Re-evaluation report

For

Change in classification of LAF from Grade A to Unidirectional Air Flow (UDAF) (Grade A supply air) in Microbiology laboratory

Activity	Name	Date	Signature
Prepared By			
Reviewed By			
Approved By			

Re-evaluation report for Change in classification of LAF from Grade A to Unidirectional Air Flow (UDAF) (Grade A supply air) in Microbiology Laboratory

1.0 Purpose of the Assessment

The purpose of the re-evaluation report is to re-evaluate the risk associated with the change in classification of LAF from Grade A to Unidirectional Air Flow (UDAF) (Grade A supply air) in microbiology laboratory.

2.0 Background

LAF are situated in MLT & water analysis room (GF-35) in microbiology laboratory. Both the LAF are classified as Grade A/Class 100. Both LAFs are used for the various analytical activities in microbiology laboratory. The surrounding area of the LAFs is MLT and water analysis room (GF-35) which is classified as Grade D. The both LAFs were qualified as grade A. The classification of both LAFs changed from Grade A to UDAF as per WHO guidelines.

3.0 Details of Risk Assessment Team

Name	Department
	Quality Control
	Quality Assurance
	Engineering

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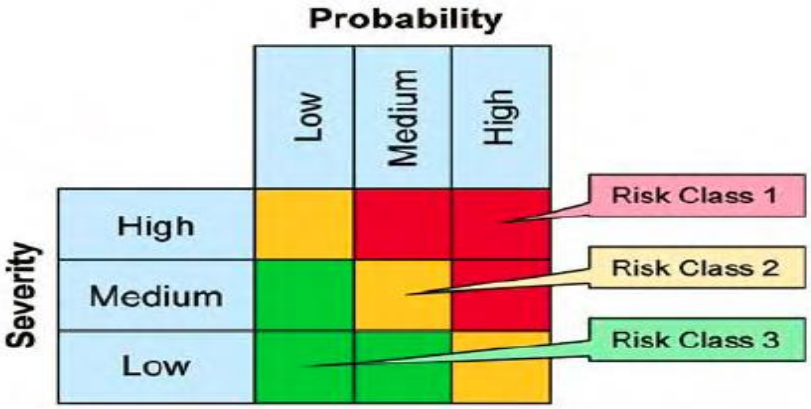
FMEA Model for change in classification of LAF from Grade A to Unidirectional Air Flow (UDAF) (Grade A supply air) in microbiology laboratory

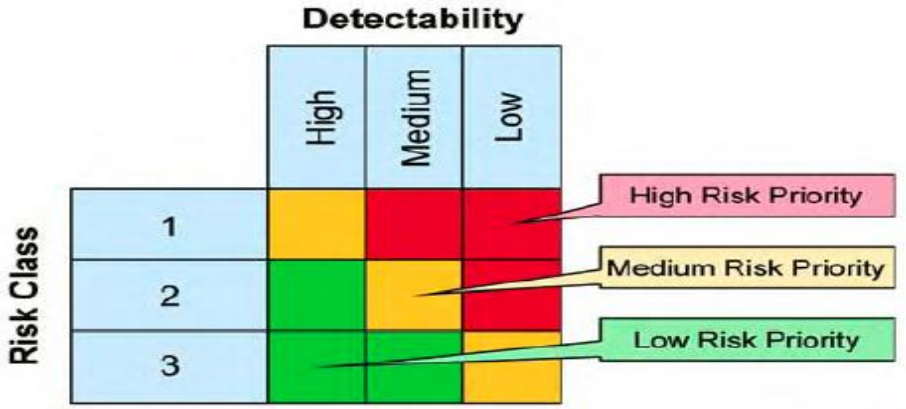
Risk assessment aims to establish controls such that the combination of severity, probability of occurrence, and detectability of failures is to be assessed. Severity refers to the possible consequence of a risk.

Each of the risks identified for a function is assessed in two stages, as shown in figure below:

- Severity and Probability will be plotted to find out the Risk Class (1/2/3).
- The risk class and Detectability will be plotted to identify the risk priority.
- The Risk Priority obtained helps to focus attention on areas where the procedure is inadequate and implemented CAPA's are ineffective. These shall be considered in relation to the risk tolerance.



Severity = Impact on Patient Safety, Product Quality, and Data Integrity (or other harm)
Probability = Likelihood of the fault occuring
Risk Class = Severity × Probability



Detectability = Likelihood that the fault will be noted before harm occurs
Risk Priority = Risk Class × Detectability

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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Risk Assessment Criteria	
Severity	**Failure Consequence/Severity Assessment Criteria**
High	Failure in the process can directly or indirectly lead to: - Severe adverse health effects Reversible or irreversible - Seizure of goods, recalls
Medium	Failure in the process can directly or indirectly lead to: - Minor patient adverse event (no harm to patient) - Regulatory Observation/Warning letter
Low	Failure in the process has insignificant impact on data integrity and/or product quality and/or patient safety.
Probability	**Probability of Occurrence Assessment Criteria**
High	Frequent e.g. multiple events per month
Medium	Occasional e.g. a yearly event
Low	Unlikely e.g. once in 2 years or less frequent
Detectability	**Probability of Detection Assessment Criteria**
High	Multiple downstream controls are in place and the objectives of the controls are focused on detecting this failure event before it occurs.
Medium	The failure maybe detected by downstream controls before the failure event occurs. But these controls are not focused on this event.
Low	The failure cannot be detected immediately before the event occurs and the failure event may not be detected during Quality Control tests.

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4.0 Detailed functional risk assessment

S.No.	Risk Parameter	Consequences of associated Failure	S	Evaluation / Cause	Current Controls (Controls by design)	P	Risk Class	D	Risk Priority	Risk Acceptable? Yes/No	Planned Mitigation
1.	Contamination or higher count observed in the Product/water analysis.	• Abnormal results / false positive observed in product/ water.	H	• Change in classification of LAF from Grade A to Unidirectional Air Flow (UDAF) (Grade A supply air) in microbiology laboratory.	• Transdermal product is manufactured at ZTL facility, which is non- sterile dosage form. • Product processing is done in the Grade D and the acceptance criteria for the product is 10^2 CFU/Patch for bacteria and 10^1 CFU/Patch for the fungi. • SOP is revised to incorporated the new frequency and limits of settle plate and active air sampling. • The purified water testing is carried out in the LAF and the specification criteria is 100 CFU/mL moreover purified water is not used in the manufacturing of the product. • There is no any failure has been identified in product and water testing w.r.t environment failure in last two years. • Negative control is tested in every product and water testing. • As per SOP, the temperature and	L	2	H	Low	Yes	Not Applicable

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S.No.	Risk Parameter	Consequences of associated Failure	S	Evaluation / Cause	Current Controls (Controls by design)	P	Risk Class	D	Risk Priority	Risk Acceptable? Yes/No	Planned Mitigation
					differential pressure in microbiology laboratory is maintained as per defined limit. • As per SOP, the temperature and differential pressure in Microbiology laboratory is monitored twice in day to ensure that the differential pressure is within the acceptance criteria. • As per SOP, microbiology laboratory is cleaned twice in a day to control the microbial contamination. • The cleaning of the microbiology laboratory is performed with validated disinfectant. • As per SOP, LAFs are cleaned before and after activity to control the microbial contamination. • The cleaning of the LAFs is performed with validated disinfectant (70 % IPA). • As per SOP, the monitoring of differential pressure of the both LAFs is performed once in a day. • The trend of environment monitoring of						

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S.No.	Risk Parameter	Consequences of associated Failure	S	Evaluation / Cause	Current Controls (Controls by design)	P	Risk Class	D	Risk Priority	Risk Acceptable? Yes/No	Planned Mitigation
					microbiology laboratory is prepared as per SOP on monthly basis to monitor the significant change in environment of microbiology laboratory. • If any results of EM shows out of limit (alert/action) then SOP is in place for the investigation. • Procedure for the Environment monitoring of the both the LAFs is incorporated in SOP.						
2.	Qualification of LAFs not meet the acceptance criteria.	• Abnormal results observed in Qualification tests	H	• Change in classification of LAF from Grade A to Unidirectional Air Flow (UDAF) (Grade A supply air) in microbiology laboratory.	• The LAF is qualified every six month as per requalification frequency. • There is no any physical modification shall be done in the LAFs due to change in classification hence there is no any risk identified w.r.t qualification of the LAFs. • Three days viable monitoring (By settle plate and air sampling) has been done for both LAFs after effective of SOP. All the results of both LAFs found within acceptance criteria.	L	2	H	Low	Yes	Not Applicable

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S.No.	Risk Parameter	Consequences of associated Failure	S	Evaluation / Cause	Current Controls (Controls by design)	P	Risk Class	D	Risk Priority	Risk Acceptable? Yes/No	Planned Mitigation
3.	Inappropriate limits of Environment Monitoring in SOP/Record	• Wrong limits shall be followed for Environment Monitoring	H	• As per change of classification recording formats not revised as per revised limit.	• SOP has been revised and new limits of settle plate and air sampling incorporated in the SOP. Limits incorporated are as follows: **Settle plate:** Alert limit: 3 cfu/plate action limit: 5 cfu/Plate **Air sampling :** Alert limit: 5 cfu/m3 of air Action limit: 10 cfu/m3 of air	L	2	H	Low	Yes	Not Applicable

Remarks: H= High, M= Medium, L=Low

5.0 Conclusion:

Based on the re-evaluation report of the risk associated with the change in classification of LAF from Grade A to Unidirectional Air Flow (UDAF) (Grade A supply air) in microbiology laboratory, there is no any further risk has been identified with associated changes.