Manufacturing Resilience for Generic Drugs and Biosimilars: A QMM Perspective

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Barriers to Manufacturing Resilience



The Quality Management Maturity (QMM) Framework

Evaluates behaviors and practices that sustain an establishment's quality culture, promote supply chain reliability, and enhance operation of the quality system.

Does not evaluate compliance with CGMPs and consequently cannot be used in lieu of, or as a surrogate for, establishment inspections or drug quality sampling and testing.

Reflects the maturity of an establishment's quality behaviors and practices around five practice areas.

Five QMM Practice Areas



Why Would Manufacturers of Generic Drugs or Biosimilars Benefit from QMM?

Drug manufacturing establishments achieve higher levels of **quality management maturity** when they successfully integrate business and manufacturing operations with quality management practices and technological advancements to optimize product quality, enhance supply chain reliability, and drive continual improvement.

QMM in Practice



XYZ Pharma's QMM Journey: From Assessment Gap to Improvement in Business Continuity

What the QMM assessment team identified at XYZ Pharma

Opportunity for Improvement –

XYZ Pharma did not have a Business Continuity Plan (BCP) and had not assessed potential risks to their continuity of operations. The establishment had not developed contingency plans to mitigate risks to the continuity of operations. XYZ Pharma did not understand potential risks of supply disruptions due to hazards such as unforeseen changes in demand, unplanned maintenance, loss of utilities, equipment, personnel, or supply of raw materials. Supply chain interruptions could lead to patient harm, reputational harm, and financial harm (e.g., failure-to-deliver penalties).

Risk Management

Did not identify hazards or evaluate risks to continuity of operations

Business Continuity Plan

Did not have a BCP to minimize impact of unexpected disruption and restore operations

Customer & Patient Supply

Did not have the mechanisms to protect supply reliability to safeguard patients, customers, and their reputation

The Improvement Plan: Rationale and Goals

XYZ Pharma's Improvement Plan – Develop a BCP to improve risk management, minimize unplanned downtime, prevent supply interruptions or minimize their impact, maintaining trust, improve employee safety, and safeguard the establishment's reputation.

Goal 1 | Perform Business Continuity Risk Assessment

Perform a Risk Assessment with clearly defined criteria to identify hazards and evaluate and prioritize continuity risks.

Goal 2 | Create a Business Continuity Procedure

Establish a BCP and procedure covering the full scope of the establishment's operations, risks, and response protocols.

XYZ's QMM Improvement Plan

Target Timeline

End of Q2 2025
(both risk assessment and procedure)

Progress Monitoring

Regular meetings to assess progress by evaluating milestones and goals.

Measure of Success

Annual BCP testing, annual review of risk assessment to re-evaluate risk levels and risk controls.

Sustained Governance

- Creating a governance structure
- Ensuring the BCP does not become a static document or paper-exercise
- Testing, reviewing, and continually improving BCP for continuity of operations

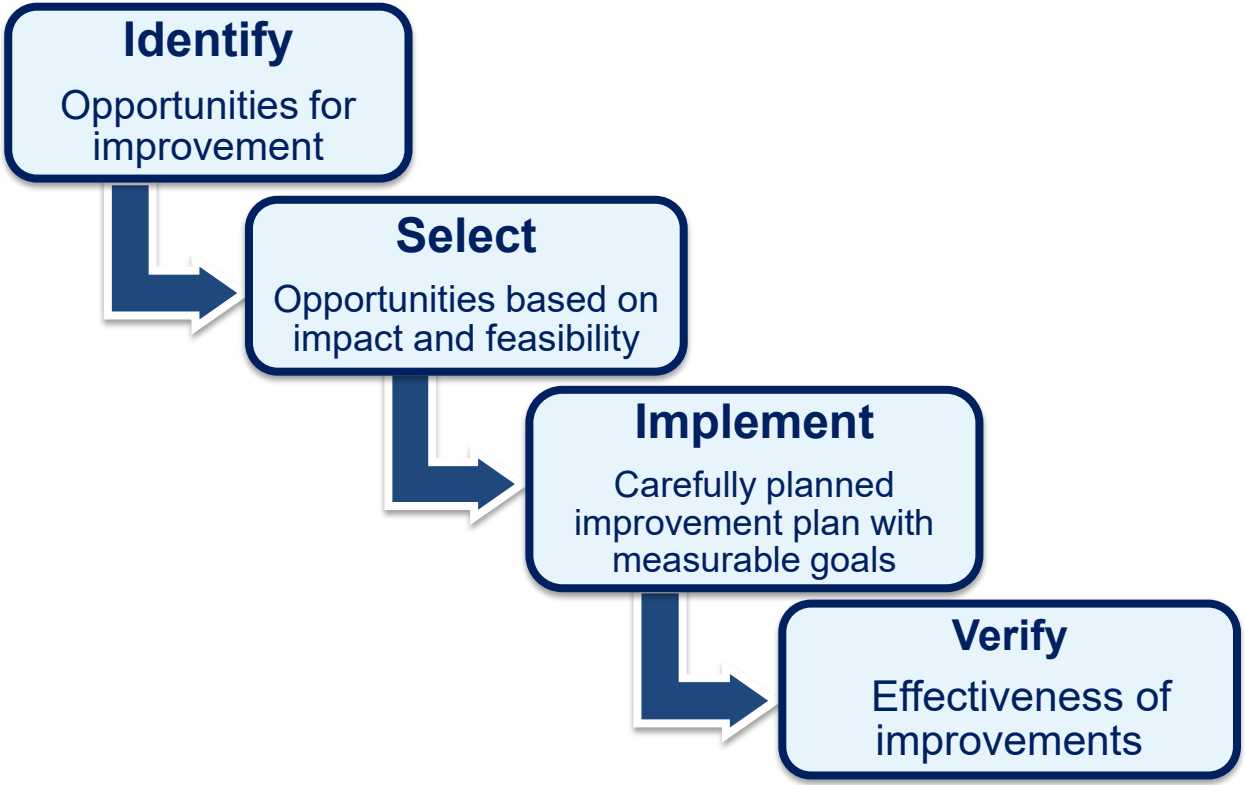
🗓 Annual BCP Testing

- Test BCP annually
- Validate that the plan remains effective as circumstances or risks evolve
- Review lessons learned to drive improvements
- Verify CAPAs from prior tests for effectiveness before the next cycle
- Maintain BCP readiness through annual review

📋 Annual Risk Assessment Review

- Review Risk Assessment annually
- Re-evaluate risk levels to reflect updates to risk controls in response to changes within or outside the establishment's control
- Adjust criteria when necessary to remain current and fit-for-purpose
- Review (annual or event-driven) provides a checkpoint to identify emerging continuity hazards and evaluate the risks
- Ensure risk decisions are data-driven

QMM Journey for XYZ Pharma
Assessment → Action → Continual Improvement



The QMM assessment evaluates a drug manufacturing establishment's quality practices and behaviors.

The post-assessment engagements create a pathway for actionable improvement.

TAKEAWAYS

- QMM enables manufacturing resilience by:
  - identifying gaps in quality practices
  - driving targeted improvements
  - building the systems needed to prevent supply disruptions before they reach patients

- Manufacturing resilience is based on organizational commitment to the idea that somewhere, a patient is counting on you to get it right.

Questions?



Contact us at: CDER-QMM@fda.hhs.gov