# Risk Based Environmental Monitoring

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# Agenda

Module 1 – What is Environmental Monitoring

Module 2 – Regulatory requirements

Module 3 – Risk-based environmental monitoring

# Guidelines

Please contribute


Please stop me to ask a question

Please relax and enjoy yourself

Please place your phone on silent mode

# What is Environmental Monitoring (EM)?

- Sampling of controlled environments for non-viable and viable air particulates as well as surface viables
- Allows for an assessment of the effectiveness of cleaning/disinfection programs
- Allows for the identification of trends
- Facilitates the early detection of potential problems

# PIC/S PE 009-13 Code of GMP Requirements

***Clause 3.3*** – Lighting, temperature, humidity and ventilation should be appropriate and such that they do not adversely affect, directly or indirectly, either the medicinal products during their manufacture or storage

***Clause 5.10*** – At every stage of processing, products and materials should be protected from microbial and other contamination.

***Annex 1 Clause 8*** – Clean rooms and clean air devices should be **routinely monitored in operation** and the **monitoring locations based on a formal risk analysis study** and the results obtained during the classification of rooms and/or clean air devices

# What is risk-based EM?

- The application of Quality Risk Management (QRM) tools and approaches into your EM program design
  - Understand your products and processes
  - Understand your microbial contamination risks
  - Ensure that proper risk mitigations are in place to help prevent contamination
  - Ensure that EM sample site selections and sampling frequencies reflect this understanding and are properly established to best detect potential contamination

# Step 1 - Risk Management Planning

- Determine team/members – cross-functional team (Micro, QA, Prod., Eng., Maint.)
- Determine the risk management tools to be used e.g. Failure Modes Effects and Analysis (FMEA)
- Define the scope of risk activities for the EM program assessment
- Determine the scoring to be used – leverage on existing company QRM procedure
- Communication of the resulting risk assessment / plan

# Step 2 - Assessment of activities affecting microbial state of control

- To determine the potential risk to the sterility of the product with respect to equipment and personnel movement from the beginning of the process (i.e. equipment preparation and sterilisation) to completion of filling (i.e. clean up and room sanitation)

- Methodology – e.g. brainstorm, Fishbone, cross-functional team (Micro, QA, Prod., Eng., Maint.)

**Identifying all areas of microbial risk**

**Current controls in place are not discussed at this point**

# Activity assessment

- The activity assessment should include the following for consideration:
  - Area / room classification
  - Activity within and adjoining each respective area
  - Room layout
  - Filling process (from start (post set up) to completion of fill)
  - Material and personnel flows
  - Frequency of room / area use

# Activity assessment (cont.)

- Equipment preparation and sterilization
- Criticality of activities – e.g. aseptic set up equipment
- Interventions – e.g. operational (routine) or random (breakdowns)
- Materials – e.g. raw materials, gowning materials, batch records, cleaning agents/supplies
- Operators – e.g. behaviour, movement, gowning, training, awareness
- Type of product being processed – e.g. freeze dried / solution

# Step 3 – Perform risk assessment

- Use the information obtained in the brainstorming activity to perform a risk assessment
  - Cross-functional team (Micro, QA, Prod., Eng., Maint.)
  - Risk management tool e.g. FMEA
  - Include known controls and risk mitigations

# FMEA process example

- **Identify hazards**
  - e.g. not meeting surface viable EM levels
- **Identify harms**
  - e.g. surface contamination in controlled environment
- **Identify hazardous honditions**
  - e.g. contamination of people, contamination of work surfaces, contamination of room equipment
- **Determine Severity, Occurrence and Detection Scores**
- **Determine Risk Priority Number (RPN)**

# FMEA process example (cont.)

- **Determine current control measures are in place**
  - e.g. cleaning and sanitation
- **Determine if additional controls are in place**
  - e.g. increase cleaning and sanitation frequency, introduce new cleaning agent

# Risk Priority Number (RPN)

The RPN is used to determine high, medium or low risk areas or the criticality of site locations

The RPN is used to determine the frequency of monitoring e.g. batch specific, daily, weekly, monthly

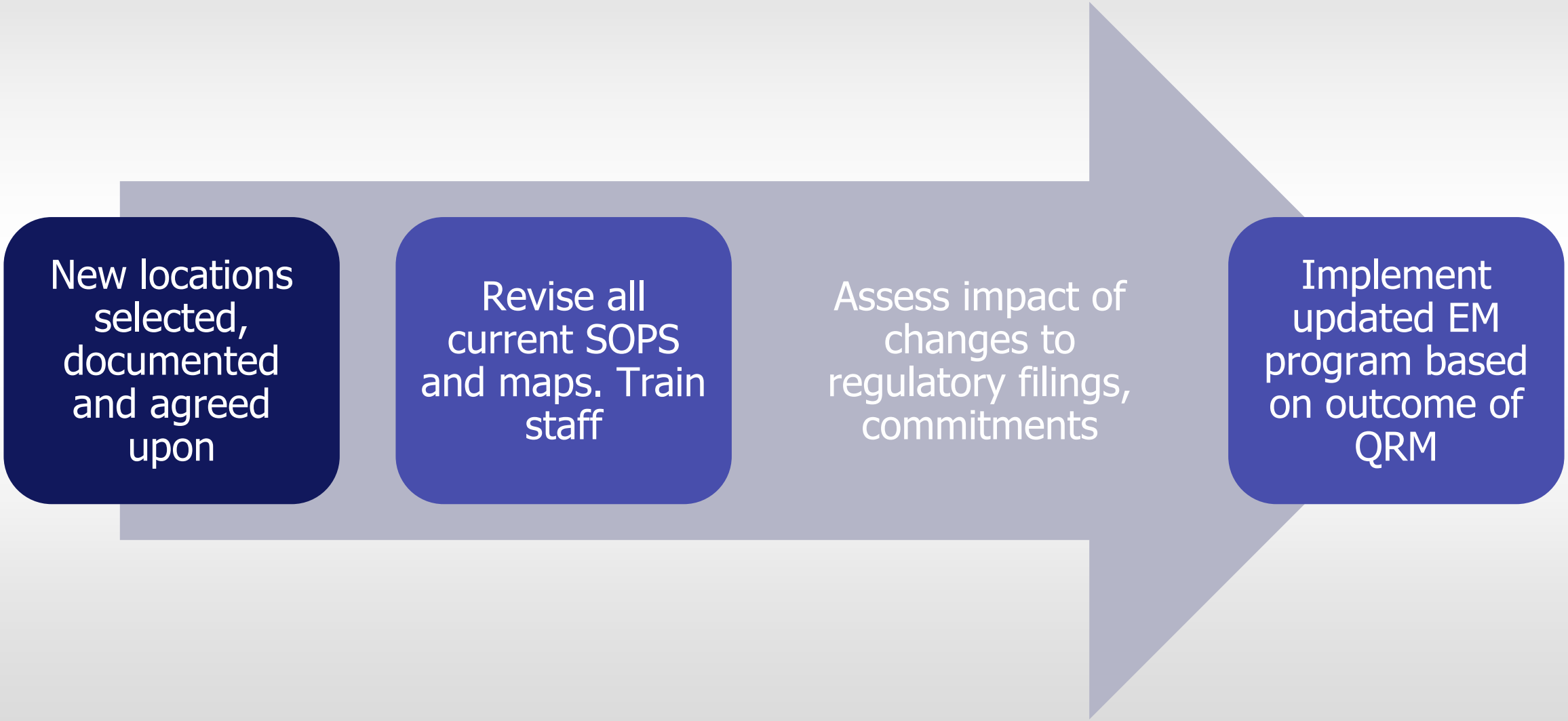
# Step 5 - Selection of Sample Locations and Sampling Frequencies

- Select sample sites and frequency of  monitoring based on the outcome of the risk assessment
- Document your rationale based on the risk of contamination
  - Sample size may vary in each room depending on the risk of contamination in each room even in room of the same size / class
  - Relate it to the activity and mater and personnel flows in the area
  - Depends on an understanding of the process in each room and microbial risk points

# Reassessment of current EM Program

- Use QRM principles to assess and make changes to your current EM program
- TGA expectation that QRM is used during investigations
- Annual review of EM program – e.g. identify trouble spots, recovery of objectional organisms, frequency of alert/actions
  - Sample site locations
  - Frequency of monitoring
  - Type of media
  - Incubation conditions

# Changes to current EM program



# Recap?

- How to use a risk based approach to develop an EM program or update your current EM program

# Questions ?

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