The Gazette

n.2 February 2024

MICROBIAL ENVIRONMENTAL MONITORING FOR CLEANROOM AND ASSOCIATED CONTROLLED ENVIRONMENTS

POINT OF SAMPLING LOCATION FOR MICROBIAL ENVIRONMENTAL MONITORING

KEY WORDS
Aseptic processing, Cleanroom, critical areas, critical point, environmental monitoring, HACCP, isolator, RABS, regulatory inspectors, RA (Risk Assessment), sampling frequency, viable, no-viable.

INTRODUCTION
The location and sampling frequency of the points of monitoring in critical areas is determined by a formal risk assessment (RA) as indicated in the FMEA and FMECA documentation.
Several steps must to be followed to prepare a correct environmental monitoring plan.
A detailed procedure with related drawing will be useful during the visit of regulatory inspectors to justify the chosen actions.

PRELIMINARY ACTIVITY
It is necessary the study of the personnel and material flows for a clear understanding of all the production process. Historical data and a smoke test can give a substantial help to organize the necessary action.

SCHEME TO FOLLOW FOR FORMAL RISK ASSESMENT AND IDENTIFICATION OF SAMPLING LOCATION
The applications:
ACTION (What to do);
OK (the action was defined);
Preparation (action still in discussion);
COMMENT (More explanations to clarify the action)
are valid for air, surface and hands.

	Action	**O.K.**	**PREP**
1	Availability of a map of the room with indication of all possible equipment and material present.		
	Comment		

	Action	**O.K.**	**PREP**
2	Identifications of the areas that need a critical sampling location. The use of HACCP (Hazard Analysis Critical Control Points) is suggested.		
	Comment		

	ACTION	**O.K.**	**PREP**
3	Identification of number of operators and their specific activity.		
	Comment		

	Action	**O.K.**	**PREP**
4	Identification of material flow to be protected inside the room		
	Comment		

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5	Action	O.K.	PREP
	Identification of the product to be protected		
	Comment		

6	Action	O.K.	PREP
	Identification of the movement of personnel flow during operation		
	Comment		

7	Action	O.K.	PREP
	Identification of interaction between the operation personnel and material flows		
	Comment		

8	Action	O.K.	PREP
	Identification of maintenance accessibility		
	Comment		

9	Action	O.K.	PREP
	Calculation probability of potential contamination		
	Comment		

10	Action	O.K.	PREP
	Evaluation of sampling methods (active air sampling, passive air sampling, surface sampling by contact plate or swab)		
	Comment		

11	Action	O.K.	PREP
	Evaluation if the sampler should be portable, stationary, remote, continuous.		
	Comment		

12	Action	O.K.	PREP
	Evaluation on how the air samplers will be fixed		
	Comment		

13	Action	O.K.	PREP
	Evaluation if the best solution is an instrument with the aspirating chamber on the command unit or with separated aspirating chamber and connected with a tubing		
	Comment		

14	Action	O.K.	PREP
	Evaluation when to use contact plate or swab for surface sampling		
	Comment		

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TRIO.BAS RABS ISOLATOR CM + 3

SATELLITES CM

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