GMP and ISO 22716

Cosmetics Information Day, September 15th 2010

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ISO 22716

• Introduction

• Scope
  Personnel
  Premises and Equipment
  Production
  Quality Control
  Quality Systems

• Next Steps
• 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.
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
Scope - Personnel

- Organization
- Key Responsibilities
- Training
- Hygiene
Scope - Premises and Equipment

Proper Design

Cleaning and Sanitization

Maintenance

Calibration
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<thead>
<tr>
<th>Purchasing</th>
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<td>Receipt</td>
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<td>Identification and status</td>
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<td>Release</td>
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<td>Re-evaluation</td>
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<td>START-UP CHECKS</td>
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<td>IN-PROCESS CONTROLS</td>
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<td>STORAGE</td>
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Production - Manufacturing/Packaging Operations

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Slide 9
Scope - Quality Control

- Sampling
- Specifications
- Testing
- OOS Investigation
- Release
Scope - Quality Systems

Documentation Control

Change control

Deviations

Internal audit

Complaints & Recalls

15 September 2010
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’
Next Steps

- Gap Analysis
- Action Plan
- Implementation
- Continuous Improvement
In Summary - QUALITY MANAGEMENT

GMP

QA

QC

Quality Risk Management