Providing Sterilization & Laboratory Services for the world's most innovative healthcare companies.

Announcement

Medistri Joins the Swiss GLP Compliance Monitoring Programme

April 13th 2026

At Medistri, we are proud to announce that our laboratory has officially been enrolled in the Swiss Good Laboratory Practice (GLP) Compliance Monitoring Programme. The formal decision was issued by the Notification Authority for Chemicals (NAChem) at the Federal Office of Public Health, following a successful inspection process conducted by Swissmedic. Our facility will appear on the official GLP register effective 13 May 2026.

What Is Good Laboratory Practice?
Good Laboratory Practice (GLP) is an internationally recognised quality system established by the Organisation for Economic Co-operation and Development (OECD). GLP principles ensure the quality, integrity, and reliability of non-clinical safety studies. Facilities operating under GLP are subject to regular inspections by national monitoring authorities — in Switzerland, this programme is overseen by the Federal Office of Public Health and inspected by Swissmedic and the Federal Office for the Environment (FOEN). Enrolled facilities are re-inspected on a routine basis every two to three years, in accordance with the Ordinance on Good Laboratory Practice (OGLP).

GLP compliance provides assurance that study data is generated under controlled, documented, and reproducible conditions. For manufacturers of medical devices and pharmaceutical products, partnering with a GLP-compliant laboratory strengthens the credibility and regulatory acceptance of safety data across international markets.

What This Means for Our Clients
For medical device and pharmaceutical manufacturers, GLP compliance at Medistri means that safety-critical data generated in our laboratory meets the highest internationally accepted standards of quality and traceability. Studies conducted under GLP are recognised by regulatory authorities worldwide, including the FDA, European notified bodies, Swissmedic, and other OECD member-country authorities. Practically, this provides our clients with:

- Enhanced regulatory acceptance: GLP study data is recognised across OECD member countries, supporting international submissions and reducing the risk of regulatory queries.
- Greater confidence in safety data: GLP principles ensure that every step of a study — from planning to reporting — is documented, traceable, and reproducible.
- A single partner for the full testing chain: Medistri's unique GLP scope means manufacturers can consolidate chemical characterization, biological safety, microbiological validation, and cleanliness testing with one laboratory — under both ISO 17025 accreditation and GLP compliance.
- Faster, more streamlined projects: Working with a single GLP-compliant partner eliminates the need to coordinate between multiple laboratories, reducing administrative burden and accelerating time-to-market.

Learn more about our Laboratory. To ensure your products meet the highest quality and safety standards, contact our dedicated team at lab@medistri.swiss.

— The Medistri Team

#Medistri

Scope of Medistri's GLP Compliance
Our GLP compliance covers a comprehensive range of analytical, biological, and microbiological testing activities. The full scope includes:

Chemical Characterization
- Total Organic Carbon (TOC)
- Hydrocarbon Testing (HCT)
- EO/ECH/EG Testing (Ethylene Oxide, Ethylene Chlorohydrin, Ethylene Glycol)
- VOC & SVOC (Volatile and Semi-Volatile Organic Compounds)

Biological Testing
- Cytotoxicity (ISO 10993-5)

Microbiological Method Validation
- Bioburden
- Sterility
- Endotoxin (Endosafe Cartridge)
- Germ Identification (VITEK)

Cleanliness & Residue Testing
- Sub-visible Particles (Light Obscuration)
- Protein & Hemoglobin

This scope complements and strengthens our existing ISO 17025 accreditation, adding a further layer of internationally recognised quality assurance to key areas of our testing portfolio.

A Unique Position in the Swiss GLP Landscape
The Swiss GLP Compliance Monitoring Programme currently includes approximately 20 test facilities, the majority of which focus on pharmaceutical toxicology, ecotoxicology, bioanalytical chemistry, or pathology review. Only a small number of facilities on the register are directly relevant to the safety testing of medical devices.

With our enrollment, Medistri becomes the only Swiss GLP-compliant facility to combine chemical characterization, cytotoxicity testing, microbiological method validation, and cleanliness testing within a

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single GLP scope. Other Swiss GLP facilities with relevance to the medical device sector tend to specialize in narrower areas — for example, analytical and physical-chemical testing, or in vivo biocompatibility and efficacy studies. No other facility on the register covers the breadth of cleaning validation and biological safety testing that Medistri now offers under GLP.

For manufacturers, this means the ability to consolidate multiple GLP-compliant safety tests with a single laboratory partner — reducing coordination complexity, shortening timelines, and ensuring consistency across the testing programme.