



GMP ISO 22716

GMP-IMPLEMENTATION

IRENA OZGA

GMP -IMPLEMENTATION

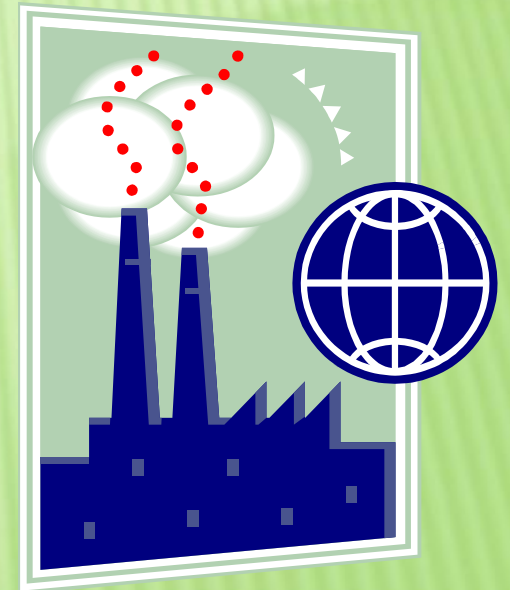
Topics to cover:

- ❖ cGMP norm ISO22716 and cGMP related legislation
- ❖ Pros and cons of GMP implementation

GMP IN COSMETICS

Relevant documents:

- ❖ **GMP ISO EN 22716:2007**
- ❖ **Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products**



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GMP ISO 22716: COSMETICS- GOOD MANUFACTURING PRACTICES -GUIDLINES ON MANUFACTURING PRACTICES

GMP ISO 22716

**ISO 22716 consists of 17 chapters
that define different areas**

GMP ISO 22716

GMP ISO 22716 gives guidelines for production, control, storage and shipment of cosmetic product.

GMP ISO 22716

GMP ISO 22716 is not applicable to research and development activities and distribution of finished product.

GMP ISO 22716

But.....also involves other departments or parts

6.2 Purchasing

- ✘ Purchasing of raw materials and packaging materials should be based on:
- ✘ a) evaluation and selection of the supplier;
(...)
- ✘ c) setting of relations and exchanges between the company and supplier such as questionnaire, assistance and audits.

GMP ISO 22716

**ISO 22716 norm does not cover
personel safety issues nor the
environmental protection area**

GMP ISO 22716

GMP ISO 22716 norm is:

- designed for cosmetic industry and differs from pharmaceutical GMP**
- guidelines that give some possibilities of different interpretation**

GMP ISO 22716

Guidelines:

‘The water treatment system should supply a defined quality of water’

‘Ventilation should be sufficient for the intended production operations’

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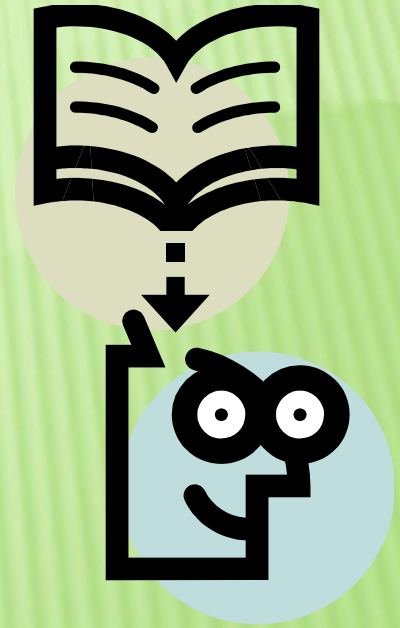
Guidelines:

**Adequate facilities for showering
and changing clothes should be
provided when appropriate**

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Why GMP ISO 22716????

ISO norms are not mandatory.....



REGULATION NO 1223/2009

REGULATION NO 1223/2009

No 1223/2009 article 8 about Good Manufacturing Practice:

1. The manufacturing of cosmetics shall comply with good manufacturing practice with a view of ensuring the objectives of Article 1 (safety of cosmetic product and human health)

REGULATION NO 1223/2009

No 1223/2009 article 8 about Good Manufacturing Practice:

2. Compliance with good manufacturing practice should be presumed where the manufacture is in accordance with relevant harmonized standards

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A harmonized standard will provide benchmark criteria for the mandatory good manufacturing practice.

However, other standards or systems providing at least an equivalent level of GMP could be used.

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This standard is expected to be EN ISO 22716:2007 Cosmetics - becoming harmonized when its reference is published in the EU's Official Journal. It has already been transposed as a national standard in several Member States.

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GMP in compliance with the harmonized ISO 22716 will offer a presumption of conformity to the GMP requirements.

While compliance with ISO 22716 is not mandatory, its harmonized status offers the simplest option.

IMPLEMENTATION OF ISO 22716

PROS + AND CONS



IMPLEMENTATION OF ISO 22716

POSITIVES

- ✘ stay in line with legal requirements
- ✘ define and link all important processes
- ✘ simplify of work flow
- ✘ increase of effectiveness /capacity
- ✘ build up efficient QA system
- ✘ significant raise of product quality

IMPLEMENTATION OF ISO 22716

POSITIVES

- ✘ increase personnel responsibility for product and production environment
- ✘ better routines for problems handling
- ✘ more competitive on the market
- ✘ good base to implement ISO 9001 standard

IMPLEMENTATION OF ISO 22716

DIFFICULTIES

- ✘ requires good knowledge of norm and of internal processes
- ✘ wrong interpretations lead to wrong system
- ✘ might be expensive due to investments in changing or rebuilding the premises

IMPLEMENTATION OF ISO 22716

DIFFICULTIES

- ✘ difficult to change personnel approach
- ✘ change control implementation

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TACK SÅ MYCKET!!!!

