



Microbiological monitoring

Background

Reliable microbiological monitoring is a key component of hygiene management in the production and quality assurance of pharmaceuticals, food and cosmetics, whereby regular checks at critical control points are not only a statutory obligation, but are also essential to ensure product safety and a consistently high standard of quality.

Strategic evaluation

Systematic microbiological monitoring offers a means of identifying **potential sources of contamination** at an early stage and verifying the efficacy of hygiene measures. It constitutes an essential element for an effective **HACCP (Hazard Analysis and Critical Control Points) concept** and, at the same time, meets the regulatory requirements imposed by various international standards (e.g., GMP, ISO 22000).

Service portfolio from a single provider

We put a comprehensive **range of microbiological services** at your disposal.

Environmental monitoring:

- Swab and smear analyses for relevant microorganisms (e.g., total bacterial count, yeasts/moulds, *Enterobacteriaceae*, Salmonella)

Water analyses:

- Microbiological testing of purified water in accordance with the European Pharmacopoeia
- Determination of the aerobic mesophilic bacterial count
- Detection of specific indicator germs (e.g., *E. coli*, coliform germs)

Airborne germ and particle counts:

- Quantitative assessment of the microbial contamination of the ambient air in production premises

Sample extraction and sampling equipment:

- Air and particle sampling equipment rental
- Pre-shipment of the materials required for sampling at your premises (e.g., agar plates, swabs), if required

Sample shipment:

- Direct shipment of your hygiene samples to our laboratory without any detours
- Support in the planning and coordination of sample shipment
- Provision of suitable transport containers and cooling options

Evaluation and interpretation:

- Evaluation based on your internal specifications and guide values
- Advice on results and derivation of recommendations for action

All analyses are carried out under **GMP conditions** and are **accredited** in accordance with **DIN EN ISO/IEC 17025**. Apart from the standard procedures, we also develop customised procedures, if required, which are tailored to meet your specific requirements. We support you when it comes to interpreting the results and are available to answer any technical questions you may have regarding the **optimisation of your hygiene management system**. If you wish, we can also **conduct product and process-specific risk assessments** in close cooperation with you.

References

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
ICH Guideline Q7 on Good Manufacturing Practice for Active Pharmaceutical Ingredients (updated July 2015)

Contact us to find out more about our microbiological service spectrum - from industrial hygiene tests to specific product analyses.



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