



Quality Risk Management (QRM) in the Pharmaceutical Industry

• Based on PIC/S Guidelines



Overview

- **Objective**: Understand principles, implementation, and tools of QRM

- Agenda:

- 1. Definitions and Importance of QRM
- 2. Key Guidelines (PIC/S and ICH Q9)
- 3. Tools and Techniques
- 4. Implementation Steps
- 5. Case Study and Practical Application
- 6. Challenges and Best Practices



What is QRM?

- A systematic process to assess, control, monitor, and review risks
- Risk = Probability x Impact
- Core Principles:
 - Decisions based on scientific data and risk levels



Why is QRM Important?

- Ensures Patient Safety: Reduces quality-related risks
- Regulatory Compliance: Integral to GMP
- Operational Efficiency: Focus on high-risk areas
- Supports Decision-Making: Data-driven decisions



PIC/S and QRM

- PIC/S ensures international harmonization of GMP standards
- Role of QRM:
 - Enhances GMP compliance
 - Promotes flexibility in audits based on risk
 - Emphasizes a science-based approach.
- Alignment with ICH Q9: Uses the same framework



QRM Tools and Techniques

- Recommended by PIC/S:
 - FMEA (Failure Mode and Effects Analysis)
 - FTA (Fault Tree Analysis)
 - HACCP (Hazard Analysis and Critical Control Points)
 - Ishikawa Diagrams (Fishbone Analysis)
- Purpose: Identify, prioritize, and control risks effectively







QRM Implementation Steps (Part 1)

1. Planning and Organizing:

- Define scope, objectives, and team roles
- Train staff on QRM principles and tools

2. Risk Identification:

- Gather data and identify potential risks
- Example: Microbial contamination during production

3. Risk Analysis:

- Evaluate severity, probability, and detectability
- Use RPN (Risk Priority Number): <u>**RPN = S × P × D</u></u></u>**





QRM Implementation Steps (Part 2)

4. Risk Evaluation:

- Compare RPN to thresholds
- Determine actions for unacceptable risks

5. Risk Control:

- Design and implement mitigation strategies
- Example: Install HEPA filters to reduce contamination risks

6. Risk Review:

- Monitor effectiveness of controls
- Update risk assessments for process or regulation changes





Application Areas of QRM

1. Production:

- Control cross-contamination risks
- Ensure batch uniformity
- 2. Process Validation:
- Verify reproducibility of critical processes
- 3. Change Control:
 - Assess risks from supplier or equipment changes
- 4. Storage and Distribution:
 - Mitigate risks in transportation and storage



- Scenario: A supplement product contained less active ingredient than labeled

- Identified Risks:

- 1. Poor supplier quality control
- 2. Inaccurate weighing during mixing
- 3. Inadequate process monitoring

- Actions:

- Enhanced supplier audits
- Installed automated weighing systems
- Increased IPC sampling frequency

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Challenges in Implementing QRM

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- Complexity of tools (e.g., FMEA can be resource-intensive)
- Resistance to change in organizations
- Documentation burden for compliance
- Need for extensive staff training

Best Practices for Effective QRM

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- Start simple: Use basic tools initially
- Invest in training: Build competency in QRM methodologies
- Leverage technology: Use software for analysis and documentation
- Foster a quality culture: Promote proactive risk management



Summary

- QRM ensures product quality and patient safety
- Core steps: Plan, identify, analyze, evaluate, control, and review risks
- Practical Impact: Enhances compliance and operational efficiency
- Final Thought: Effective QRM is essential for pharmaceutical excellence



