Environmental Monitoring Performance Qualification (EMPQ) Readiness Checklist

Purpose of the EMPQ Readiness Checklist:

The EMPQ readiness checklist serves as a valuable tool for organizations aiming to streamline their project execution process and minimize errors in EMPQ implementation. By conducting this assessment, companies can proactively identify potential issues, address areas for improvement, and ensure compliance with regulatory standards and industry best practices in clean room manufacturing.

Objective of the EMPQ Readiness Assessment:

The primary objective of the EMPQ readiness assessment is to evaluate the preparedness of a clean room manufacturing facility in meeting the requirements for environmental monitoring. Through this assessment, organizations can gain insights into their current state of readiness, pinpoint areas that require attention or enhancement, and ultimately ensure the facility's ability to adhere to regulatory guidelines and industry standards.
By engaging in the EMPQ readiness assessment, organizations can avoid delays and the incurrence of additional costs, make informed decisions, and pave the way for successful EMPQ execution, all while maintaining a high level of quality and compliance.
It should be a team effort to execute the assessment, including representatives from the following departments: quality assurance (QA), quality control (QC), validation (Val), project management (PM), and regulatory affairs (RA).

Review the table below step by step and assess the readiness by determining if each step is completed or documents exist.

Table 1.: Assessment Table

#	Verification Steps or Document Name	Verification Step is Completed/Document exist (YES/NO/NA)
1	User Requirements Specifications document is written and approved by QA.	
2	Commissioning of the clean room is completed, and final report is approved by QA.	

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#	Verification Steps or Document Name		Verification Step is Completed/Document exist (YES/NO/NA)
3	Execution of clean room IOQ is completed, and final report approved by QA		
4	Quality Management System is established with the following SOPs		
5	Document Control SOPs	Generation of new SOPs	
		Numbering of SOPs	
		Revising of SOPs	
		Issuance of SOPs and controlled documents	
		Obsoleting of SOPs	
6	Quality Assurance SOPs	Change control	
		Deviations	
		Vendor approval	
		Equipment management	
		Material Management	
		GDP	
		GMP Training	
		CAPA	
		Internal Audits	
7	Quality Control SOPs	QC Sample submission	
		Non-Viable sample collection and results reporting	
		Viable Air sample collection and testing	
		Surface viable sample collection and testing	
		Growth promotion procedure	

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		Environmental Monitoring Investigation	
		Non-Viable sampler operation and maintenance SOP	
		Viable sampler operation and maintenance SOP	
		Gowning qualification SOP	
8	Regulatory Affairs SOPs	Risk Assessment	
9	If EM sampling and testing are outsourced, the lab needs to go through the vendor qualification process and be qualified before the EMPQ commences.		
10	Microbiological media is qualified by growth promotion testing to be used in EMPQ execution.		
11	EM sampling and testing equipment is within calibration due dates. (Non-Viable and Viable samples, incubators, and refrigerators)		
12	Environmental Monitoring System (EMS) for DP, temp, and relative humidity is validated and the sensors are within calibration due date.		
13	SOP is in place for operation and maintenance of EMS.		
14	HVAC is on backup generator and SOP for operation and maintenance is written.		
15	The risk assessment for EM sample locations within the clean rooms, the number of sampling locations per room, and the frequency of sampling is written and approved by the QA department.		
16	Have the regulations to be used for clean room compliance been identified? Such regulations may include ISO 14644, Annex 1, or FDA guidelines.		