IX PAN-RUSSIAN GMP CONFERENCE

MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

Approaches to the Development of a Pharmaceutical Quality System

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Introduction to Quality System Models and Different Approaches to PQS Development

A pharmaceutical quality system (PQS) ensures that pharmaceutical products meet required quality standards and regulatory requirements.

The PQS is based on quality management principles outlined in various models such as ISO 9001 and ICH Q10.

These models provide frameworks for organizations to develop robust quality systems that emphasize continuous improvement, risk management, and regulatory compliance.

ICH Q10 Key Messages

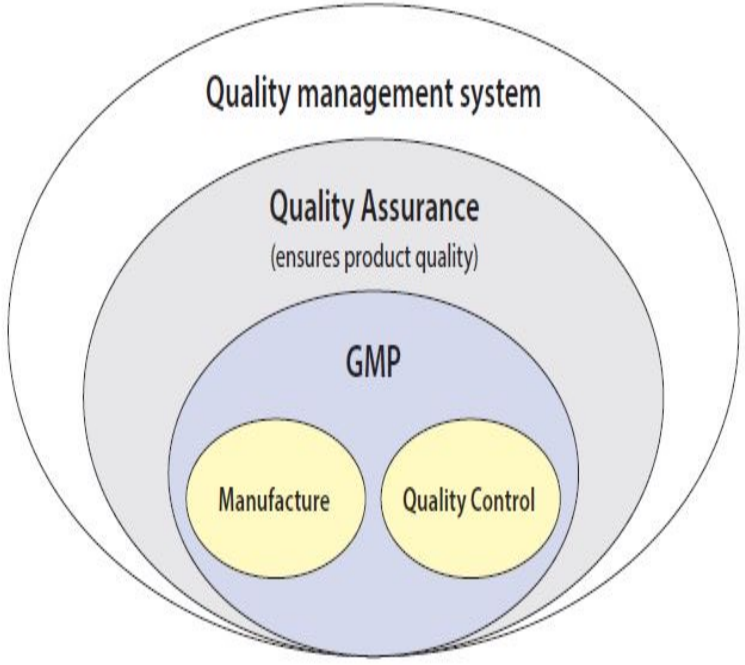
ICH Q10 is a guideline on the essential elements of a PQS throughout the product life cycle

Implementation of PQS should provide enhanced assurance of product quality

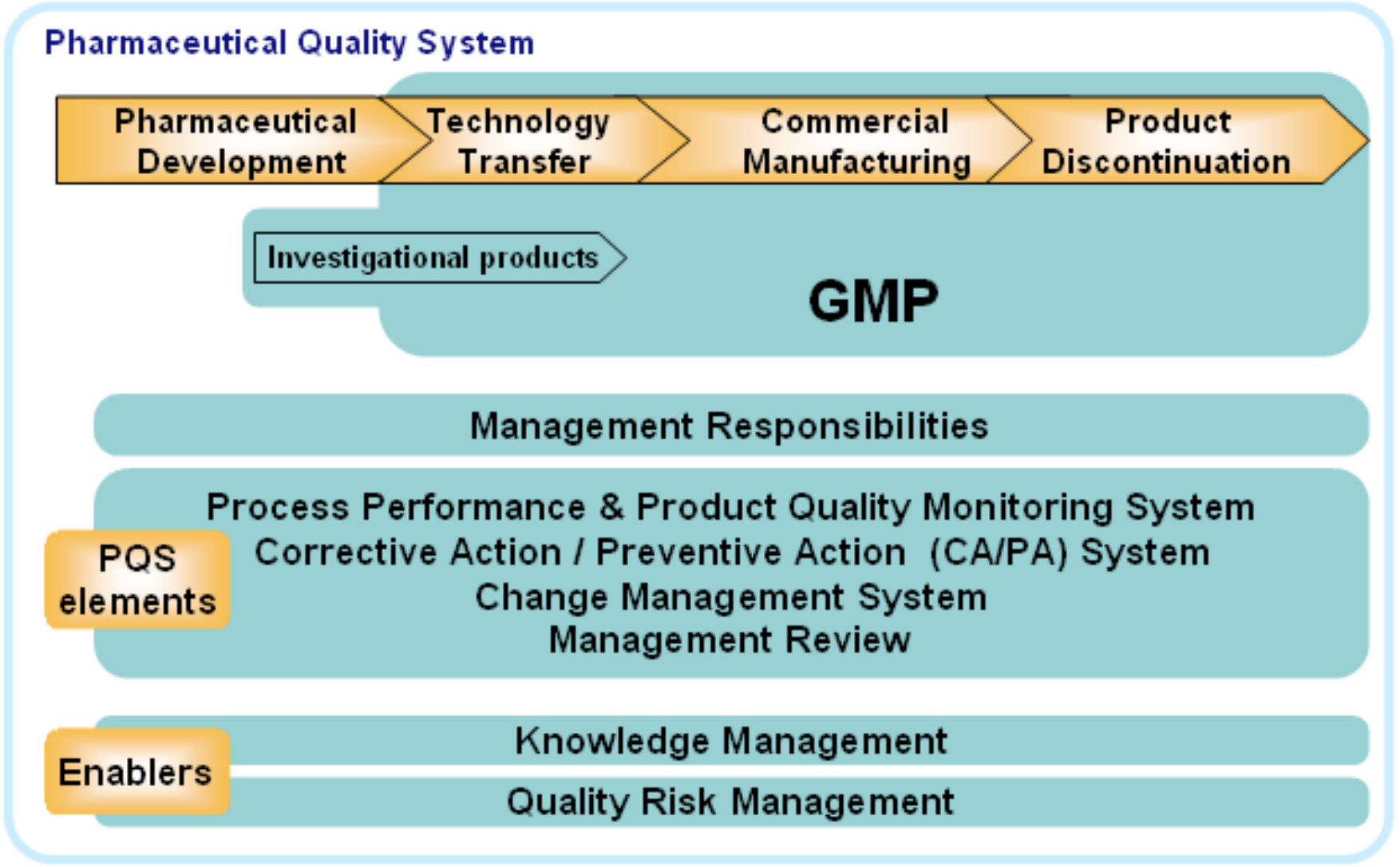
GMP is applicable to the Manufacturing part of the life cycle

Manufacturing of Investigational (medicinal) Product

Manufacturing of commercial products



Pharmaceutical Quality System - Q10



Quality Management Maturity

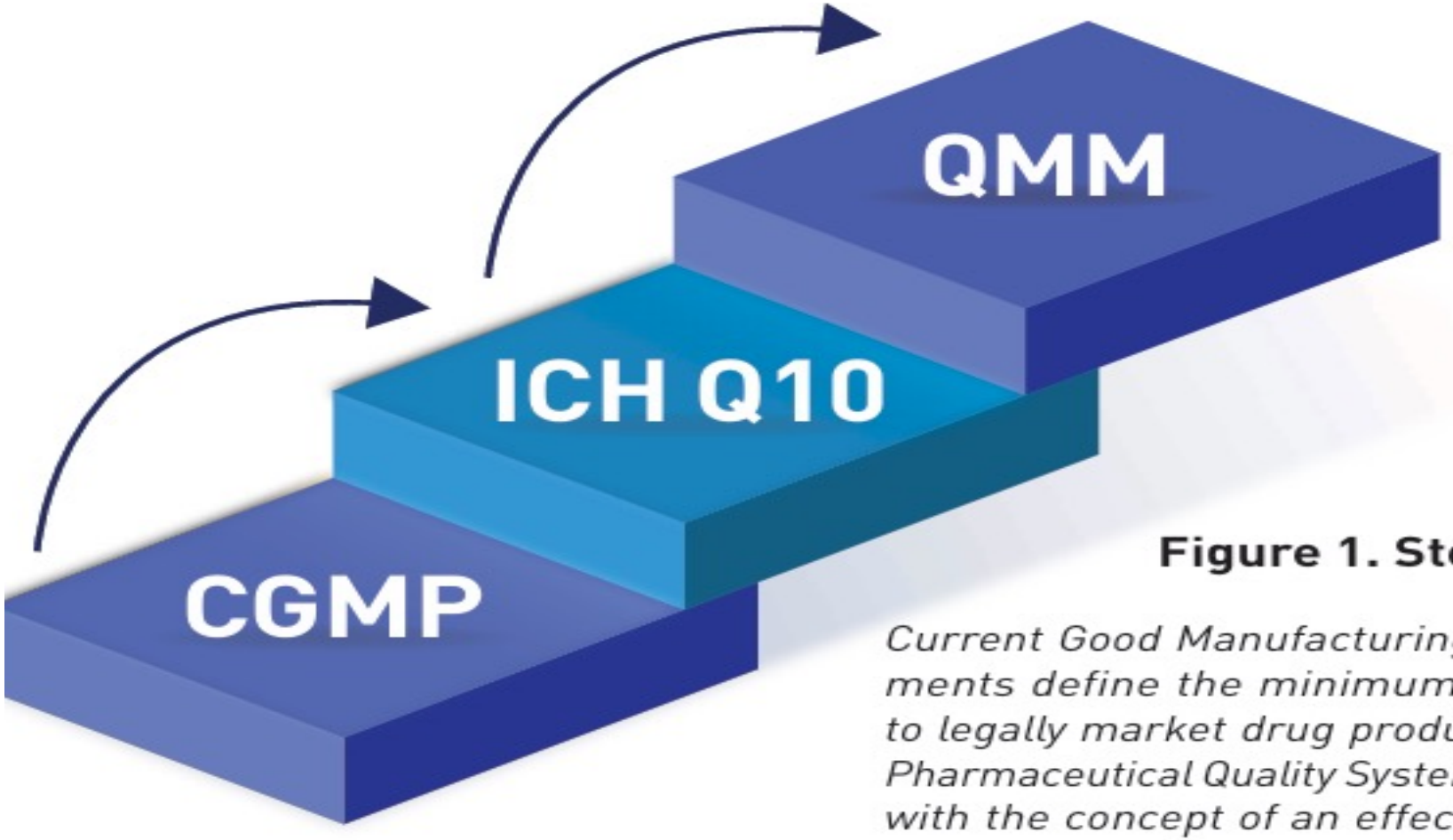
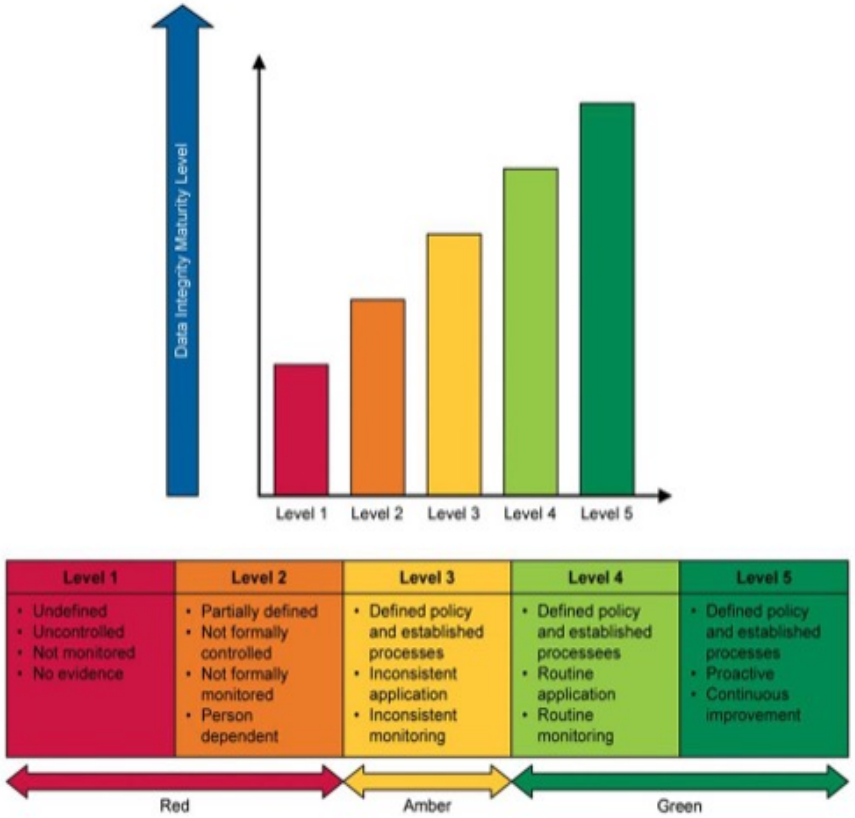


Figure 1. Steps to QMM

Current Good Manufacturing Practice (CGMP) requirements define the minimum manufacturing standards to legally market drug products in the US. The ICH Q10 Pharmaceutical Quality System guidance augments CGMP with the concept of an effective pharmaceutical quality system over the lifecycle of a product. QMM requires, in part, thoroughly implementing the concepts of ICH Q10 to promote continual improvement.

Maturity Model

Process Areas define the areas to be assessed, and for each area defines the *Maturity Factors* to be assessed against
Maturity Level Characterization gives examples of possible or typical states related to the levels



Example Process Area	Example Maturity Factor	Example Maturity Level Characterizations				
		Level 1	Level 2	Level 3	Level 4	Level 5
Data Ownership	Clear ownership of data and data-related responsibilities	Process, system, and data owners not defined	Process, system, and data owners identified in few areas.	Process, system, and data owners typically defined in many, but not all cases, and responsibilities not always clear	Process, system, and data owners are well defined and documented.	Process, system, and data owner responsibilities considered and clarified during management review.

Elements for a Code of Compliance for data integrity

PDA Code of Conduct for Data Integrity
Document Review

Microsoft Word Document

Live demonstration of the document

Parenteral Drug Association Points to Consider

Elements of a Code of Conduct for Data Integrity

Introduction

Data Integrity has been and currently is a major global concern of Health Authorities and the pharmaceutical industry. Although not a new issue, numerous recent Health Authority enforcement actions such as Warning Letters, Import Alerts, Product Detentions, and suspension or revocation of Marketing Authorizations has focused attention on Data Integrity. Data Integrity can result from lack of awareness of regulatory requirements, employee errors, failure to check accuracy of data, software or system malfunction, or configuration problems with electronic data handling, or malfeasance by employees. To holistically address Data Integrity, the Parenteral Drug Association (PDA) is developing a set of tools in the form of PDA Technical Reports, PDA Training Program, Data Integrity Workshops, and Points to Consider documents that can be used by industry to address this serious issue. This document presents the views of the Parenteral Drug Association (PDA) on the benefits for companies to voluntarily adopt a Code of Conduct for assuring data integrity.

How to Use this Document

This document was developed by a team with expertise in the fields of quality, regulatory affairs, auditing, and manufacturing and reviewed by attorneys specialized in food, drug and labor law. This document is written for easy adoption, in part or in its entirety, by companies, if they so choose, without the need for extensive rewriting of the document. Therefore, the terms 'shall' and 'must' have been used to permit the Code to be enforceable by a company, if adopted. This document is intended to reinforce a culture of quality and trust within the pharmaceutical industry. It is not intended to be a regulatory standard or guidance, nor is it intended to supersede any country specific or local laws and regulations governing labor, privacy and/or employee rights.

Why the focus on Data Integrity in the Pharmaceutical Industry?

- Data Integrity: Not a New Concept but has become one of the most important and relevant topics currently discussed by industry and regulators from around the world.

That is due to :

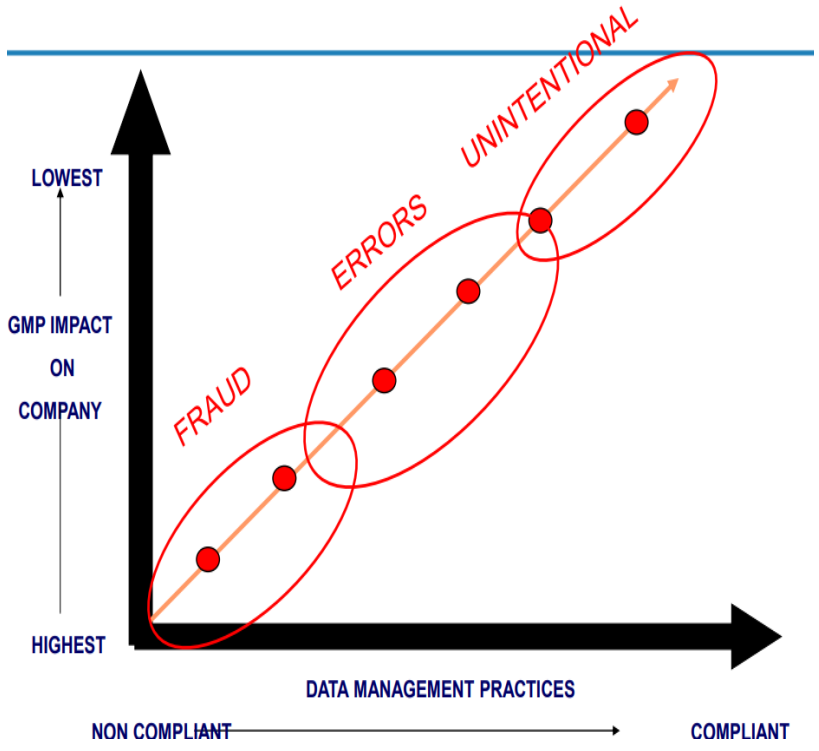
✓ Integrity" of the data provided to make critical patient orientated decisions.

✓ A breach in data integrity is a fundamental failure of the Quality System.

✓ Data integrity breaches cast doubt on all results and records

✓ As a result,

- A drug Manufacturer must have systems in place to identify "Honest Mistakes" as well as "Data Fraud "Testing into compliance," data manipulation, data deletion/record destruction, misreporting, disregarding failing and/or questionable results"
- And all what leading to possible breaches in the integrity of critical data.



Thank you

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