



# Environmental Monitoring Performance Qualification (EMPQ) Risk Assessment

*Lilly*

# Agenda

Risk Assessment

Environmental Monitoring Performance Qualification

Risk Identification

Risk Analysis

Risk Analysis Exercise

Summary

# RISK ASSESSMENT

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a systematic process of evaluating the potential risks that may be involved in an activity or undertaking.

The Lilly logo is written in a white, elegant, cursive script font, centered on the slide.

# Risk Assessment

Checklist

FEMA

Fishbone Diagram

Flow Chart

**HACCP** Hazard Analysis and Critical Control Points = Systematic preventative approach to microbiological hazard ingress

Process Mapping

Statistical Tools

# ENVIRONMENTAL MONITORING PERFORMANCE QUALIFICATION

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Documented evidence that an area is capable of meeting specified levels for the proposed classification and control measures

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# EMPQ

Microbial Control

Particulate Control

Routine Site Selection

Difficult Areas

Indirect Indicators

# RISK IDENTIFICATION

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Systematic use of information or data to identify hazards

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# Risk Identification

Proximity

Duration

Activity

Cleanability

Personnel

Sterile Components  
Sterile Equipment  
Sterile Product



# Risk Analysis

## Risk Criteria

High (3)

Medium (2)

Low (1)

Numerical Risk Factor Value	Qualitative Risk Factor Value	Description for Risk Factor Values
1	Low	Distant from exposed sterile product, sterile components, and/or sterile product-contact parts
2	Medium	Areas adjacent to exposed sterile product, sterile components, and/or sterile product-contact parts
3	High	Areas where sterile product/components/equipment are exposed; areas where aseptic connections are made.

# RISK ANALYSIS

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An estimation of the risk associated with the identified hazards



# Risk Analysis

Spatial Evaluation

Highest Potential

Enhanced Detectability

Routine Robustness / Reliability

Product Impact

# RISK ANALYSIS EXERCISE

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# Risk Analysis Exercise

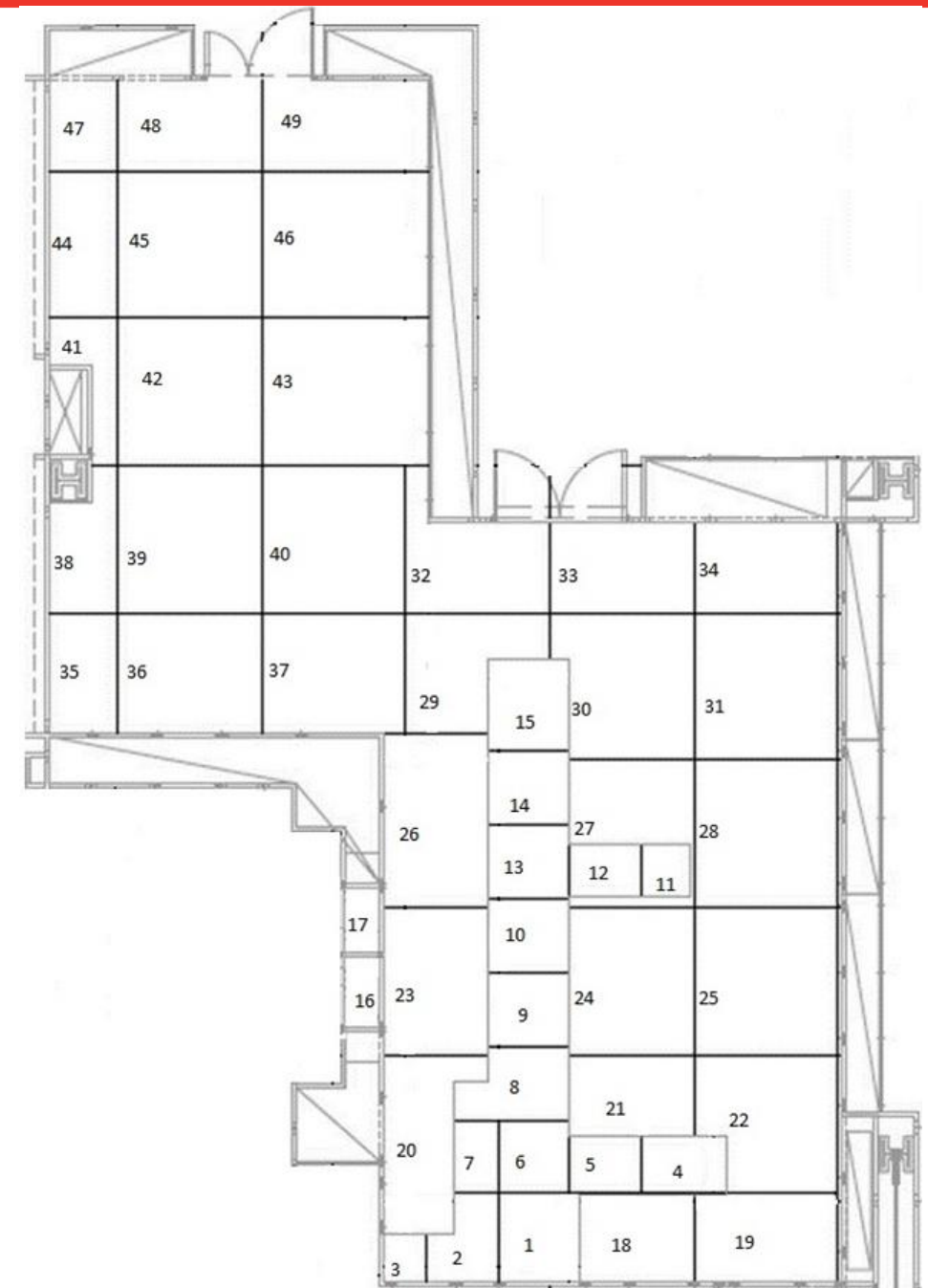
Up-to-date Drawings

Grid Facility

Higher to Lower

Multi-functional

Risk Rankings



# Risk Analysis Report

Grid No.	Area Classification	Room Number	Activity	Proximity to Product (A)	Duration of Exposure (B)	Frequency of Activity (C)	Duration of Activity (D)	Cleanability (E)	Risk Rankings (A x B x C x D x E)	Rationale for Risk Rankings
8	A	X123	RABS Filling	3	3	3	3	2	162	<ul style="list-style-type: none"> <li>Proximity is ranked 'high' (3) due to sterile filling equipment exposure within the grid.</li> <li>Duration is ranked 'high' (3) due to the sterile filling equipment being exposed throughout the entirety of the filling process.</li> <li>Frequency is ranked 'high' (3) due to aseptic personnel performing set-up activities within the area; additionally, 'high risk' interventions may be required due to operational difficulties within the grid.</li> <li>Duration is ranked 'high' (3) as set-up activities are executed prior to the batch and multiple interventions can be performed throughout the filling process.</li> <li>Cleanability is ranked 'medium' (2) as areas within the grid have smooth surfaces, but some areas not easily accessible for sanitization.</li> </ul>
45	B	X124	Sterile Equipment Cooling	2	1	3	2	3	36	<ul style="list-style-type: none"> <li>Proximity is ranked 'medium' (2) due to the grid being adjacent to RABS Filler and protected sterile equipment and components stored within the grid.</li> <li>Duration is ranked 'low' (1) due to no exposure of sterile components, equipment, or within the grid.</li> <li>Frequency is ranked 'high' (3) due to aseptic personnel moving and repositioning sterilized equipment / material racks throughout the grid.</li> <li>Duration is ranked 'medium' (2) due to aseptic personnel moving and repositioning sterilized equipment / material racks throughout the shift.</li> <li>Cleanability is ranked 'high' (3) as areas within the grid have some areas that are not easily sanitized, due to equipment / material racks in area.</li> </ul>

# SUMMARY

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# Summary

Risk Analysis

EMPQ Site Selection

EMPQ Execution

Routine Site Selection

Risk Based

Scientific Excellence





**KEEP  
CALM  
AND  
ASK  
QUESTIONS**