



IRISH MEDICINES BOARD

# GMP and ISO 22716

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Cosmetics Information Day , September 15<sup>th</sup> 2010

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Catherine Neary  
Inspector

- **Introduction**

- **Scope**

Personnel

Premises and Equipment

Production

Quality Control

Quality Systems

- **Next Steps**



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# Introduction

- **Good Manufacturing Practice**



*is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.*

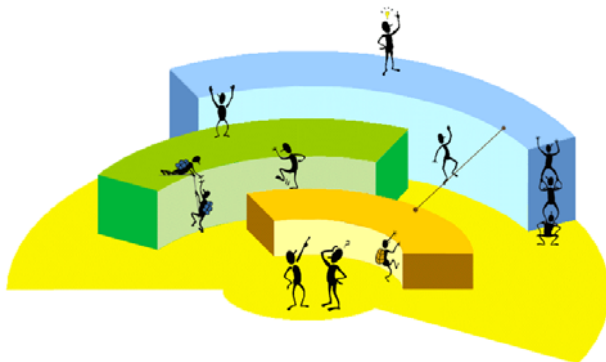


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# Introduction

## Aims of ISO 22716

1. Guidance for organizing & conducting activities of a plant
2. Common/harmonised perception between companies and authorities
3. Reference document



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# Scope - Personnel



Organization

Key Responsibilities

Training

Hygiene



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# Scope - Premises and Equipment

Proper Design

Cleaning and Sanitization

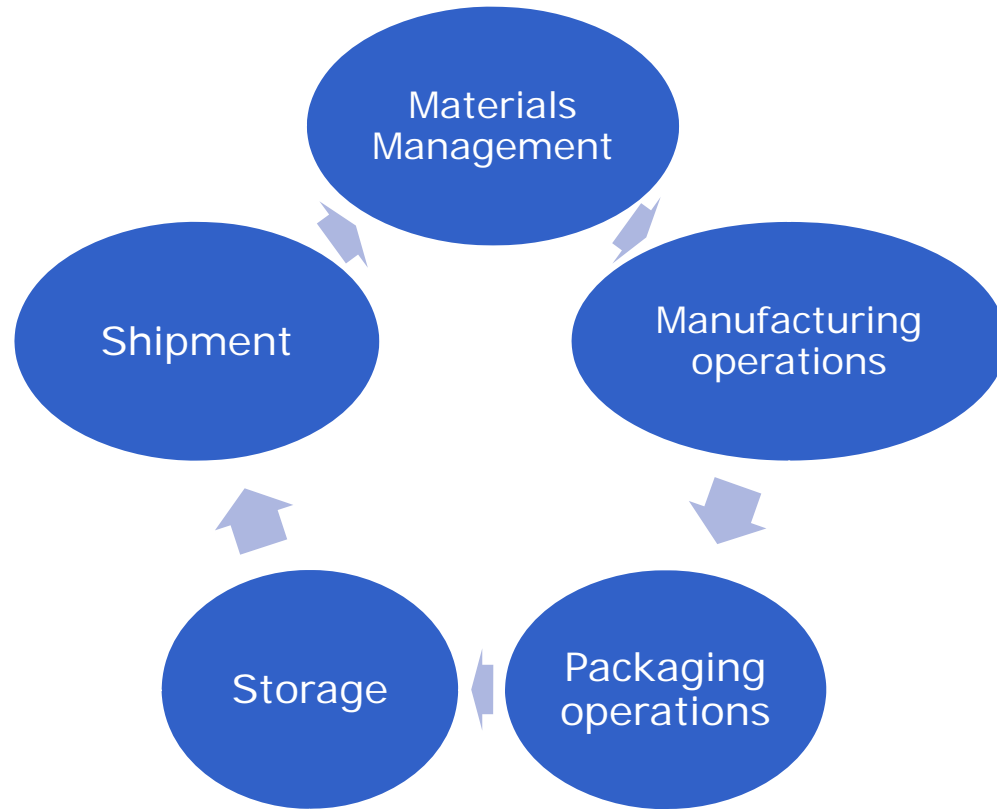
Maintenance

Calibration



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# Scope - Production



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# Production - Materials Management

**Purchasing**

**Receipt**

**Identification and status**

**Release**

**Storage**

**Re-evaluation**



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# Production - Manufacturing/Packaging Operations

**DOCUMENTATION**

**START-UP CHECKS**

**IN-PROCESS CONTROLS**

**STORAGE**

**SHIPMENT**

**RETURNS**



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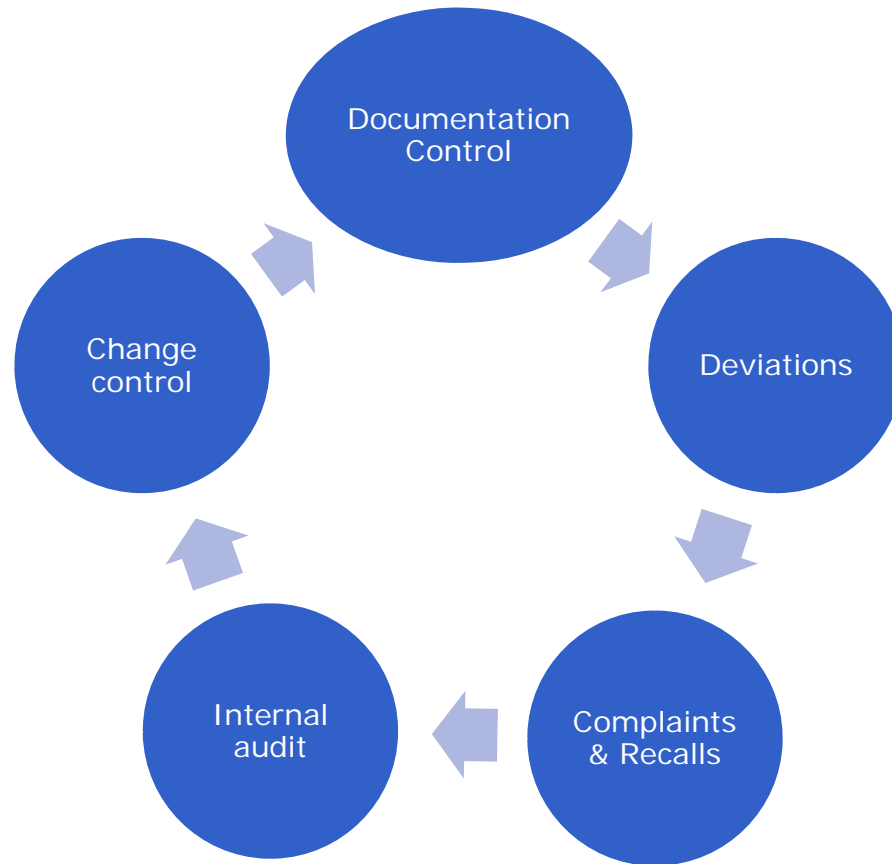
# Scope - Quality Control

- Sampling
- Specifications
- Testing
- OOS Investigation
- Release



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# Scope - Quality Systems



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# Quality Risk Management

## Quality Risk Management

*‘A systematic process for the assessment, control, communication and review of risks to the quality of the product across the product lifecycle’*

*‘based on scientific knowledge, experience with the process and ultimately links to the protection of the consumer’*

*‘level of effort, formality and documentation commensurate with the level of risk’*



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# Next Steps

- Gap Analysis
- Action Plan
- Implementation
- Continuous Improvement



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# In Summary - QUALITY MANAGEMENT



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