Risk Assessment Planner, QAP/MLCM/0043/FMT/0005".
- 5.9.9 Each addendum shall have the details of history of changes in 'Document Review Status Sheet' as per QAP, "Design and Control of Documents, QAP/MLCM/0003".
- 5.9.10 For subsequent addition of any other activity, the addendums shall be numbered as ADDEN 1, ADDEN 2... and so on until the planner is updated for next year.
 Initial planner of year:QRM:MLXX:YY:001.; Addendum: NA
 Addendum for first version:QRM:MLXX:YY:001; Addendum: ADDEN 1
 2nd Addendum for first version:QRM:MLXX:YY:001; Addendum: ADDEN 2
- 5.9.11 Master copy of the addendum shall be maintained with the Annual Planner by Site QA.

5.10 Selection of Risk Assessment Team:

- 5.10.1 Selection shall be done by originating department head in coordination with Head of Site QA by considering their qualification, experience, training and knowledge about the identified risk system / Operation / area. Guidance for selection of risk assessment team is provided in "Selection of Risk Assessment Team, QAP/MLCM/0043/ANX/0003".The examples listed in QAP/MLCM/0043/ANX/0003 is not limited, any other activity which triggers the requirement of Risk Assessment shall also be considered. In such cases Selection of Risk Assessment team shall be done by Head of Site QA.
- 5.10.2 Head of Originating department / Head of Site QA shall ensure that all the selected team members are qualified for performing Quality Assessment.

5.10.3 Training and Qualifying a Quality Risk Assessment team member

- 5.10.3.1 All the team members shall be trained on the training module "Training Module – Risk Assessment, QAP/MLCM/0043/ANX/005" and certified before getting selected as a QRM Team member. During training working examples / case studies shall be utilized for easy understanding of the trainee. Based on the training , individuals shall be assessed and qualified as SME (Subject Matter Expert) by Head of QA, as per format "SME Certificate, QAP/MLCM/0043/FMT/0010" & details shall be updated in "List of identified SMEs for Risk Assessment, QAP/MLCM/0043/FMT/0012".
- 5.10.3.2 Site QA shall maintain the list of identified SMEs for Risk Assessment as per the format, 'List of identified SMEs for Risk Assessment, QAP/MLCM/0043/FMT/0012 . The list shall be numbered as LISME:YYY,

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Where,

LISME stands for List of Identified Subject Matter Expert,

YYY stands for running serial number 001, 002,

If the list undergoes a revision the document number shall be revised to the next serial number i.e. 002, 003.etc for each subsequent revision.

- 5.10.3.3 Any changes to approved List of Identified SMEs, an Addendum shall be prepared as per “List of identified SMEs for Risk Assessment, QAP/MLCM/0043/FMT/0012” and the addendum shall be numbered as ADDEN 1,ADDEN 2.... And so on until the respective approved list is updated.

Ex: Approved List of Identified SMEs shall be numbered as

First version: LISME:YYY; Addendum: NA

Addendum for first version: LISME:YYY; Addendum: ADDEN 1

2nd Addendum for first version: LISME:YYY; Addendum: ADDEN 2

- 5.10.3.4 Master Copy of the addendum shall be maintained with the List by Site QA.

- 5.10.3.5 An annual planner shall be prepared by Site QA and a refresher training shall be conducted on training module to all the qualified individuals, by head of site QA.

5.11 Conducting Brain Storming Session / Meeting:

- 5.11.1 Brain Storming session / Meeting shall be conducted by originating department in coordination with Site QA and Risk Assessment Team. Details of discussions in Brain storming session shall be documented in the form “Brain storming session/Meeting schedule, QAP/MLCM/0043/FMT/0009”.

- 5.11.2 Wherever applicable, a process flow chart / process mapping shall be used during brain storming session.

- 5.11.3 During brain storming session, assessment of raw risk, current control measures, RPN and potential additional control measures shall be discussed.

5.12 Risk Assessment

The following activities shall be carried out as part of Risk assessment.

- 5.12.1 **Risk Identification:** After identification of area/activity/operation for the risk assessment, the failure / risk / hazard shall be identified for each process step by risk assessment team through review of available data and past experience. This shall be followed by evaluation of potential causes of failure. The identification of risk shall begin with the fundamental question “What might go wrong?”

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5.12.2 Risk Analysis: Analysis of the identified risk shall be done to estimate the raw risk associated with the identified hazard. Based on potential effect of each failure/risk/hazard, probability of failure shall be evaluated and probability score (P) shall be assigned without considering the current control measures. Severity or effect of each risk on Product quality / Systems / Process / Regulatory compliance, in the event of its occurrence shall be assessed and severity score (S) shall be assigned. By evaluating the probability of detecting the risk before its occurrence, detectability Score (D) shall be assigned. Based on the assigned scores, Risk Priority Number (RPN) shall be calculated to analyze the Raw Risk. The following questions shall be asked while assigning the scores,

- What is the likelihood (probability) it will go wrong? (P)
 - What are the consequences (severity)? (S)
 - What are the chances of detection? (D)
- Risk Priority Number (RPN) = P x S x D

5.12.3 Risk evaluation

The risk evaluation shall be conducted with patient safety as primordial objective however, it shall also consider Product quality / Systems / Process / Regulatory compliance. For each risk identified, evaluate the reduction in probability of occurrence and increase in detection of the risk based on the current control measure in place. After evaluation, the score for Probability (P) and Detectability (D) shall be reassigned with a justification for scores & RPN shall be calculated. Severity score shall remain same as of the risk analysis.

5.12.4 Ranking:

Ranking	Probability of Occurrence of Failure	Severity of Effect	Likelihood of Detection
5	Very High, Failure is almost inevitable	Can cause serious adverse health consequence including death of the patient	Very Low: The risk will not be detected
4	High, Repeated Failures	May cause permanent medically irreversible adverse health condition	Low: The risk is unlikely to be detected
3	Moderate, Occasional Failures	May cause temporary medically reversible adverse health condition	Moderate: A potential risk may be detected
2	Low, Relatively few failures	May cause discomfort but not likely to cause adverse health consequences	High: Has a good chance of detecting the risk
1	Remote, Failure is unlikely	May cause temporary discomfort	Very High: Will almost certainly be detected

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5.12.4.1 The action to be taken shall be based on RPN assigned as detailed below:

- | | |
|---------------------------------|-------------------------------|
| RPN below or equal to 20 | : No actions required. |
| RPN above 20 and below 60 | : Actions required. |
| RPN with 60 and above 60 to 125 | : Immediate actions required. |

Note: The Risk evaluation shall be done by following FMEA (Failure Mode Effects Analysis) by assigning ranking on a scale of 1 to 5 to the probability, severity and Detectability of the identified risk. Other appropriate risk management tools such as Flow Charts, Process mapping, Fish Bone diagrams, HAZOP- Hazard Operability Analysis shall be used as per the requirement.

5.12.5 Risk Control (Risk Reduction / Risk Acceptance):

5.12.5.1 Based on the risk evaluation acceptance of risk shall be decided. If the RPN is 20 or below 20, the risk can be accepted without any additional control measures. If the RPN is above 20, risk shall be accepted with additional control measures. For each additional control measure proposed, Risk reduction shall be calculated theoretically, by evaluating reduction in probability of occurrence & increase in detectability. The Probability (P) and detectability scores shall be assigned accordingly. RPN shall be calculated, based on the assigned (P) & (D) scores and severity (S) score from initial risk assessment.

If the RPN is reduced as compared to risk evaluation step, the additional control measure shall be accepted for implementation & responsibility for implementation shall be assigned.

After these measures are implemented re-evaluation of the risk shall be done to evaluate the reduction in risk and for its acceptance.

Note: For RPN 20 and below, additional control measures may be assigned to bring RPN further down.

5.12.5.2 If the identified risk is with RPN above 20 and below 60 and the risk has any impact on Product quality, Systems, Process and Regulatory compliance, the action required shall be initiated within 7 working days from the date of risk assessment initiation.

5.12.5.3 If the Identified risk is with RPN 60 and above and has any impact on Product quality/ Systems/Process/ Regulatory compliance immediate action required shall be initiated within 48 hours or before depending on the severity of the risk. Originating department head shall propose the action plans in the format "Action plan for the risk with RPN 60 and above, QAP/MLCM/0043/FMT/0015" and reviewed by site QA Head, Unit Head & CQA Head. The immediate action may include the following:

- Affected batches / materials (including in-process materials, un-released finished products and previously released materials) are kept 'Under Hold' till the investigation is completed.
- Discontinuation of products / materials or the impacted systems
- Recall, in case the product / Batch is already distributed.

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- 5.12.5.4 The corrective and preventive action required for all the identified risk shall be taken within 30 working days from the date of initiation of risk assessment for Reactive Risk assessment & the risk Assessments performed as per Annual Risk assessment planner. For the proactive risk assessment, timeline shall be decided based on severity of the risk and the additional control measures proposed.
- 5.12.5.5 Where the identified risk is an outcome of any non-conformance, root cause for the same shall be investigated as per the instructions of procedure "Investigations and Root Cause Analysis, QAP/MLCM/0062". Implementation of identified corrective and preventive actions and monitoring of its effectiveness shall be handled in accordance with the procedure, "Handling of Corrective and Preventive Action, QAP/MLCM/0040".
- 5.12.5.6 Risk identification & evaluation details shall be compiled by originating department as per the format, "Risk Identification and evaluation Record, QAP/MLCM/0043/FMT/0001". The details shall be reviewed by Risk assessment team & further reviewed and approved by Unit Head & Site QA Head.
- 5.12.5.7 Once "Risk identification & evaluation record, QAP/MLCM/0043/FMT/0001" is approved, site QA shall document initial risk assessment completion details in, "Quality Risk Assessment Register, QAP/MLCM/0043/FMT/0003".
- 5.12.5.8 Wherever, additional control measures are proposed, reduction in risk/RPN shall be reevaluated after implementation of proposed additional control measures.
- 5.12.5.9 If additional control measures are not proposed, risk assessment summary shall be prepared as detailed in section 5.14, "Risk Assessment Summary".

5.13 Risk Re-Evaluation

- 5.13.1 After implementation of additional control measure identified for each risk, re-evaluation shall be carried out to assess the reduction in risk.
- 5.13.2 Once the additional control measures are implemented, probability of the occurrence & detection of the risk shall be reassessed and probability score (P) and Detection Score (D) shall be assigned. RPN shall be calculated, by considering the severity score from the initial risk analysis. If,
- | | |
|--------------------|---|
| RPN 20 or below 20 | : The Risk is accepted. |
| RPN is above 20 | : The risk is not accepted and risk assessment shall be repeated. |
- 5.13.3 Details of re-evaluation shall be documented, as per format "Re-evaluation of risk after implementing the additional control measures, QAP/MLCM/0043/FMT/0007" by originating department head /designee and approved by site QA Head.
- 5.13.4 After reevaluating all the risks, a risk assessment summary shall be prepared as per the format, "Risk Assessment Summary, QAP/MLCM/0043/FMT/0011".

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5.14 Risk Assessment Summary

- 5.14.1 Risk assessment summary shall be prepared by originating department as per the format, "Risk Assessment Summary, QAP/MLCM/0043/FMT/0011".
- 5.14.2 During summary preparation, frequency for periodic review of risk assessment shall be specified. If the periodic review is not recommended, the same shall be justified. The Risk assessment summary shall be further approved by Head QA. After approval, Site QA shall document the closure details in "Quality Risk Assessment Register, QAP/MLCM/0043/FMT/0003".
- 5.14.3 All the documents related to Risk assessment & Reevaluation of risk assessment shall be enclosed with the risk assessment summary.
- 5.14.4 The risk assessment identified for periodic risk review shall be included in Annual Risk Assessment Planner of the respective year and completion shall be monitored through the planner.

5.15 Periodic Review of Risk Assessment

- 5.15.1 Originating department shall carry out periodic review of risk assessment as per the frequency specified in risk assessment summary which is further tracked through Annual risk assessment planner. Periodic Assessment shall be carried as per the format, "Periodic review of risk assessment, QAP/MLCM/0043/FMT/0013".
- 5.15.2 Originating department in coordination with site QA, shall form a cross functional team for evaluation & the team members shall be decided based on the nature of Risk to be assessed.
- 5.15.3 As a part of periodic review of risk assessment, team shall verify all control measures in place, their effectiveness and any non-conformances reported during the review period. Based on the assessment, additional control measures required (if any) shall be proposed.
- 5.15.4 During the review, if the current control measures found to be not effective or if a new risk is identified, risk assessment shall be redone and an addendum risk assessment report shall be prepared.
- 5.15.5 Periodic review documents shall be identified as PR1, PR2, PR3 & so on. Example, first periodic review of RA:24:001 shall be numbered as RA:24:001/PR1 & second periodic review shall be numbered as RA:24:001/PR2.

5.16 Risk Communication:

The outcome of the risk assessment process shall be communicated to applicable departments for implementation of necessary actions (as applicable).

Risk which have impact on product Quality / regulatory compliance shall be informed to Contract giver (CG) / MA Holder / Regulatory department through format "Communication of Risk assessment outcome to Contract Giver / MA Holder / Regulatory Department",

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QAP/MLCM/0043/FMT/0016. Communication to CG/MA Holders shall be given as per the terms & conditions defined in Technical agreements.

Details of risks with RPN above 60, shall be communicated to Corporate QA as part of Quality System Review (QSR).

5.17 Identification of Risk Assessment Report:

5.17.1 Risk Assessment shall be numbered as RA:YY:XXX

Where,

RA : stands for Risk Assessment

YY : Stands for Current Year

XXX : Stands for Serial Number starting from 001.

For Example RA:24:001 is the first risk assessment number for the year 2024.

5.17.2 After allocating the number, Site QA shall enter the details of risk assessment in “Quality Risk Assessment Register, QAP/MLCM/0043/FMT/0003”

5.17.3 Whenever required, an addendum risk assessment can be prepared for the risk assessment. The same shall be numbered as RA:YY:XXX/A. Where “A” denotes, first addendum to risk assessment number RA:YY:XXX.

6.0 REFERENCES:

6.1 ICH Q9 – Quality Risk Management.

6.2 WHO guidelines on Quality Risk Management, TRS 981, Annex 2

6.3 Handling of Corrective and Preventive Action : QAP/MLCM/0040

6.4 Investigations and Root Cause Analysis : QAP/MLCM/0062

6.5 Quality System Review : QAP/MLCM/0045

6.6 Validation of Computerized System : QAP/MLCM/0095

7.0 ENCLOSURES:

7.1 Risk Identification and Evaluation Record : QAP/MLCM/0043/FMT/0001-012

7.2 Quality Risk Assessment Register : QAP/MLCM/0043/FMT/0003-007

7.3 Annual Risk Assessment Planner : QAP/MLCM/0043/FMT/0005-007

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7.4 Quality Risk Assessment Initiation Form	:	QAP/MLCM/0043/FMT/0006-007
7.5 Re-Evaluation of Risk after Implementing the additional control measures	:	QAP/MLCM/0043/FMT/0007-006
7.6 Brain Storming session / Meeting schedule	:	QAP/MLCM/0043/FMT/0009-005
7.7 SME Certificate	:	QAP/MLCM/0043/FMT/0010-005
7.8 Risk Assessment Summary	:	QAP/MLCM/0043/FMT/0011-004
7.9 List of identified SMEs for Risk Assessment	:	QAP/MLCM/0043/FMT/0012-003
7.10 Periodic Review of Risk Assessment	:	QAP/MLCM/0043/FMT/0013-002
7.11 Action plan for the risk with RPN 60 and above	:	QAP/MLCM/0043/FMT/0015-002
7.12 Communication of Risk assessment outcome to Contract Giver / MA Holder / Regulatory Department	:	QAP/MLCM/0043/FMT/0016-000
7.13 List of Activities or Operations or Areas for Quality Risk Assessment	:	QAP/MLCM/0043/ANX/0001-007
7.14 Risk Assessment Flow Chart	:	QAP/MLCM/0043/ANX/0002-006
7.15 Selection of Risk Assessment Team	:	QAP/MLCM/0043/ANX/0003-005
7.16 Training Module – Risk Assessment	:	QAP/MLCM/0043/ANX/0005-003
8.0 ABBREVIATIONS:		
8.1 FMEA	:	Failure Mode Effects Analysis
8.2 RPN	:	Risk Priority Number
8.3 HAZOP	:	Hazard Operability Analysis
8.4 QRM	:	Quality Risk Management Attributable Legible Contemporaneous
8.5 ALCOA+	:	Original Accurate Complete

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		Consistent Enduring Available
8.6	QSR	: Quality System Review
8.7	SME	: Subject matter Expert
8.8	RA	: Regulatory Affairs
8.9	CG	: Contract Giver
8.10	MA	: Marketing Authorization Holder

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016	23/03/2024	CCR-ML00-2024-0007	<p>Quality Risk management, QAP/MLCM/0043 is revised to include below mentioned changes.</p> <p>1. As per Response to Pharmacy and Medicine Regulatory Authority (PMRA), Section no.5.16 ,details are updated regarding risk communication to Contract Giver / MA Holder / Regulatory Department, accordingly new format is included to communicate the risk through format "Communication of Risk assessment outcome to Contract Giver / MA Holder / Regulatory Department, QAP/MLCM/0043/FMT/0016".</p> <p>2. Raw Risk Definition is included at section no.4.22.</p> <p>3. Statement updated as, the topics which are mentioned at section no.5.9.4 shall be a part of annual risk assessment planner. All the activities shall be considered at least once in three years and contamination & cross contamination topic is included.</p> <p>4. Annotation \$ in selection of Risk assessment team (QAP/MLCM/0043/ANX/0003) is described.</p> <p>5. Mentioned as "Certified On QRM" instead of "Trained on QRM" and "Qualified on" in the formats "Brain Storming Session / Meeting Schedule, QAP/MLCM/0043/FMT/0009" & List of Identified SMEs for Risk Assessment QAP/MLCM/0043/FMT/0012 for better clarity.</p>
015	31/07/2023	CCR-ML00-2023-0114	<p>1. Section no.5.1 is updated as the risk management process shall focus on potential risk to product Quality, GMP compliance, patient safety and product availability.</p> <p>2. Section no.5.6.Quality Management process Diagram is updated.</p> <p>3. At section no. 5.9.7 procedural instruction is included as Risk Assessments, which are planned as a part of Annual Risk Assessment planner/periodic Risk assessment shall be completed within 3 months of the scheduled month.</p> <p>4. Section no.5.10.3.2 to 5.10.3.4, Numbering system for List of Identified SMEs for Risk assessment is included.</p> <p>5. Format for "Risk Identification and Evaluation Record QAP/MLCM/0043/FMT/0001" is revised to include provision including conclusion in section no.2.0.</p> <p>6. Format "Quality Risk assessment Register QAP/MLCM/0043/FMT/0003 is revised to include Periodic review/annual planner in type of Risk assessment along with proactive/Reactive.</p> <p>7. Format "Risk assessment summary QAP/MLCM/0043/FMT/0011" is revised to include in the</p>

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014	19/10/2022	CCP-ML00-22-0192	<p>section 3.0, NA/No action recommended along with an option yes/No and in section no.4.0 NA is included along with Yes/No.</p> <p>8. Numbering system is updated in format QAP/MLCM/0043/FMT/0012 .</p> <p>9.List of activities or operations or areas for Quality Risk assessment QAP/MLCM/ 0043/ANX/0001-005 is revised to include Supply Chain controls to ensure Product availability.</p> <p>10.Annexure Training module of Risk assessment QAP/MLCM/0043/ANX/0005 is updated to remove Qualitative and Quantitative words.</p> <p>11."Annual Risk assessment planner QAP/MLCM/0043/FMT/0005" is revised to include closure date for initial risk assessment and final closure date instead of completion date.</p> <p>12.In Format "Quality Risk Assessment Initiation form, QAP/MLCM/0043/FMT/0006 "mentioned as Reference document Number if any instead of Reference document number.</p> <p>1.Scope of the procedure is updated.</p> <p>2.Responsibility section is updated as per the updated procedure.</p> <p>3.At section no.5.0, requirement of conducting data integrity risk assessment for every systems that produces and stores data is included, to comply with the WHO audit observation at ML06 & ML08.</p> <p>4.At section no.5.0, the statement is modified as Risk assessment involves Risk/Hazard identification, Risk Analysis & Risk Evaluation.</p> <p>5. At section no.5.0, Periodic risk assessment in list of activities involved in risk assessment is included.</p> <p>6. At section no.5.0, Categories of risk assessment are redefined as Reactive Risk assessments, Proactive risk assessment and Risk assessments carried out to be carried out as per Annual planner</p> <p>7. At section no.5.0 Provision for Qualitative or Quantitative risk assessment are removed and Redefined the procedure to carry out risk assessment quantitatively. All the instructions in procedure/Formats/Annexures stating Qualitative/Quantitative risk assessment are modified to define as a "Risk assessment".</p> <p>8.Procedure & requirements of "Periodic Risk Assessment" and a Format to document the details is</p>

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			<p>introduced.</p> <p>9.Requirement of trending of risk assessments is removed.</p> <p>10.Provision to prepare addendum for risk assessments is included.</p> <p>11.Risk Assessment flow chart as per the above procedure is redefined.</p> <p>12.Format QAP/MLCM/0043/FMT/0001 is modified to modify the Title as "Risk Identification and Evaluation Record" & Contents of the formats to carryout risk assessments. The format is revised to include an initial assessment of risk without considering current control measures, followed by assessment of risk with considering current control measures. Also, provision is included for stage wise evaluation of RPN with a justification.</p> <p>13.Format of Re Evaluation of Risk, QAP/MLCM/0043/FMT/0007, is modify the title as "Re-evaluation of risk after implementing the additional control measures". The format is revised to include a provision for Process Step, Failure/ Risk/ Hazard, details of Additional Control Measures proposed and to include a provision to document detailed re-evaluation with the reason. Relevant sections of the procedure are modified to detail the procedure for Risk assessment as per the revised format.</p> <p>14.Format of Risk Assessment Summary (QAP/MLCM/0043/FMT/0011) is modified to include a provision to document, details of additional control measures implementation & periodic review requirement. Relevant sections of the procedure are modified to detail the procedure as per the revised format.</p> <p>15.Formats, "Risk Identification and Quantitative Evaluation Record, QAP/MLCM/0043/FMT/0002", "Re-evaluation of risk after implementing the additional risk control measures for Quantitative evaluation, QAP/MLCM/0043/FMT/0008 and "Trend report for Risk Assessment, QAP/MLCM/0043/ANX/0004" made obsolete.</p> <p>16.New formats, "periodic review of Risk assessment, QAP/MLCM/0043/FMT/0012" and "Action plan for the risk with RPN 60 and above, QAP/MLCM/0043/FMT/0014" are introduced.</p>
013	26/10/2021	CCP-ML00-21-0104	1.To give better clarity, in section no.15.13.3.3.2.1

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			<p>examples are modified (Description of severity of event) for qualitative risk ranking based on severity.</p> <p>2.In section no. 5.13.3.3.2.1 Severity /likelihood rating is provided as high, medium, low instead of in numbers in order to align with table 5.13.3.3.3.</p> <p>3.step no.5.13.3.3.2.3 modified to risk/controls available for early detection of the potential cause of failure.</p> <p>4.section no.5.4.1,5.13.3.2.5,5.13.3.3.2.2, 5.13.3.3.2.3 and 5.13.3.3.7 are modified to have better clarity.</p> <p>5.Note is included in section no. 5.13.3.3.5 and 5.13.3.3.8 i.e, For the risks with RPN of below 20 also actions can be recommended (if required). Completion of these actions shall be ensured prior to closure of risk assessment.</p> <p>6.Risk identification and Qualitative Evaluation Record (QAP/MLCM/0043/FMT/0001- 008) and Risk identification and Quantitative Evaluation Record (QAP/MLCM/0043/FMT/0002-008) formats are revised to provide an option to assess probability after assessment of current control measures, provision is included to write conclusion and Review and approval by Unit Head is incorporated.</p> <p>7.In Quality Risk Assessment Register (QAP/MLCM/0043/FMT/0003-003) Provision is provided for Risk Assessment Logged by sign/Date.</p> <p>8.In Risk assessment summary format QAP/MLCM/0043/FMT/0011-000, Risk score is included in Section no 3.0 ,in section no.4.0 QMS document No.if any is included along with reference CAPA and in section no.9.0 Review and Unit Head- Approval comments are removed.</p> <p>9.QAP/MLCM/0043/FMT/0006-003,QAP/MLCM/0043/FMT/0007-002,QAP/MLCM/0043/FMT/0008-001 and QAP/MLCM/0043/FMT/0009-001 formats are modified to have better clarity.</p> <p>10.QAP/MLCM/0043/ANX/0001-003 and QAP/MLCM/0043/ANX/0002-002 are modified inline with existing procedure</p> <p>11.New format is introduced to prepare list of SMEs for Risk Assessment QAP/MLCM0043/FMT/0012 and instructions are included in section no.5.4.2</p> <p>12. New Annexure is introduced for "Training Module Risk Assessment" QAP/MLCM/0043/ANX/0005-000 and instructions included in section no.5.4.2.</p>

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012	31/08/2020	CCP-ML00-20-0096	<p>1. QAP is prepared in DMS template. Format numbers & Annexure numbers are modified in DMS format.</p> <p>2. Section 5.13.2 is included as a part of continuous improvement it is proposed to include the process flow chart / process mapping</p> <p>3. Section 5.13.3.1 Risk Identification is modified to include instructions for risk identification, from the available data or past experience, identify the failure mode/risk for each process step/activity and evaluate potential effect of failure mode/risk.</p> <p>4. Section 5.13.3.2 Risk Analysis is modified to include, calculate the severity score for each identified risk. Analyze the potential causes of the identified risk and calculate the probability score. Then evaluate current control measures for each identified risk and calculate the detectability score.</p> <p>5. Section 5.13.3.3 Risk evaluation section is including for better control</p> <p>6. In Qualitative risk evaluation section is modified to include Qualitative analysis is used for subjective decisions based on the non-quantifiable information</p> <p>7. Qualitative Ranking section is modified to include Qualitative Risk Ranking Based on Severity, Qualitative Risk Ranking Based on Probability, Qualitative Risk Ranking Based on Detectability</p> <p>8. New reference procedure is "Computer System Validation, QAP/MLCM/0095" is included to in line with the procedure "Design and Control Of Documents, QAP/MLCM/0003".</p>
011	26/06/2019	CCP-ML00-19-0020	Revision/Change Details uploaded along with Main document through Initial mass upload. Refer DRS(Document Review Sheet) in main document

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