Using Quality Risk Management to Enable the Contamination Control Strategy

Developed by

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Topics

- QRM and the Pharmaceutical Quality System (Q10)
- The ICH Q9-R1 QRM model and contamination control strategy
- Risk management principles and options
- Beyond FMEA: Tools/methods that can be used
- Summary

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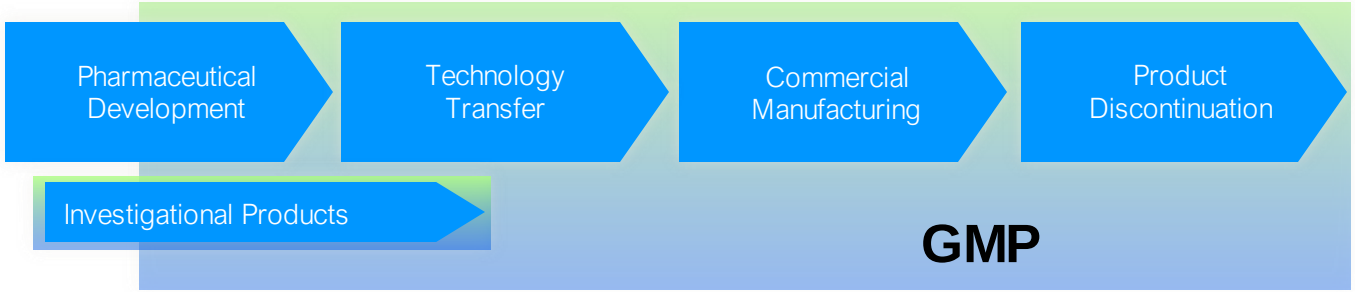
ICH Q10 Pharmaceutical Quality System



PQS elements

Management Responsibilities

Process Performance and Product Quality Monitoring System
Corrective Action / Preventive Action (CAPA) System
Change Management System
Management Review

Enablers

Knowledge Management

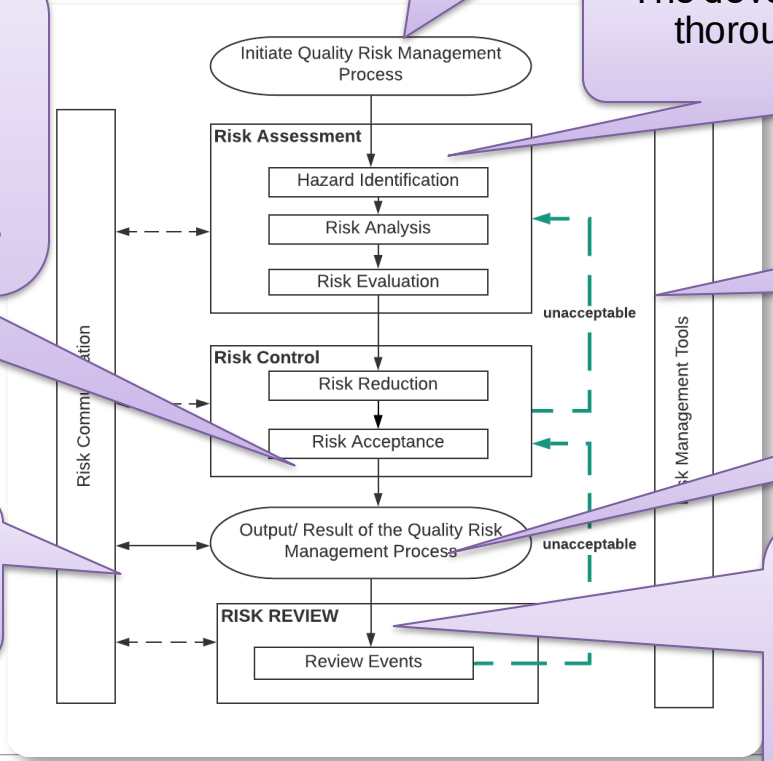
Quality Risk Management

Graphic recreated from ICH Q10 model

QRM Program

"Contamination control and steps taken to minimize the risk of contamination from microbial, endotoxin/pyrogen and particle sources includes a series of interrelated events and measures."

"The development of the CCS requires thorough technical and process knowledge."



The QRM Tool Kit

Contamination Control Strategy Inputs

"Its (CCS) effectiveness should form part of the periodic management review."

"Changes to the systems in place should be assessed for any impact on the CCS before and after implementation."

"The CCS should be actively updated and should drive continuous improvement of the manufacturing and control methods."

Contamination Control Strategy Goal

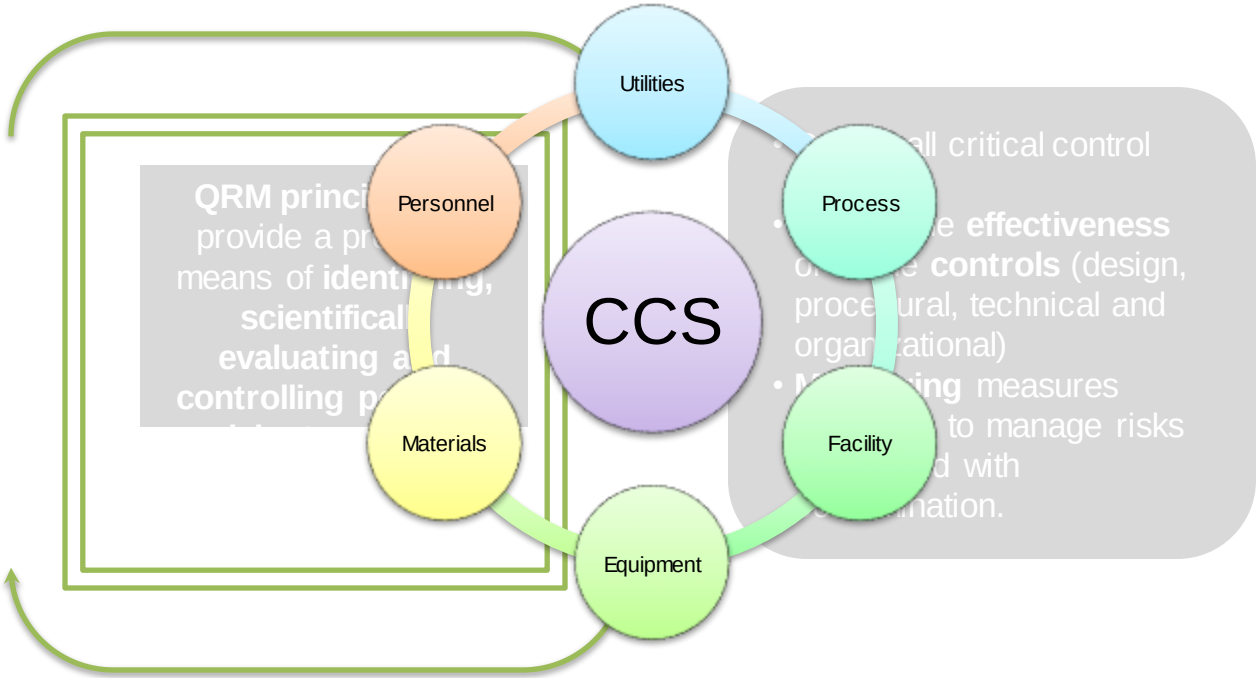
Processes, equipment, facilities, and manufacturing activities

QRM principles to provide a proactive means of **identifying, scientifically evaluating and controlling potential risks to quality**.

- **Define** all critical control points
- Assess the **effectiveness** of all the **controls** (design, procedural, technical and organizational)
- **Monitoring** measures employed to manage risks associated with contamination.

Contamination Control Strategy Goal

Processes, equipment, facilities and manufacturing activities



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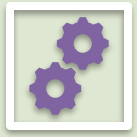
Quality Risk Management Principles

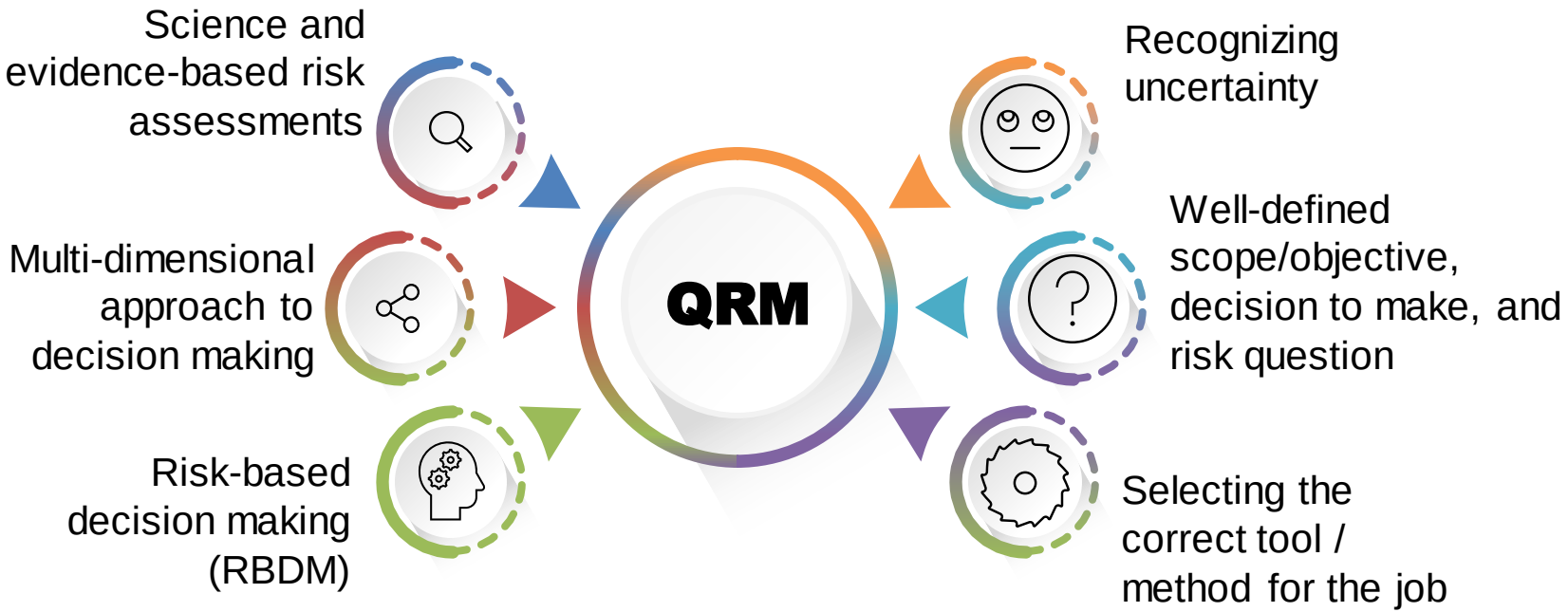
The evaluation of risk to quality should be based on scientific knowledge and ultimately link to the **protection of the patient**.
Note: Risk to quality includes situations where product availability may be impacted, leading to potential patient harm.

The level of effort, formality and documentation of the QRM process should be **commensurate with the level of risk**.



Use of knowledge management and quality risk management enable the PQS. These enablers provide the means for **science- and risk- based decisions related to product quality**.

Applying QRM Principles



Risk Management in Eight Questions

1. What can go wrong?
2. What is the likelihood that it could happen?
3. What are the consequences if it does happen?
4. What are the “priority risks” to address?
5. What can be done and what are the options available?
6. What can be done to communicate what has been done?
7. What can be done to document what has been done?
8. How will we know if any conditions or assumptions have changed?

What is Risk-based Decision Making (RBDM)?

Risk-based decision making: an approach to, or a process of, making decisions that considers knowledge about risks relevant to the decision and whether risks are at an acceptable level.

Risk-based decisions

Selecting the Best Risk Management Approach

Uncertainty

- How much do you **know** about the system you are assessing?

Complexity

- How complex is the system?

Importance

- What is the criticality of the system?

Risk Parameters

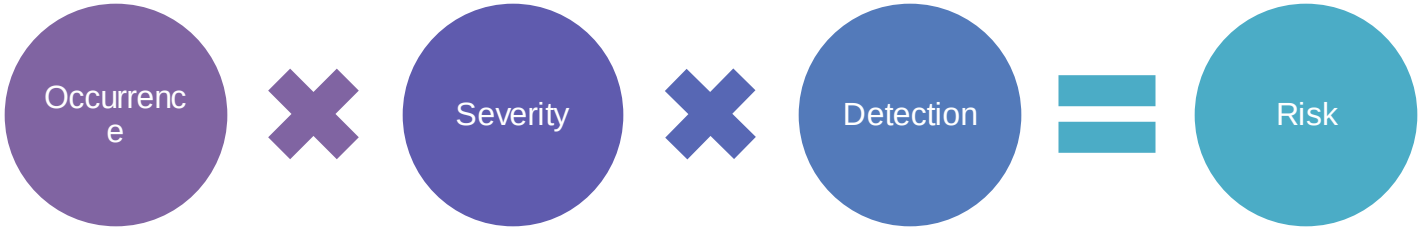
- How will risk be measured?

Measurement of Overall Risk

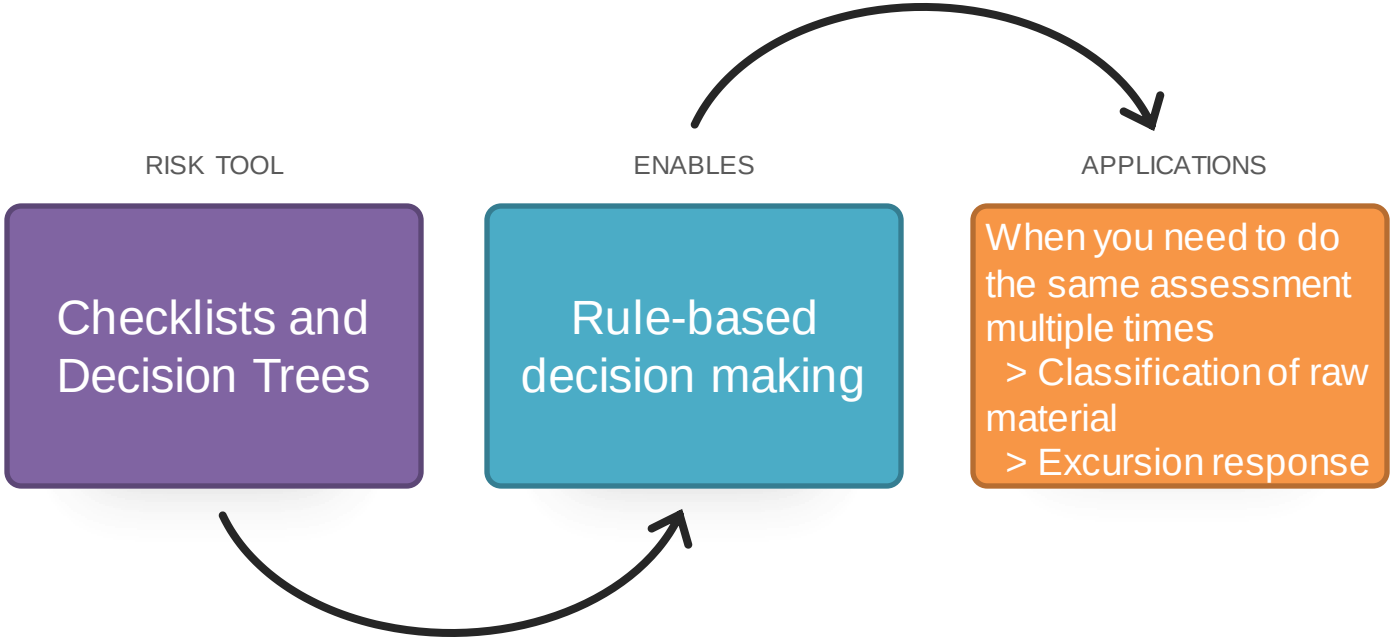
Severity: A measure of the possible consequences of a hazard.

Likelihood/Frequency of Occurrence: The condition of being likely or probable; probability.

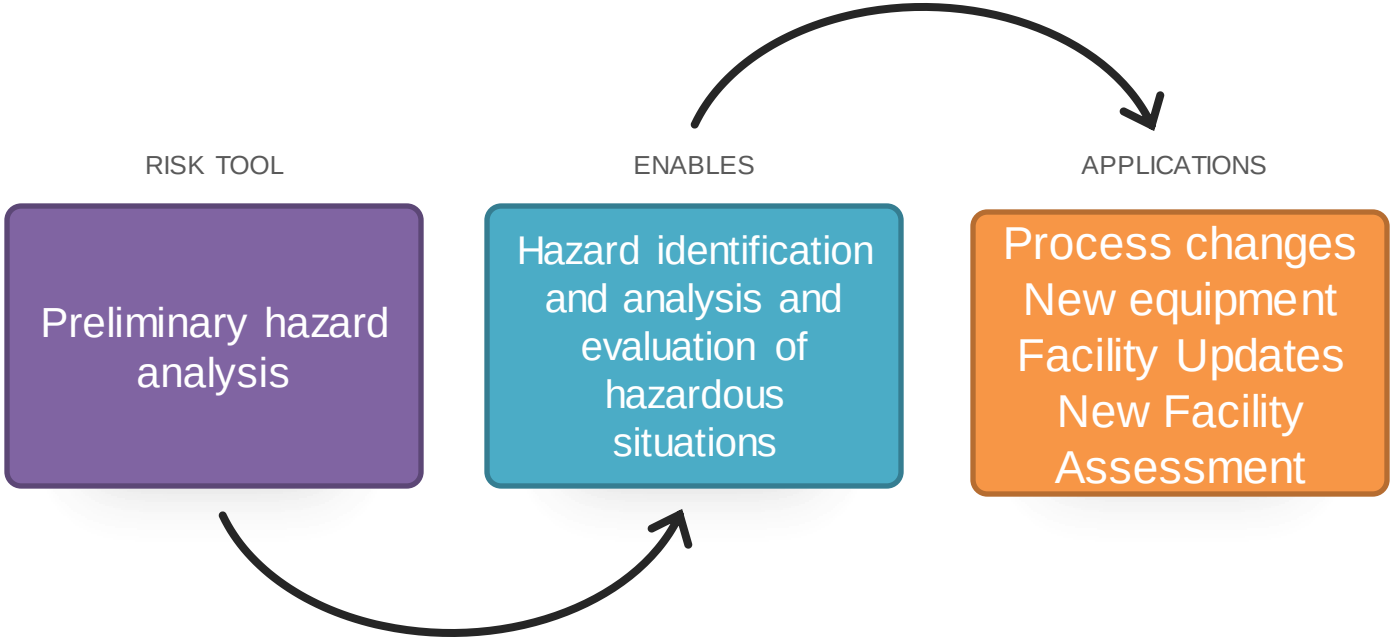
Detectability: The ability to discover or determine the existence, presence, or fact of a hazard.



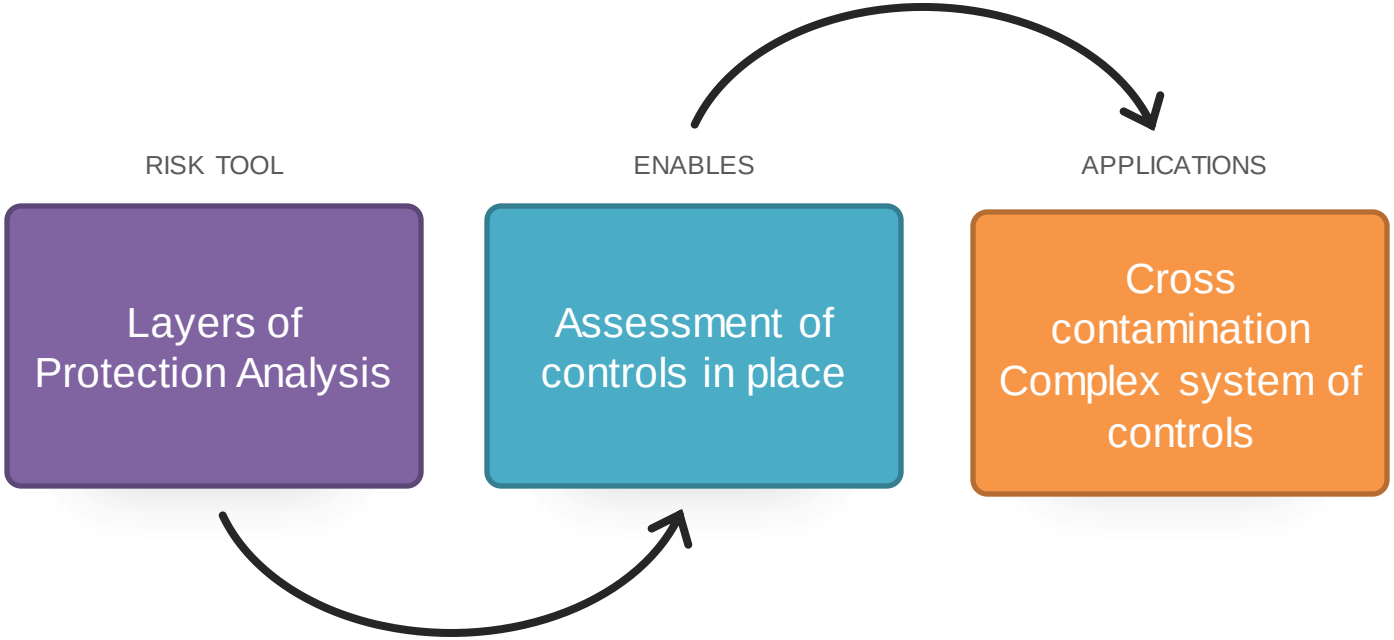
Checklists and Decision Trees



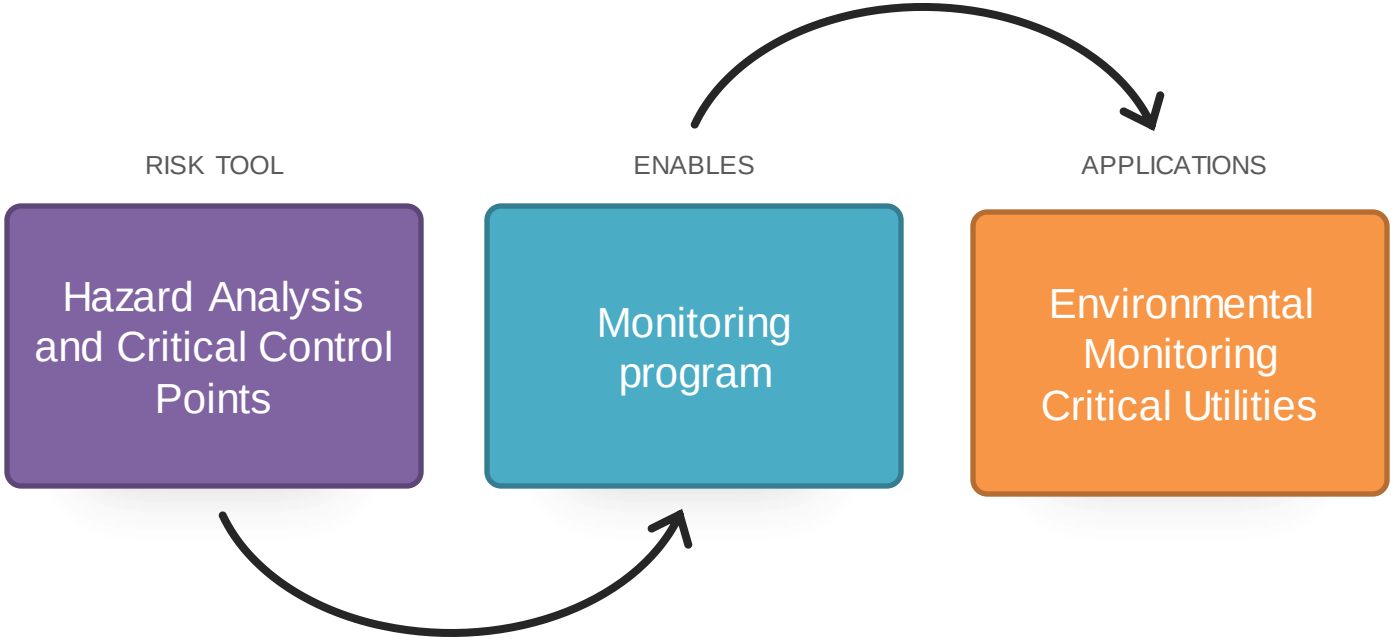
Preliminary Hazard Analysis (PHA)



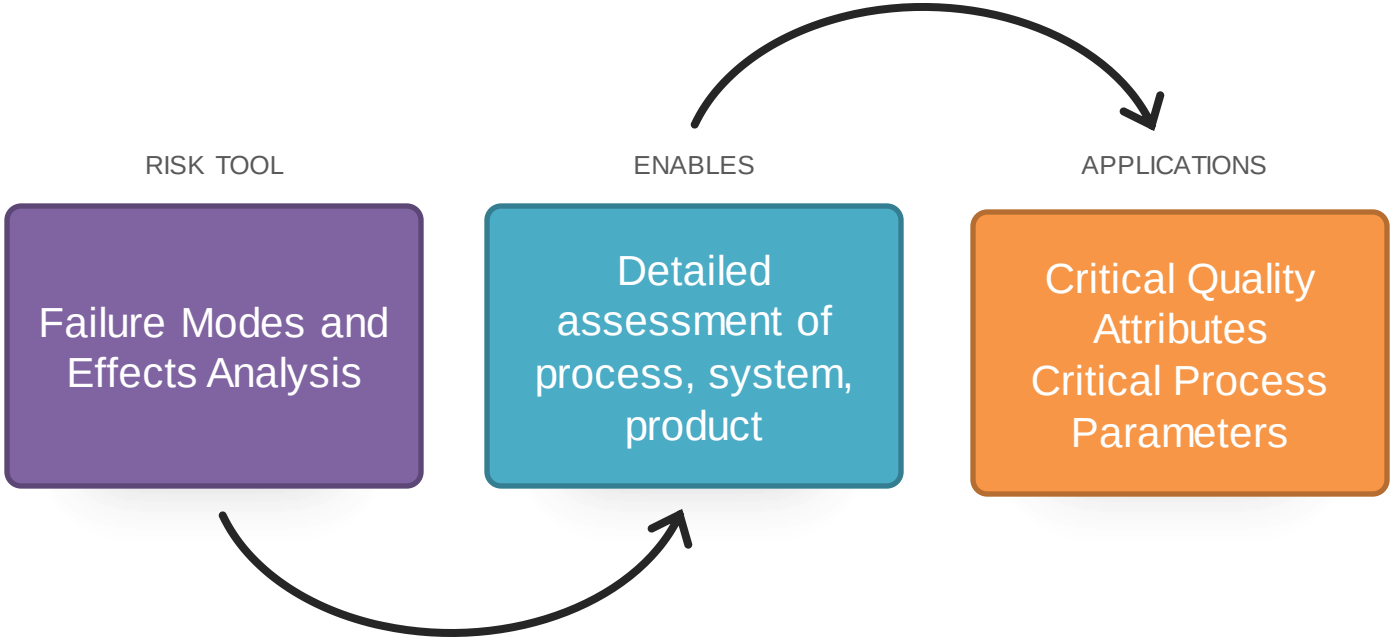
Layers of Protection Analysis (LOPA)



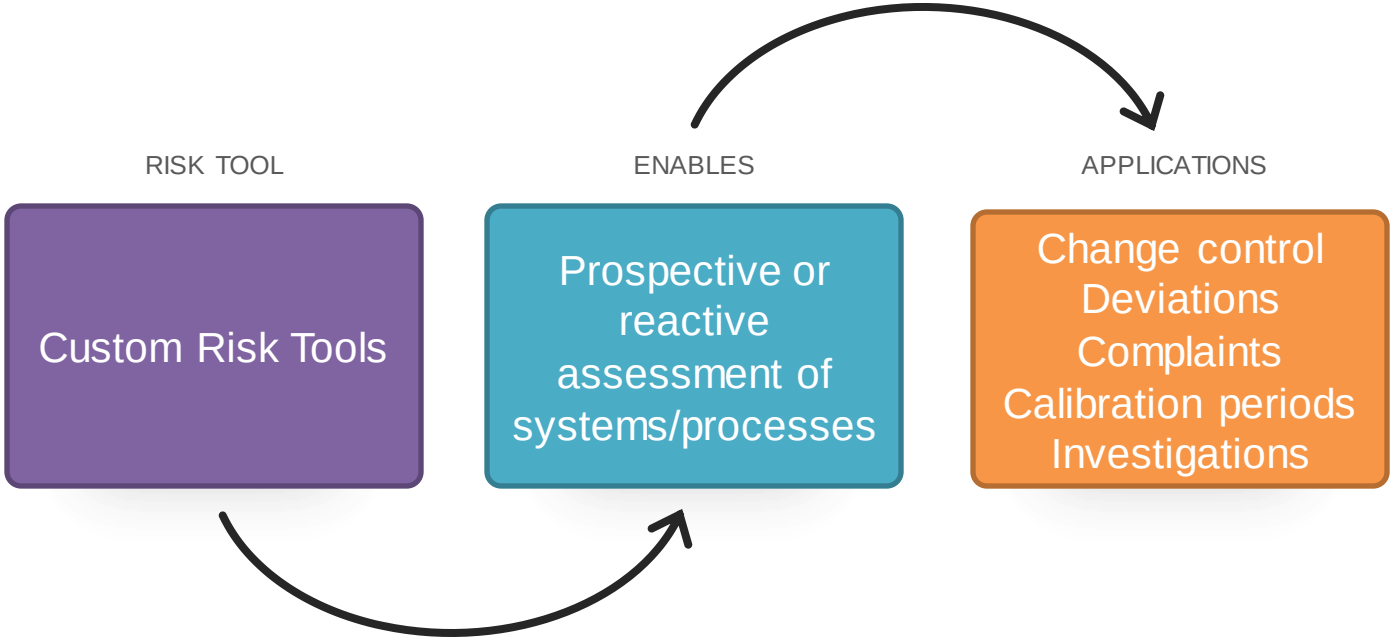
Hazard Analysis & Critical Control Points (HACCP)



Failure Modes and Effects Analysis (FMEA)

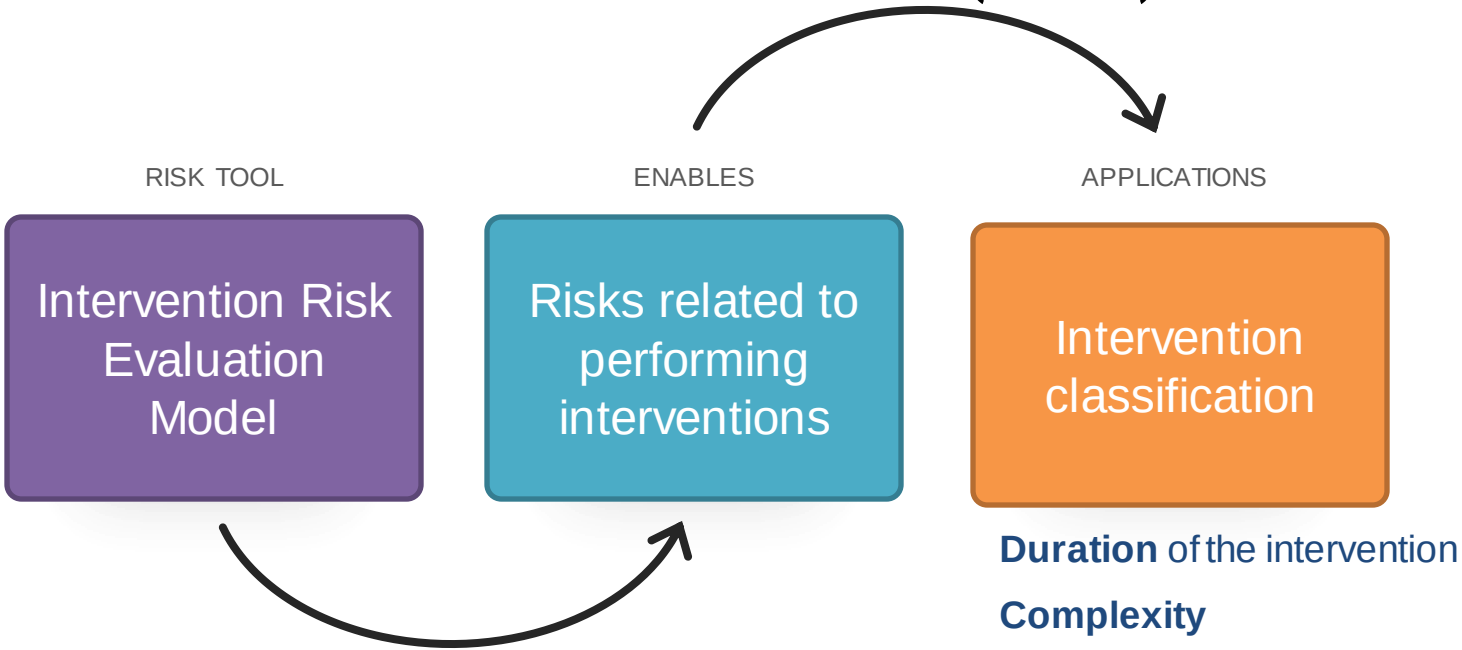


Custom Risk Tools



Customization of risk tool to meet a specific scope/objective

Example Custom Tool: Intervention Risk Evaluation Model (IREM)

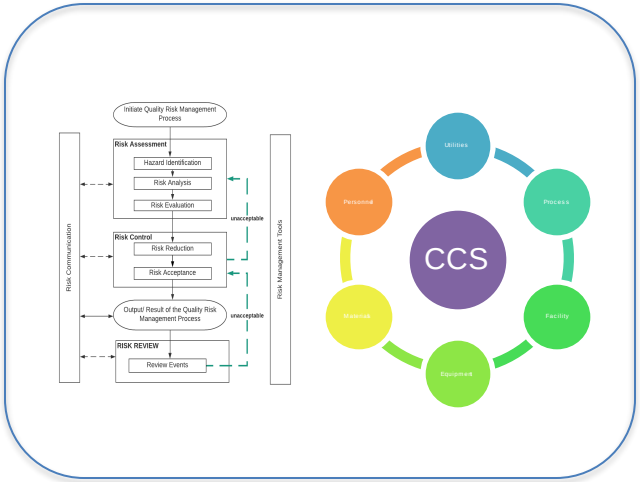


*Interventions Risk Evaluation and Management in Aseptic Manufacturing - A Case Study
Hal Baseman, Subrata Chakraborty and Michael K Long
PDA Journal of Pharmaceutical Science and Technology May 2022, pdajpst.2020.012245; DOI: https://doi.org/10.5731/pdajpst.2020.012245

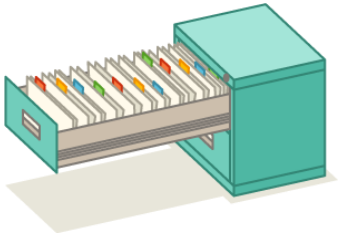
ANSI Standard: Aseptic Processing Risk Assessment Tool (being developed by PDA)

- Evaluate entire suite of Aseptic Processing Controls
- Criteria based on reliable evidence
- Detection linked to prediction
- Controls ranked according to ability to:

Developing the CCS



Portfolio of Risk Assessments



Contamination Control Strategy

The Big Picture

Risk Assessments are the foundation of your control strategy

The control strategy is the protective layer your organization builds to protect product quality and patient safety

The foundation of your strategy needs continuous care to ensure relevance

Questions for discussion

1. How will you / your firm identify and map out the risk assessments needed for the CCS?

2. What risk assessment tools/methods will be (or have been) used for this effort?

3. What do you see as the biggest challenge in pulling together the risk assessments for the CCS?

Thank You

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