Good manufacturing practices (GMP) for the biotrade cosmetics sector

Minimum requirements to ensure quality

GUIDE

ABioSA GUIDE

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THE ABS CAPACITY DEVELOPMENT INITIATIVE

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This case study is part of a series of knowledge products produced by ABioSA. These knowledge products and other biotrade resources can be found at www.abs-biotrade.info/projects/abiosa/resources

A glossary of biotrade terms can be found at www.abs-biotrade.info/resources

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Introduction

This ABioSA guide aims to help biotrade companies to understand and comply with Good Manufacturing Practices (GMP), with a specific focus on cosmetics.

It is based on the International Standards Organisation's ***ISO 22716: 2007 - Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices***.

Templates for standard operating procedures and sample checklists or worksheets can be found at ***www.abs-biotrade.info/projects/abiosa/resources***.

GMP is also applied in other sectors, and there are other related ISO standards covering good laboratory, agricultural and clinical practice.

What is Good Manufacturing Practice (GMP)?

GMP defines systems and behaviours that enable manufacturers to conform to guidelines recommended by agencies which control the authorisation and licensing for manufacture and sale of cosmetics, food and drink, pharmaceuticals and other products.

It is a set of minimum requirements that a manufacturer must meet to ensure its products are consistently high in quality. The main purpose of GMP is to prevent harm to the end user. It ensures end products are free of contamination, that the manufacturing process is well documented, that personnel are well trained, and that products are checked for quality.

GMP is overseen by regulatory agencies, who also monitor Good Agricultural Practice, Good Laboratory Practice and Good Clinical Practice.

GMP for cosmetics

Guidelines on GMP in the cosmetics sector were developed by the International Organisation for Standardization (ISO) and are governed by the ***ISO standard 22716:2007***.

The guidelines address product quality as well as the production, control, storage and shipment of cosmetic products. Standard operating procedures are required to define how manufacturing activities are performed, and for an organisation to formally develop, implement and maintain GMP according to the ISO 22716 standard.

Benefits of implementing GMP to the ISO 22716 standard

GMP enables organisations to achieve the following:

- Provide assurance to customers and other stakeholders on product quality
- Comply with legal and other requirements for production of cosmetic products
- Facilitate local and global market competitiveness
- Reduce the risk of barriers to trade

Overview of the ISO 22716:2007 requirements

Personnel

- Assign responsibilities to staff involved in production, control and storage of raw materials and finished products
- Provide appropriate training to ensure persons involved in GMP implementation possess the necessary knowledge and skills to produce, control and store products with a defined quality

Premises

- Manufacturing premises should be located, designed, constructed and utilised to:
  - Ensure protection of the product
  - Permit efficient cleaning, sanitizing and maintenance
  - Minimize the risk of mixing up products, raw materials and packaging

Equipment

- Equipment should be suitable for its intended purpose and capable of being cleaned, sanitized and maintained

Raw materials and packaging

- Raw materials and packaging should meet defined acceptance criteria relevant to the quality of finished products. The acceptance criteria are defined by the purchasing organisation, which may test the materials through trial orders, product sampling, etc.

Production

- Measures should be taken at each stage of manufacturing and packaging operations to produce a finished product that meets defined characteristics such as colour, appearance and smell

Finished products

- Finished products should meet the acceptance criteria defined by the manufacturer, customer or regulatory body

Quality control laboratory

- Principles described for personnel, premises, equipment, subcontracting and documentation should also apply to the quality control laboratory, which may be in-house or outsourced to a certified laboratory specialist

Treatment of product that is out of specification

- Investigation of rejected products or materials includes examination of the entire production cycle, from receipt of raw materials to storage and manufacturing
- Reprocessed finished products and bulk products should be approved by personnel responsible for quality

Waste

- Waste should be disposed of in a timely and sanitary manner. Waste includes any residue from a production operation, or any substance, material or product intended for disposal
- The procedure for handling and disposal of the different types of waste should define how it should be discarded

Subcontracting

- A written contract or agreement about sub-contracted activities should be established, mutually confirmed and controlled between the contract giver and the contract acceptor, which may include any person, company or external organisation carrying out an operation on behalf of another person, company or organisation

Deviations

- Deviations from the specified customer requirements should be authorised by the person responsible for quality control, with sufficient data to support the decision

Complaints and recalls

- Product recalls and complaints from customers, retailers and wholesalers should be promptly reviewed in accordance with the written procedure

Change control

- Changes to activities covered by Good Manufacturing Practice, or that could affect the quality of a product, should be performed and approved by authorised personnel on the basis of sufficient data. This is to ensure that manufactured, packaged, controlled and stored products correspond to the defined acceptance criteria.

Internal audit

- An internal audit is a tool designed to monitor the implementation and the status of Good Manufacturing Practices and to propose corrective actions if necessary

Documentation

- A company should establish, design, install and maintain its own system of documentation appropriate to its organisational structure and type of products. This helps to demonstrate Good Manufacturing Practices and provide an assurance of quality and compliance to customers and regulators.
- Templates for standard operating procedures and sample checklists or worksheets can be found at ***www.abs-biotrade.info/projects/abiosa/resources***.

Useful GMP references

International Organization for Standardization (ISO), ISO 22716:2007 (First Edition) Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices
https://www.iso.org/standard/36437.html

GMP Guidelines for Manufacturers of Cosmetic Products (2018), Health Sciences Authority, Singapore
https://www.hsa.gov.sg/docs/default-source/hprg/cosmetic-products/guide-mqa-016.pdf

ASEAN Cosmetic Documents Appendix VI – ASEAN Guidelines for Cosmetic Good Manufacturing Practice ***https://asean.org/storage/2012/05/Appendix-VI-ASEAN-Guidelines-for-Cosmetic-GMP.pdf***

A WHO guide to good manufacturing practice (GMP) requirements- Part 1: Standard operating procedures and master formulae ***https://apps.who.int/iris/bitstream/handle/10665/64465/WHO_VSQ_97.01.pdf;sequence=1***

Guide to Good Manufacturing Practice (GMP) requirements for Cinnamon Processors (2016) published by United Nations Industrial Development Organization (UNIDO) jointly with The Spice Council (TSC) of Sri Lanka and Funded by Standards and Trade Development Facility (STDF)
https://www.standardsfacility.org/sites/default/files/PG_343_Guide_GMP.pdf