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Quality Risk Management
Moderated Discussion

What is Quality Risk Management? (ICH Q9)

Risk is the combination of:

- The likelihood of occurrence of harm
- The severity of that harm

Appropriate use of quality risk management can facilitate, but does not obviate, industry's obligation to comply with regulatory requirements.

The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient

The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk

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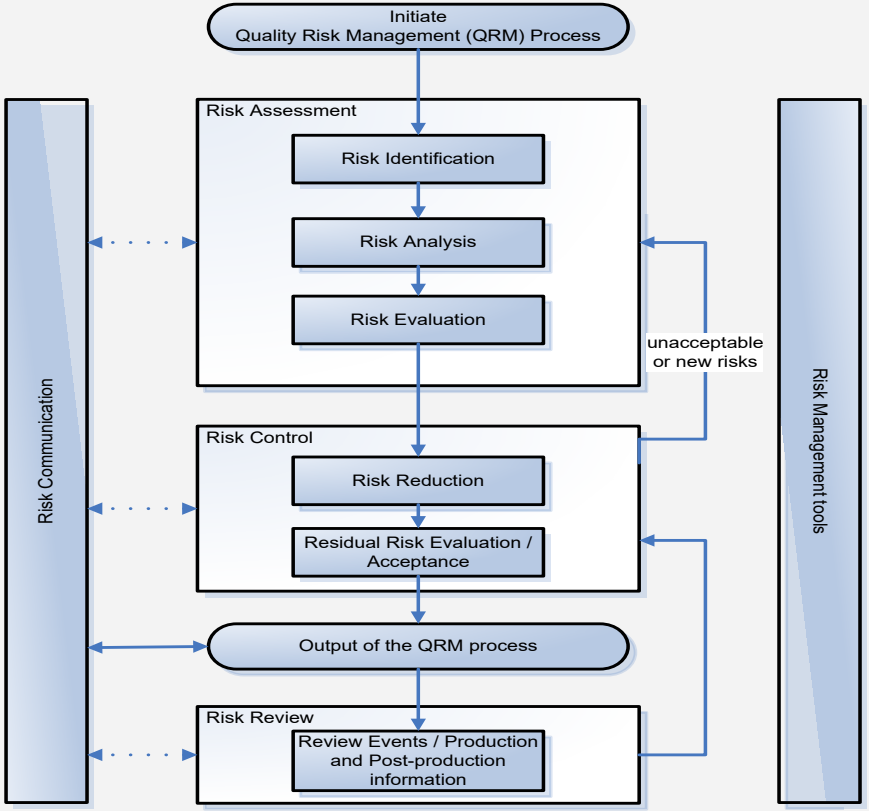
Quality Risk Management Lifecycle (ICH Q9)



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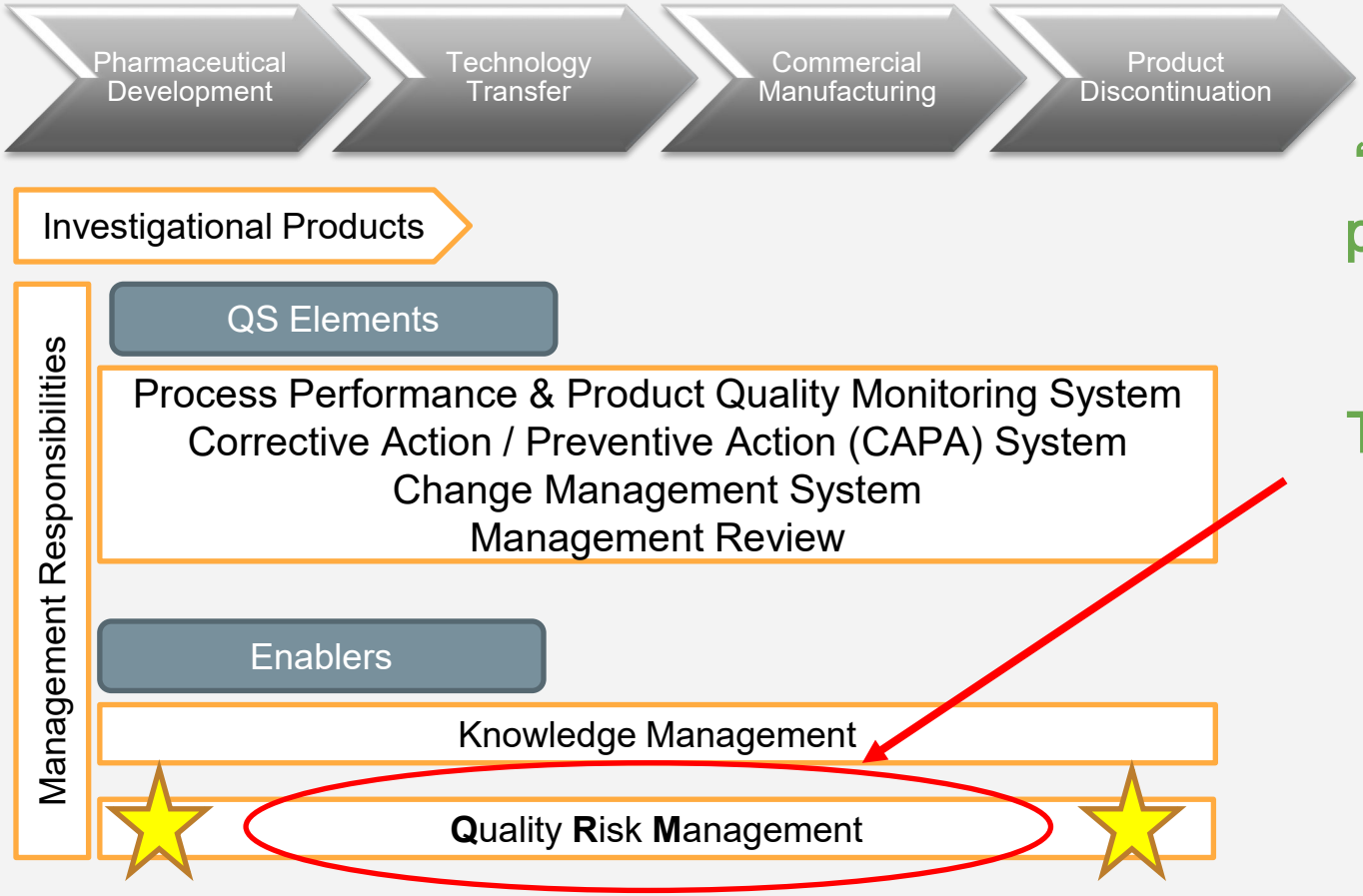
QRM as an enabler of the Pharmaceutical Quality System (ICH Q10)



QRM is as an "enabler" of the pharmaceutical quality system.

Therefore, QRM helps with everything we do.

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Risk Tools

- FMEA (Failure Modes and Effects Analysis)
  - Identify critical or significant design or process characteristics requiring controls to prevent or detect risks
- HACCP (Hazard Analysis and Critical Control Points)
  - Systematic, preventive approach to identify facility contamination related hazards in a process and/or system to produce a documented plan to control these scenarios
- LOPA (Layers of Protection Analysis)
  - Identifies risk associated with a particular cross contamination related hazard and evaluated the effectiveness of controls to prevent that hazard
- REM (Risk Estimation Matrix)
  - Focuses on the identification of risk scenario (s) and the overall risk associated with each
- RBIA (Risk Based Impact Assessment)
  - Focuses on assessing impacts of events that have already occurred to determine the risk of that individual impact.

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Where is QRM now incorporated?

EU GMPs – QRM required

CA GMPs – QRM required

Annex 1 – new draft incorporates over 50 QRM references

ISO 14644-1,2 Risk based EM

ICH Q13 – QRM in support of Continuous Manufacturing

US FDASIA– QRM required (supply chain emphasis)

21 CFR 820 – RA/RM required (medical devices)

ICH Q8 – QRM discussed as it applies to development of finished products

ICH Q9 – QRM guideline as it applies to the national authorities and industry

NOM059 – requirements connected with PIC/S Annex 20

ICH Q10 – QRM is an "enabler" of a PQS

ICH Q11 – QRM discussed as it applies to development of APIs and drug substances

FDA guidance on validation – QRM can be used to prioritize qualifications

FDA Warning Letters – rarely mentioned in the past, now much more frequent

More WHO support beyond drug HACCP

ICH Q12 – QRM in support of pharmaceutical lifecycle management

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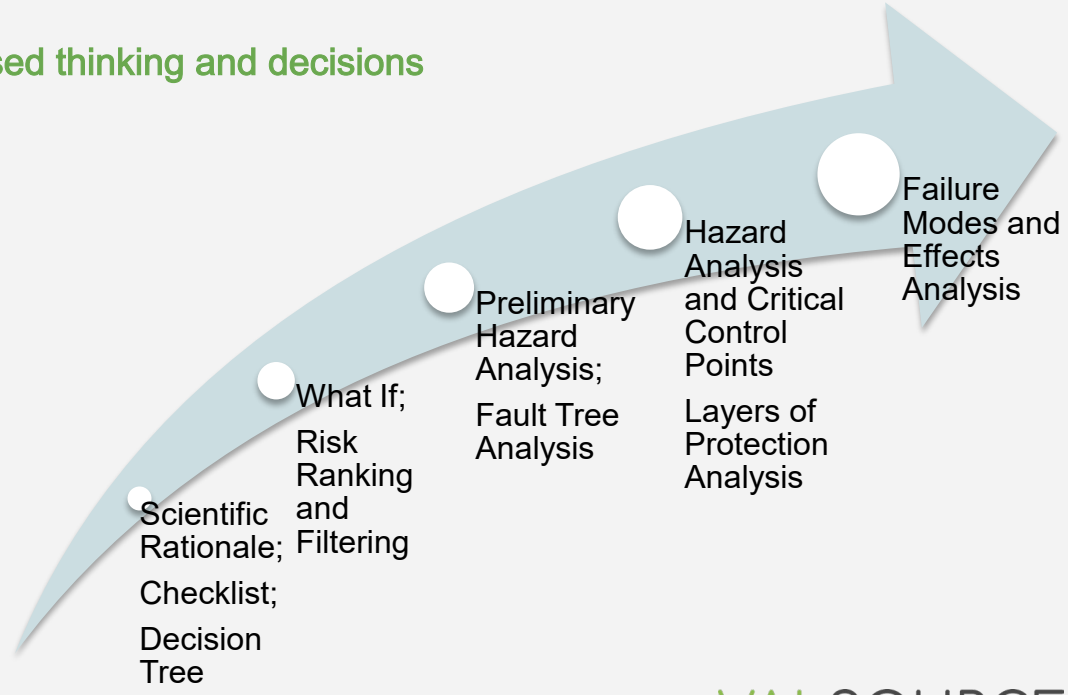
Hot Topics in QRM

- EU Annex 1 Revision
  - Increased use of risk -based thinking and decisions
  - 50 new QRM references
- ICH Q9 Revision
  - Formality spectrum
  - Risk-based thinking



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