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EUROPEAN NEWS

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Eurofins Medical Device Services Europe Acquires ac.biomed GmbH

October 2025

Eurofins Medical Device Services Europe, a leading provider of comprehensive testing, consulting, sterilisation, and packaging services for medical devices, is pleased to announce the acquisition of ac.biomed GmbH, a highly specialised cardiovascular testing laboratory based in Aachen, Germany.

This strategic acquisition marks a significant milestone in Eurofins Medical Device Services Europe's mission to deliver best-in-class safety and performance testing services to medical device manufacturers worldwide.
With over three decades of experience, ac.biomed has earned a reputation as a centre of excellence in cardiovascular device testing, offering unmatched expertise and a unique portfolio of services.

ac.biomed is the only European laboratory accredited to ISO 17025 that provides safety and performance testing for oxygenators, blood pumps, and cannulas. Furthermore, it is the sole European facility offering the full scope of testing according to the ISO 5840 family of standards, which govern heart valve prostheses. This positions ac.biomed as a critical partner for manufacturers seeking regulatory approval and market access for complex cardiovascular devices.

The team at ac.biomed is composed primarily of biomedical engineers, many of whom actively contribute to international standardisation committees such as ISO and IEC.

Their commitment to scientific rigour and innovation has led to the development and validation of proprietary testing methods and equipment, tailored to the specific requirements of cardiovascular devices. The laboratory's quality management system is certified to ISO 9001 and fully compliant with ISO 17025, ensuring reliable and reproducible results.

Beyond technical excellence, ac.biomed is recognised for its client-centric approach, supporting manufacturers from early-stage development through to clinical approval and post-market surveillance. Its services are trusted by a diverse client base, ranging from ambitious start-ups to global industry leaders. The company's independence and confidentiality protocols make it a preferred partner for a wide range of stakeholders in the medical device ecosystem.

Eurofins Medical Device Services Europe's acquisition of ac.biomed strengthens its position as a comprehensive service provider across the entire medical device lifecycle. By integrating ac.biomed's specialised cardiovascular testing capabilities, Eurofins Medical Device Services enhances its ability to offer bespoke consulting, sterile packaging, and accelerated market access solutions tailored to the unique challenges of cardiovascular device development.

Like Eurofins Medical Device Services, ac.biomed is committed to scientific excellence, innovation, and sustainability, evidenced through active investment in ecological practices, support to local charities, and fostering young talent through university partnerships.

Eurofins Medical Device Services will continue to advance the safety, efficacy, and regulatory compliance of medical devices, supporting stakeholders in bringing life-saving technologies to patients more efficiently and reliably.

For more information, visit https://www.eurofins.com/medical-device or ac-biomed.de.

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When Devices Meet Medicines: Chemistry, Biology, and Regulatory Synergy

Daniele Lioi, Business Unit Manager and Senior Consultant, Eurofins Medical Device Consulting, Italy.

The convergence of medical devices and pharmaceuticals has created a class of products—combination products—that demand a rigorous, integrated approach to development and compliance. Unlike standalone devices or drugs, these products require simultaneous consideration of material biocompatibility, drug stability, and regulatory alignment.

From a regulatory perspective, the U.S. FDA defines combination products under Section 503(g) of the FD&C Act, assigning primary jurisdiction based on the Primary Mode of Action (PMOA). This determines whether the premarket pathway follows device routes (PMA, 510(k), De Novo) or drug/biologic pathways (NDA, ANDA, BLA). In the EU, while the term "combination product" is not formally recognised, the MDR (2017/745) and Directive 2001/83/EC govern integral products through coordinated assessments by Notified Bodies and Competent Authorities. The classification hinges on whether the medicinal component is principal or ancillary to the device function.

Technical assessment is equally complex. ISO 10993-1 and ISO 10993-18 remain foundational for biological evaluation and chemical characterisation, but additional pharmaceutical methodologies are often required. Extractables and leachables studies must account for drug formulation, packaging interactions, and potential new chemical entities introduced during manufacturing. FDA guidance emphasises testing on the final combination product or representative samples, considering sterilisation and processing conditions.

Case studies such as drug-eluting stents and implantable fillers illustrate the multidimensional testing strategy: cytotoxicity, genotoxicity, hemocompatibility, and implantation studies for the device; degradation, drug release kinetics, and stability for the drug; and combined evaluations for synergistic effects. Post-market surveillance and clinical follow-up further ensure long-term safety and performance.

Ultimately, the successful development of combination products relies on a multidisciplinary approach integrating chemistry, biology, and regulatory science—transforming complex innovations into safe, effective solutions for patients.

No Repetition of in-vivo Testing to re-proof Biocompatibility in case of Product & Manufacturing Changes

Anja Friedrich, General Manager Eurofins Medical Device Services France, Business Unit Manager Consulting, France.

The medical device industry is a strong, growing and highly innovative industrial sector in Europe. Apart from improving the products, Medical Device Regulation (MDR) requirements, supply change problems and price pressure are leading to regular changes in the product design, materials, composition and/or manufacturing steps. When introducing changes, the impact on the biocompatibility of the device has to be assessed. Changes in product characteristics, body contact, the intended use, in additives and manufacturing procedures, sterilisation and packaging can influence the biological safety of the product.

To examine if the product is still biocompatible and to determine if or which studies are necessary to prove the biological safety, a step-wise approach is proposed (ISO 10993-1). Especially the repetition of in-vivo studies shall be avoided (ISO 10993-2).

First, the change is assessed based on available literature, toxicological information, supplier certificates, already performed studies on the previous product, and further available information. If the risk of the change cannot sufficiently be addressed by the collected information, a bridging approach with chemical characterisation comparing the extractables and leachables profile of the product before and after the change is recommended by ISO 10993-18. In addition, a test for cytotoxicity (ISO 10993-5), as a very sensitive basic biological study, supports the biological safety of the product after the change. In case no new risks have been identified, the already performed studies (especially in-vivo studies) on the product before the change are also applicable for the product after the change.

It is important that the biological evaluation and the biocompatibility studies of the product before the change or of the initial product have been conducted in compliance with the actual ISO 10993 series, are complete and still valid.

With a thoroughly performed change assessment the manufacturer can save a lot of time, money and can avoid in-vivo studies.

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The End of an Era: USP Class VI is Being Replaced

Kristin Roedig, Consulting Specialist & Deputy Head of Eurofins Medical Device Consulting Germany;
Dr. Torben Gehring, Deputy Head of Department of in vitro Pharmacology/ Toxicology & Group Leader Cytotoxicity and Haemocompatibility Testing, Eurofins Medical Device Testing, Germany.

Recent regulatory developments have significantly reshaped the biocompatibility evaluation of polymeric materials used in pharmaceutical packaging and combination products. Traditionally, the United States Pharmacopeia (USP) Class VI testing framework—comprising systemic injection, intracutaneous reactivity, and implantation tests—served as the primary method for assessing material safety.

However, this approach has been increasingly criticised for its reliance on animal testing and limited relevance to modern risk assessment methodologies. In response, a revised framework has emerged that aligns more closely with ISO 10993 standards and promotes a risk-based, science-driven evaluation strategy. Central to this shift is the prioritisation of in vitro testing over in vivo methods, aiming to reduce animal use while maintaining rigorous safety standards. USP Chapters <87> and <88> are undergoing substantial revisions, effective 1 December 2026. These updates include the removal of intracutaneous and implantation tests and the replacement of the outdated Class I–VI classification system with the term "Pharmaceutical Grade Polymeric Packaging Materials." USP <1031>, effective since December 2024, provides comprehensive guidance for biocompatibility assessment through chemical risk evaluation, cytotoxicity testing, and in vitro irritation models.

Successful outcomes from these tests may eliminate the need for further animal-based studies. In cases of adverse results, additional chemical characterisation and toxicological risk assessments—such as those outlined in USP <1663>—may be required.

Furthermore, USP <87> will be reorganised to incorporate advanced in vitro methodologies, including the Neutral Red Uptake (NRU) assay, reconstructed human epidermis (RhE) models for skin irritation, and a genotoxicity test battery. USP <88> will retain the systemic injection test only under narrowly defined conditions. Collectively, these changes reflect a paradigm shift toward more ethical, scientifically robust, and regulatory-aligned biocompatibility evaluations.

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Cleaning Validation: How To Keep Your Manufacturing Process Under Control

Dr. Vincent Rietsch, Project Management & Business Unit Manager Eurofins Medical Device Testing France.

Cleaning validation is a critical step in the manufacturing of medical devices, ensuring that final products are free from harmful contaminants that could compromise patient safety. Contaminants may include organic and inorganic residues, particulates, microorganisms, and endotoxins, all of which can originate from manufacturing, handling, or storage processes. These impurities can lead to severe clinical outcomes such as inflammation, thrombosis, or even sepsis.

The cleaning validation process follows international standards such as ISO 19227, ASTM F3127 and DIN/TS 5343, which provide frameworks for assessing cleanliness. Preparatory steps include detailed characterisation of the product (material, geometry, surface, etc…), mapping of the manufacturing process to identify potential contaminants, and defining the cleaning procedures and agents used. Cleaning methods may involve ultrasonic baths, thermal or plasma cleaning, the use of solvents and/or chemical or enzymatic detergents.

To assess cleanliness, several parameters can be measured like visual inspection (EN 13018), bioburden (ISO 11737-1), bacterial endotoxins (USP <85>, ISO 11737-3), cytotoxicity (ISO 10993-5), particulate matter (USP <788>), and chemical residues (TOC, THC, ICP-MS, GC-MS). These tests ensure that the cleaning process effectively removes contaminants and does not introduce new risks.

The validation process follows a structured approach: Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ), typically conducted under worst-case conditions and repeated in triplicate for PQ to ensure reproducibility. Documentation of results, establishment of routine release parameters, and periodic revalidation are essential for maintaining manufacturing process under control.

Finally, cleaning validation must be integrated with biological and sterilisation validations. If unacceptable biological risks are identified, revalidation may be necessary. This comprehensive approach ensures compliance with regulatory requirements and protects patient health.

ISO 18562 Series: Biological and Toxicological Evaluation of Gas Pathway Medical Devices

Anja Friedrich, General Manager Eurofins Medical Device Services France, Business Unit Manager Consulting, France.

The ISO 18562 series (published in 2024) establishes methodologies for the biological and toxicological evaluations of gas pathways in medical devices. These standards are crucial for ensuring the safety and efficacy of medical devices that utilise gas pathways, such as ventilators and nebulizers, which are vital in clinical settings. By providing a structured approach to assess potential risks associated with gas exposure, these standards help manufacturers meet regulatory requirements and safeguard patient health.

The first step in the evaluation is to thoroughly understand the clinical use of the medical device, differentiating the parts where ISO 18562 series applies (gas pathways) from components that come into contact with the patient by other exposure routes, which are governed by ISO 10993-1. As a result, medical devices with gas pathways require a dual evaluation approach, considering both sets of standards.

When evaluating gas pathways, it is essential to tailor the biological assessment to specific risks, such as particles, Volatile Organic Substances (VOSs), and condensates. If tests are necessary, they should be conducted under conditions that closely simulate clinical use to ensure relevance. Chemical tests on gas pathways (VOSs and condensates) must be followed by a thorough toxicological evaluation adapted to the clinical use of the medical device. Finally, the biocompatibility evaluation should encompass all risks, whether originating from gas pathways or parts in contact with the patient by other exposure routes.

A solid understanding of the medical device and its specific clinical use is essential for developing an effective biological evaluation plan, guiding the identification of risks and planning necessary tests to ensure patient safety.

If you have questions or would like more information, please contact us. Additionally, we invite you to view our recent webinar, where we discussed this subject in detail, providing practical examples and deeper insights into applying the standards in real-world scenarios.

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