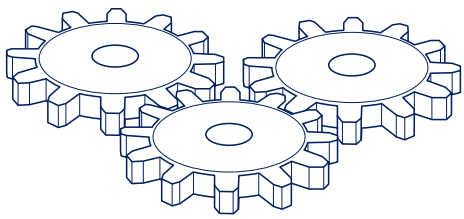
Technical Report No. 54-2

Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations

Annex 1: Case Study Examples for Quality Risk Management in Packaging and Labeling

PCMO℠
Paradigm Change in Manufacturing Operations℠

2013



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PDA Task Force on Technical Report No. 54-2: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations

Annex 1: Case Study Examples for Quality Risk Management in Packaging and Labeling

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Paradigm Change in Manufacturing Operations (PCMO[SM])

PDA launched the project activities related to the PCMO program in December 2008 to help implement the scientific application of the ICH Q8, Q9 and Q10 series. The PDA Board of Directors approved this program in cooperation with the Regulatory Affairs and Quality Advisory Board, and the Biotechnology Advisory Board and Science Advisory Board of PDA.

Although there are a number of acceptable pathways to address this concept, the PCMO program follows and covers the drug product lifecycle, employing the strategic theme of process robustness within the framework of the manufacturing operations. This project focuses on Pharmaceutical Quality Systems as an enabler of Quality Risk Management and Knowledge Management.

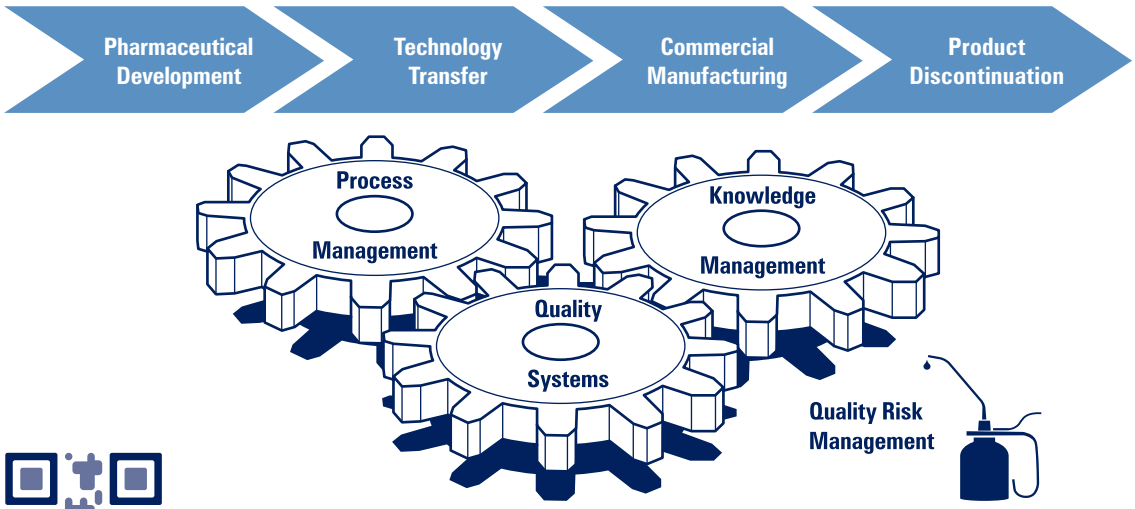
Using the Parenteral Drug Association's (PDA) membership expertise, the goal of the Paradigm Change in Manufacturing Operations Project is to drive the establishment of 'best practice' documents and /or training events in order to assist pharmaceutical manufacturers of Investigational Medicinal Products (IMPs) and commercial products in implementing the ICH guidelines on Pharmaceutical Development (ICH Q8, Q11), Quality Risk Management (ICH Q9) and Pharmaceutical Quality Systems (ICH Q10).

The PCMO program facilitates communication among the experts from industry, university and regulators as well as experts from the respective ICH Expert Working Groups and Implementation Working Group. PCMO task force members also contribute to PDA conferences and workshops on the subject.

PCMO follows the product lifecycle concept and has the following strategic intent:

- Enable an innovative environment for continual improvement of products and systems
- Integrate science and technology into manufacturing practice
- Enhance manufacturing process robustness, risk based decision making and knowledge management
- Foster communication among industry and regulatory authorities

The Product Life Cycle



For more information, including the PCMO Dossier, and to get involved, go to www.pda.org/pcmo

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1.0 Introduction

Quality Risk Management (QRM) is a systematic process for the assessment, control, communication, and review of risks. It is a mechanism of ensuring product quality is maintained throughout the product lifecycle.

An effective QRM program ensures high quality of drug product to the patient. QRM can be applied both proactively and retrospectively and should ensure that:

- the evaluation of the risk to quality is based on scientific knowledge, experience with the process, and ultimately links to the protection of the patient;
- the level of effort, formality and documentation of the quality risk management process is commensurate with the level of risk.

QRM should include systemic processes designed to coordinate, facilitate, and improve science-based decision making with respect to risk. Since the basis of any usable risk assessment is scientific knowledge and experience with the process being assessed, the evaluation of identified and analyzed risks should be defined by the risk to product quality and patient safety. Furthermore, there should be evidence for effectiveness of risk control, appropriate rationale where residual risk elements are accepted, and clear evidence that supports the decisions made.

To apply the principles of QRM, it is not always necessary or appropriate to use a formal risk assessment tool (e.g., PHA, FMEA, FTA): the use of informal risk management tools is acceptable for areas of less complexity and lower potential risk. The decision of formality in documentation should be based on each company's risk management program. The complexity of the events surrounding each decision and the potential risk involved are important inputs in determining the appropriate risk assessment methodology and corresponding level of analysis required to ensure the appropriate risk decision is made.

For the less complex and/or those decisions involving little risk, a qualitative analysis (e.g., decision tree) of the options may be all that is required. Generally, as the complexity and/or risk increases, so should the sophistication of the risk assessment tool used to facilitate the corresponding analysis.

When performing risk assessments, it is vital to use a cross-functional team so that all aspects of the process are adequately evaluated. Another critical component of this effort is to identify the key experts in the team, those who are knowledgeable in risk management principles and possess a specific set of skills in order to facilitate and lead the risk assessment sessions.

1.1 Purpose and Scope

PDA *Technical Report No. 54-2* is a supplemental annex to PDA *Technical Report No. 54: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations* ***(1)***. The technical report was distributed for peer review for comment prior to publication to ensure its suitability as a valuable guide for QRM implementation in packaging and labeling operations.

In this document, specific case studies on how to apply quality risk management (QRM) to pharmaceutical manufacturing, specifically packaging and labeling operations, are presented. Each case study highlights the different applications of QRM throughout the pharmaceutical and biotechnology manufacturing operations in packaging and labeling.

The various risk-scoring criteria in this document serve to emphasize the many uses of QRM across the industry when implementing the ICH Q9 guideline ***(2)***. They also are a reminder that there is no "one way" of using QRM.

The illustrated examples highlighted in this document of how to apply QRM tools to the packaging and labeling of products are solely based on the opinion and experience of subject-matter experts

(SMEs) who served on the authoring Task Force. Therefore, the content in this report does not represent the QRM practices of any one particular organization, because every organization may have unique elements to its QRM program.

NOTE: To further demonstrate the different approaches companies may employ, each case study is organized differently, though they share similar elements.

This report is intended to align with ICH Q9 and is one in a series of similar documents that provide additional examples of how to apply risk management tools across the product supply chain, from the starting materials (APIs and excipients) through manufacturing, labeling, packaging, and shipping.