CTPA Webinar – Good Manufacturing Practice (GMP) Consideration 23 October 2025

Questions and Answers

Q. What is the advice on cleaning and sanitisation when making a cosmetic product at home?
A. Cleaning and sanitisation procedures differ significantly between professional manufacturing sites and home setups. In manufacturing facilities, all systems must be thoroughly flushed, and stronger chemicals are typically used for sanitising.

For home environments, it's best to use biocidal disinfectants that have been tested according to the EN1276 standard—this information is usually found on the product label. These disinfectants are proven to eliminate specific organisms within a designated contact time, so it's important to follow the usage instructions provided. Other relevant EN/ISO compliant that are relevant are 1650, 13697 and 13704.

To deep clean water systems or vessels at home, start with an acidic disinfectant to remove debris, followed by an alkaline disinfectant to kill microorganisms. Finally, rinse thoroughly with water to ensure no disinfectant residue remains, as leftover chemicals could contaminate the finished product. This rinsing step is vital because certain disinfectants may leave residue that can leach into the product.

Q. Is tap water fine to use when making cosmetic products at home?
A. Determining whether tap water is suitable for making cosmetic products at home depends on several factors. While tap water can be used, it is important to consider its hardness, which varies by location. Hard water should be treated and softened, as untreated hard water can affect the physical and chemical properties of your product.

Microbiological quality also varies across the UK, so it's essential to have the water tested before use and make an informed decision based on the results.

Another consideration is that all water used, if it is not part of a controlled water system, should be boiled water. Whilst boiling water cannot be used in formulation and manufacturing processes, the cooled boiled water should be from the same day to prevent stagnation of previously boiled water, since the environment of the room will not be sterile.

In summary, tap water may be acceptable, but you must provide a clear justification for its suitability in your specific circumstances.

Q. What is a bio-burden?
A. Bio-burden is microbial contamination and anything related to it, such as microbiological content testing, environmental monitoring testing, checking the type of microorganisms present.

Q. Are there any types of raw materials that are particularly high risk, for example for micro contamination or possibly harmful impurities? Would manufacturers especially need good documentation and checks for these high risk raw materials?
A. Water is considered the highest risk raw material in cosmetic manufacturing, as its quality can vary and may not always meet required standards—even tap water can pose risks. For this reason, it is essential to test water for microbial contamination before use.

Natural ingredients, such as clays, talc, and other materials sourced from the ground, also present significant risks. These ingredients should be checked not only for microbial contamination and impurities but also for dormant spores that could develop into microorganisms under favourable conditions. Additionally,

desiccated natural ingredients may carry organic contaminants from fertilizers, which can further compromise product safety.

Q. Does microbiological quality of the cosmetic product have to be justified in the Cosmetic Product Safety Report (CPSR)?
A. The Cosmetic Product Safety Report (CPSR) must include, at a minimum, all information required under Part A and Part B of Annex I of the UK Cosmetics Regulation. This includes details on the microbiological quality of both the ingredients and the finished cosmetic product.

If the CPSR states that a product is lacking the Preservative Efficacy Test, these claims must be supported by scientific evidence. Any conclusions about the microbiological quality of ingredients or the product that lack scientific justification should be questioned.

Q. What advice can be given to a micro-manufacturer (e.g. making cosmetic products at home)? Are there any resources available to improve knowledge of GMP and microbiological quality?
A. The recording of the CTPA webinar on GMP considerations is a great resource.

Furthermore, companies can access the below CTPA resources on this topic.

- CTPA Guide on GMP - A Practical Guide for the Cosmetic Industry
- CTPA Guide on Microbial Quality Management
- International Organisation for Standardisation (ISO) 17516:2014 on Cosmetics Microbiological Limits
- ISO 18415:2017 Cosmetics — Detection of specified and non-specified microorganisms
- ISO 22716:2007 Cosmetics GMP
- ISO 29621:2017 Cosmetics — Guidelines for the risk assessment and identification of microbiologically low-risk products

Q. Is there a best practice or a recommended way to document GMP?
A. There is no specific format required under the UK Cosmetics Regulation for documenting Good Manufacturing Practice (GMP) and demonstrating compliance. You may use dedicated software, or simply keep records in Word or Excel documents. Manual documentation is also acceptable, though it may be more time-consuming from an administrative perspective. The key requirement is that GMP records are well-documented and traceable.

Q. If a brand owner manufactures goods with an overseas manufacturer, they may not have the chance to visit and audit the manufacturing site. In this case, is the importer required to undertake a microbiological testing regime for the products produced overseas?
A. Under the UK Cosmetics Regulation, there are no specific requirements to conduct a separate testing regime for imported products from overseas manufacturers. The expectation is that the manufacturing site

will have already performed microbiological testing on released batches. It is recommended to verify that the received batches meet product specifications, such as appearance, odour, colour, specific gravity, pH, and viscosity.

Nonetheless, each situation should be assessed individually. Additional testing may be appropriate if the product formulation is particularly susceptible to microbial contamination, or if the brand owner is working with a new manufacturer and wishes to confirm the reliability of the site.