


Cosmetics: Manufacturing and Quality Control

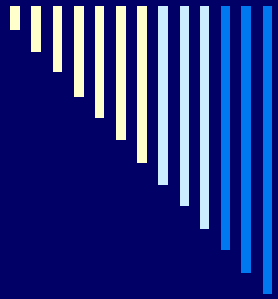
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General Consideration

- The Manufacturer, Importer or Person responsible for placing the product on the market is fully responsible for ensuring the product's safety for consumers in normal or reasonable foreseeable use conditions:
 - Formulate products as safety as possible
 - Allow a safety margin between the level of risk and the level of use the product
 - Inform consumer, as clearly as possible, in order to avoid misuse of the product
 - Adopt Good Manufacturing and Control Practices

How to make it happen?



Know How / Information and Policies & Procedures

- Know How / Information

- Should be shared around the Company, however, have to be a company property.

- Policies & Procedures

- Have to be standardized, controlled and managed by efficient Management System



Product Development

- Raw ingredient
 - Released by Toxicologist or experts
 - MSDS
 - Fragrances ingredients
 - Animal derivatives
 - Botanicals
 - Heavy Metals
 - Regulatory Review
 - Ingredients regulation
 - Product launch requirements
 - Issue final Raw Ingredient specification agreed and signed by the Vendor (s)
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Formulation

- Formula Prototype
 - Stability Test
 - Package Compatibility Test
 - Microbiologic Challenge Test

 - Safety Test
 - Potential Irritation risk
 - Potential allergic effect
 - Potential systemic effect

 - Claims
 - Claims must be substantiated:
 - SPF, No comedogenic, hypoallergenic, etc
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Formulation (cont)

- Regulatory Affairs
 - Label copy : How to use, Warnings.
 - Legal requirements

 - Processing Development
 - Lab scale prototype validation
 - Manufacturing scale prototype validation
 - Technology required
 - Processing validation
 - Filling equipments requirements
 - Package components validation

 - Formula, Processing Procedure and Specification Released
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Product Approval Process

- Formula approval signed off
- Safety approval signed off
- Claims approval signed off
- Processing Development approval signed off
- Package approved signed off
- Regulatory Affairs approval signed off

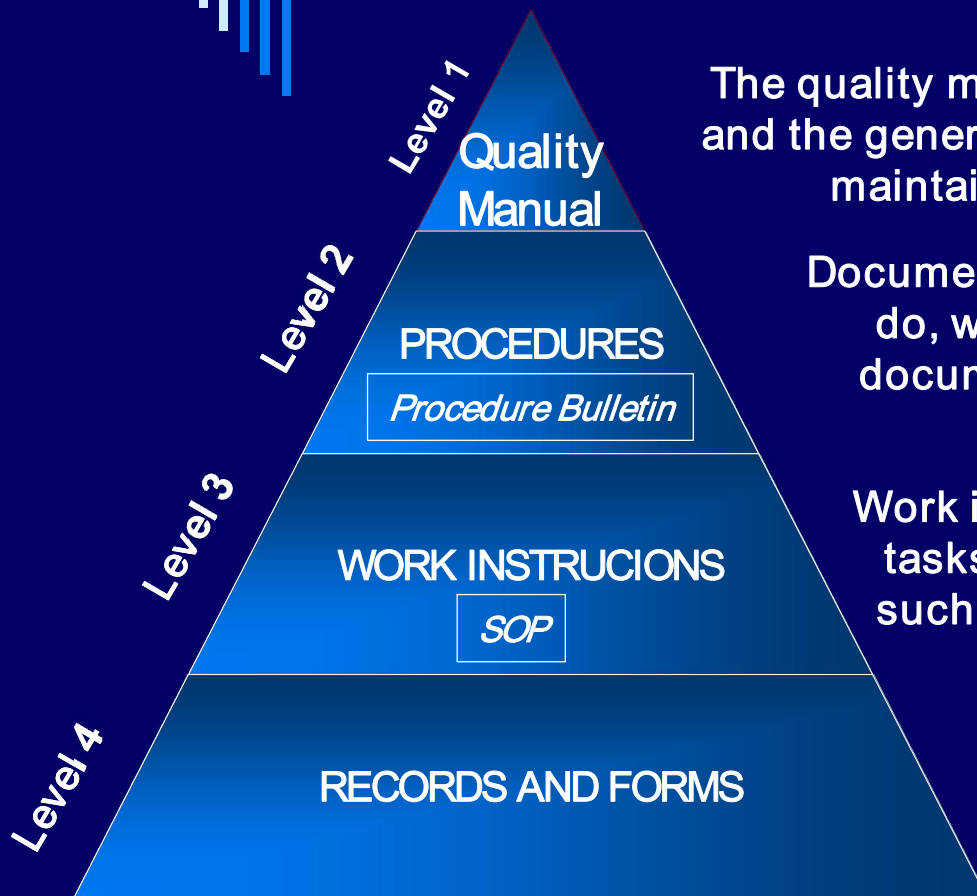
Product is ready to go to Manufacturing



Manufacturing Requirements

- Manufacturing site must be approved by all Government Authorities levels, where required
 - GMP must be in place
 - Local standard, if not available, International standard
 - EHS must be in place
 - Occupational Health and Safety,
 - Hazardous and Risks,
 - Environment Aspects and Impacts.
 - Quality System
 - Procedures governance
 - Training
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Quality Management System

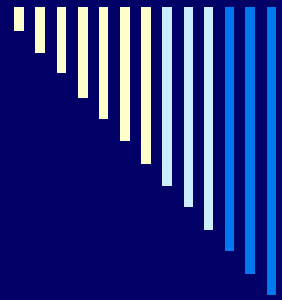


The quality manual describes a company's quality policy and the general company-wide structure and methods for maintaining the quality management system.

Documented procedures are used to specify what to do, who does what, when it is done, and what documentation is used to verify that the quality activity was executed as required.

Work instructions are used to detail how particular tasks are to be performed where the absence of such instructions would adversely affect quality.

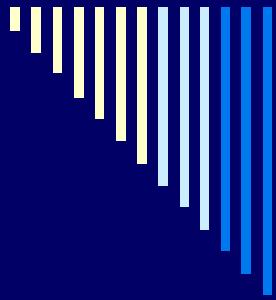
Records are used to provide assurance/evidence that the required product or service quality was achieved.



To Think

- Quality is never an accident:
 - It is a result of a strong intension;
 - A sincere effort;
 - A cleaver direction;
 - And a carefully execution.

A TEAM WORK



Gracias

Thank You

Muito Obrigado
