Medical Device NEWS

Spring 2026

Delivering timely Medical Device testing, package testing, and consulting solutions to clients who help make the world healthier and safer.

Building what's next in MedTech

Eurofins Medical Device Services welcomes EAG St. Louis Chemistry and Medical Device Testing Teams

The medical device industry is embracing an exciting new chapter of groundbreaking innovation and excellence, driven by the dynamic integration of top-tier expertise and expanded capabilities.

Eurofins Medical Device Services' integration of the St. Louis Chemistry and Medical Device Testing business units from Eurofins EAG Laboratories—effective May 1—positions the organization to elevate the standards of medical device testing, development, and regulatory support, ushering in a new era of innovation and excellence.

This strategic move underscores a shared commitment to advancing MedTech and delivering exceptional solutions to clients. *Read more on p. 2*

In this Issue

Contact US to learn more about how we are Testing for Life.

From prototype to patient: why medical device developers need more than testing

A smarter path to medical device safety with Eurofins

Early in medical device development, innovation often takes center stage—new materials, mechanisms, and clinical applications. But innovation alone doesn't bring a device to market. *Read more on p. 3*

Regulatory must reads: FDA's policy pivot – impacts of CDRH 'leveling up' use of guidance documents

In the U.S., FDA guidance documents shape how regulated industries understand agency expectations, policy shifts, anticipated data, and sometimes enforcement authorities. *Read more on latest updates and how we can help navigate p. 4*

Building what's next in MedTech

Eurofins Medical Device Services welcomes EAG St. Louis Chemistry and Medical Device Testing Teams

Continued from front page

Eurofins Medical Device Services, recognized as a leader in comprehensive medical device testing and regulatory services, welcomes the highly respected St. Louis teams into its network. The St. Louis facility, celebrated as a center of excellence for chemical characterization of medical devices, brings deep scientific rigor, technical depth, and a reputation for outstanding client service. In joining Eurofins Medical Device Services, the St. Louis teams will gain access to additional analytical platforms and cross-functional expertise, enhancing the ability to support product development, regulatory submissions, and ongoing quality programs. By integrating St. Louis capabilities, Eurofins strengthens its Biocompatibility Accelerator program, delivering faster, more predictable regulatory outcomes through end-to-end chemical characterization and biological safety alignment.

"This integration marks a pivotal step forward for our clients and our teams," said Mike Bond, President, Medical Device Services. "By uniting Eurofins Medical Device Services with EAG's St. Louis operations, we deliver broader expertise, faster innovation, and seamless support—empowering clients at every stage of the medical device lifecycle."

The transition, effective as of May 1, 2026 will be smooth and uninterrupted, ensuring that day-to-day operations, scientific staff, and client commitments continue as usual. Importantly, all other EAG Laboratories business units and service lines remain unchanged and will continue operating as part of EAG.

St. Louis Medical Device Testing is widely regarded as "best in class" for ISO 10993-18 testing, with more than 700 studies completed over the last several years. To date, all submissions using St. Louis data have been accepted by the FDA. The lab also offers particulate analysis as well as *in vitro* sensitization and irritation studies.

"By joining Eurofins Medical Device Services, we further expand our technical capabilities, accelerate innovation, and continue delivering the high-quality, science-driven solutions our clients expect, without disruption to projects or partnerships," Al Lee, PhD, Vice President of St. Louis Chemistry and Medical Device Testing, emphasized. "It's our people and our commitment to clients that made us "best in class" for ISO 10993-18 testing. Kevin Trankler, PhD, is our Senior Director and leads our scientists. Dr. Trankler has done an outstanding job listening to client needs, understanding the expectations of regulatory bodies, and delivering high quality work with our St. Louis Medical Device Testing team." Dr. Lee added, "The St. Louis Chemistry team, which traces its roots to 1959 when the company was founded by Dr. Clara Craver as ChemIR, offers a large suite of investigative analytical testing for a wide range of industries, including medtech and pharma. We are very excited about this move."

The addition of the St. Louis teams strengthens Eurofins Medical Device Services' position as a solutions partner as it remains steadfast in its mission: to build what's next in medical technology, grounded in scientific excellence and client-centered innovation.

To learn more about the enhanced capabilities and the ways Eurofins Medical Device Services is building what's next in MedTech, visit www.eurofins.com/medical-device/testing/together-were-building-whats-next/ or contact your account manager for personalized guidance.

Global Expertise | Local Access | Proven Results

From prototype to patient: why medical device developers need more than testing

Jessi Dōne, Sr. Director of Microbiology & Sterilization, Medical Device Services

Continued from front page

Safety, usability, and regulatory alignment ultimately determine success. Increasingly, manufacturers are turning to partners like Eurofins not just for testing, but for integrated, strategic support across the development lifecycle.

Rethinking when biological evaluation begins

Biological testing is often treated as a late stage requirement, but delaying it can lead to failures, redesigns, and regulatory setbacks. Aligning with ISO 10993 early enables creation of a Biological Evaluation Plan (BEP) tailored to device materials, contact duration, and clinical use. Early toxicological input helps teams make informed design and material decisions before they become costly to change—shifting biocompatibility from a compliance task to a design driver.

Building a complete biological profile

A device's biological safety profile must be developed systematically. Foundational tests—cytotoxicity, sensitization, and irritation—establish baseline compatibility. Devices with prolonged or invasive contact require deeper evaluation, including systemic toxicity, genotoxicity, and pyrogenicity. Blood contacting devices undergo hemocompatibility testing to assess coagulation and immune interactions. Implantable devices add *in vivo* studies to evaluate long term tissue response. Together, these assessments create a comprehensive understanding of biological risk rather than isolated test results.

Microbiology: ensuring clean, controlled, and sterile products

For sterile or reusable devices, microbiological control is essential. Key evaluations include bioburden quantification, sterility testing, bacterial endotoxin testing, and environmental monitoring of manufacturing spaces. These studies support both initial approval and ongoing quality management.

Reprocessing: safety across reuse cycles

Reusable devices must remain safe after repeated cleaning and sterilization. Reprocessing validation confirms that devices can be effectively cleaned, disinfected or sterilized, dried, and maintained without functional or material degradation. Studies typically include simulated use, worst case contamination, cleaning efficacy, sterilization validation, and post cycle integrity testing. Regulators expect robust evidence that devices remain safe throughout their intended lifespan.

Usability as a core safety requirement

Even a biologically and mechanically sound device can pose risks if users cannot operate it correctly. Human factors engineering identifies use related risks, validates critical tasks, and ensures devices can be used safely in real world conditions. Regulators increasingly require this evidence, recognizing that usability is inseparable from overall safety.

EO sterilization: a critical enabler for sensitive devices

Ethylene oxide (EO) sterilization remains essential for many heat and moisture sensitive devices. Eurofins supports EO sterilization through development scale chambers and expert guided cycle development, validation to ISO 11135, pilot scale processing, and requalification support. Addressing sterilization early reduces risk and prevents costly redesigns tied to material compatibility, packaging, or regulatory strategy.

Extending safety beyond the device

As commercialization nears, packaging, distribution, and aging studies become critical. Packaging must maintain sterility and integrity through transport and storage. Distribution testing simulates real world stresses, while aging studies establish shelf life. Each element represents a potential failure point if not addressed holistically.

The regulatory lens

Successful submissions—whether 510(k), De Novo, or PMA—depend on aligning testing strategies with regulatory expectations and sequencing studies appropriately. Early engagement with regulators helps clarify requirements and reduce uncertainty.

From service provider to strategic partner

Fragmented testing and consulting approaches introduce inefficiency and risk. Integrated partners like Eurofins provide coordinated expertise across toxicology, microbiology, human factors, packaging, sterilization, and regulatory strategy. This model improves study design, accelerates issue resolution, and enhances the overall development experience. Ultimately, success is defined not by passing tests, but by delivering safe, reliable devices to patients. For more information, visit: *Eurofins.com/medical-device*

FDA's policy pivot – impacts of CDRH 'leveling up' use of guidance documents

Hal Stowe, Senior Manager, Regulatory Intelligence, Eurofins Medical Device Services

Continued from front page

The guidance process also provides an opportunity for public comment on proposed updates—an important public-private mechanism to protect patients while mitigating innovation bottlenecks. When that process is bypassed, uncertainty often follows.

In Q1 2026, the FDA's Center for Devices & Radiological Health (CDRH) signaled a notable shift: using Level II guidance to make substantial updates to existing regulatory frameworks—creating near- and long-term implications for MedTech.

Level II guidance explained

FDA guidance is governed by Good Guidance Practices (21 CFR 10.115), which defines categories (Class I and Class II) and prescribes FDA procedures for development and issuance.

Level I guidance addresses interpretations of statutory or regulatory requirements, significant changes to those interpretations, complex scientific matters, and/or highly controversial issues.

Level II guidance sets forth existing practices or minor changes in interpretation or policy; it also includes documents not classified as Level I.

Level I guidance generally uses draft guidance with public comment. Level II is typically issued faster, with limited stakeholder input; updates are effective immediately (or as specified). The distinction is illustrated by the Jan 6, 2026 updates to *Clinical Decision Support Software* and *General Wellness: Policy for Low Risk Devices*. The changes were substantial, which many stakeholders viewed as more consistent with Level I processes. The choice of Level II signals a shift in CDRH's mechanism for updating policy, aligning with the Administration's deregulatory agenda.

The shift & its implications

These guidance areas have long attracted varied interpretations about applicability and enforcement. Against that backdrop, CDRH's use of Level II guidance—bypassing public comment—is notable for avoiding stakeholder-driven clarification. This is especially visible in the General Wellness update, where added interpretive scenarios appear to conflict with prior understandings. On issuance, FDA Commissioner Makary said the intent was, "*to cut unnecessary regulation and promote innovation,*" consistent with an overarching *deregulatory agenda*. In practice, this approach all but eliminates the ability to issue Level I guidance, pushing CDRH toward faster, less procedurally burdensome mechanisms that omit industry comment.

Key policy areas affected

Sponsors should track three key areas affected by CDRH's shift in guidance policy:

1) Clinical Decision Support (CDS) software: the update significantly narrows the scope of software regulated as a medical device. Introduces enforcement discretion for certain functions that provide a single "clinically appropriate" recommendation.

2) General wellness products: updates expand products exempt from FDA regulation, allowing non-invasive wearables that measure variables such as blood pressure and blood glucose to be marketed for general wellness without premarket review.

3) Real-world evidence: final guidance on real-world evidence is expected in FY2026.

CDRH's full FY2026 guidance agenda is available *here*.

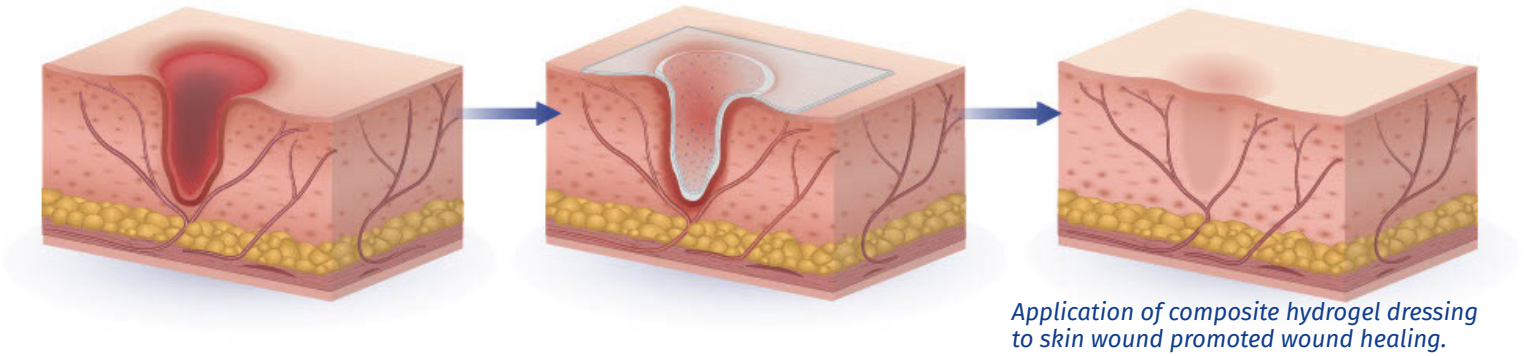
Impact on startups and commercial-stage companies

For startups, Level II guidance is a double-edged sword. For Digital Health & Wellness products, reduced barriers may lower market-entry costs and accelerate time-to-revenue. But without public comment, expectations can shift with minimal notice, creating regulatory risk that is often intolerable for startups with limited risk-absorption capacity.

For commercial-stage sponsors, CDRH's agenda signals direction but is not definitive. Regulatory intelligence becomes essential: track CDRH updates, assess potential impacts, and audit existing CDS or General Wellness claims against revised guidance. When applicability is unclear, sponsors should use external resources to support near-term compliance and long-term strategy.

In this environment, regulatory policy may feel like a gray area. For startups and commercial-stage companies navigating this uncertainty, regulatory intelligence must be corporate infrastructure. Eurofins' regulatory intelligence and policy experts are your guide in navigating the nuance of current, and future, Level II guidance. That expertise, partnered with our leading medical device testing capabilities, takes strategy beyond the bench. For more information, contact us at: ***Medical-Device@BPT.EurofinsUS.com***

Human Factors in biomaterials: a practical advantage for product development and regulatory success



Application of composite hydrogel dressing to skin wound promoted wound healing.

Christina Mendat, Vice President, Eurofins Human Factors MD

Why this matters now

Biomaterials are sometimes treated as "straightforward" to evaluate because performance testing and biocompatibility data do so much of the heavy lifting. In practice, however, real world outcomes also depend on how clinicians interpret labeling, choose application techniques, and integrate a biomaterial into established standards of care. For product developers, human factors (HF) methods provide a structured way to surface these use-related variables early, supporting design decisions, strengthening risk management, and building clearer regulatory rationale.

Human factors isn't just for active devices

HF engineering is often associated with active medical devices, delivery systems, and combination products, but the same principles strengthen biomaterials programs. Even when the intended user is a trained healthcare professional, variability in experience, time pressure, and site practices can influence whether the product is applied as intended—and whether key limitations are recognized at the point of use.

As biomaterials diversify in mechanism and handling requirements, HF studies can confirm that the "product system" (packaging, labeling, instructions, and workflow fit) reliably supports correct use across care settings.

The Role of Human Factors in biomaterials evaluation

Traditional biomaterials testing focuses on material properties, sterility, degradation, and biological response. HF complements these evaluations by addressing how users interpret the instructions for use, make choices during application, and incorporate the biomaterial into existing clinical workflows.

In biomaterials programs, HF evaluations can include:

- Understanding of intended use and limitations
- Interpretation of labeling and instructions
- Application techniques and dosing assumptions
- Compatibility with existing standards of care
- Recognition of contraindications and warnings

This perspective is especially useful when formal training is limited or inconsistent, or when products are used across multiple sites of care.

Labeling as a high value risk control

HF testing often shows that the most important information—contraindications, application limits, and compatibility considerations—needs to be easy to find, easy to scan, and clearly differentiated. Content that is technically present but hard to locate (or embedded in dense text) is less likely to be used at the moment it matters.

Because training approaches can vary by site and over time, HF practice encourages designing the full product system (including packaging, labeling, and instructions) to support safe and effective use without relying on memory or specialized experience. In wound care, where users may range from highly specialized clinicians to generalists working in diverse settings, this design-for-clarity approach is particularly impactful.

What to do with this: practical takeaways

For developers and regulatory teams, HF offers a practical bridge between design intent and real world use. It strengthens your usability related risk analysis, clarifies labeling rationales, and generates evidence to support safe and effective use in the intended environment.

- Build HF checkpoints into development: evaluate use steps, decision points, and workflow fit before design is "locked."
- Treat labeling and instructions as design outputs: test for findability and comprehension, not just completeness.
- Use HF results to support regulatory narratives: connect observed use needs to mitigations and risk controls in your documentation.

By incorporating human factors testing early and iteratively, developers can identify and mitigate use related risks that may otherwise go undetected until post market use. This approach supports regulatory expectations, product adoption, correct usage, and patient outcomes. For more information, visit: *Human Factors MD - Human Factors, Medical Devices*

Understanding needle-based combination product design verification and validation

Tyler Harris, Senior Scientific Advisor; Ryan Bair, Manager of Medical Device Package Testing/CCIT; Medical Device Services, Christina Mendat, Vice President Eurofins Human Factors MD

Bio/pharmaceuticals have rapidly shifted from conventional small-molecule products to complex biologic modalities, often delivered by injection. Historically, administration occurred in medical facilities by healthcare professionals. Over the past decade, new product configurations have accelerated growth and shifted point-of-care administration to the home through combination products.

Combination products may be device-led or, more commonly, drug-led. Device constituents include auto-injectors, prefilled pens, and on-body delivery devices (OBDD), with automated or semi-automated features that require in-depth design verification and usability testing.

Design verification

For drug-led combination products, design verification demonstrates the system meets mechanical, functional, stability, and user requirements so both drug and device constituents perform under expected use conditions. Design Verification Testing Protocols vary by intended use, critical quality attributes (CQAs), critical material attributes (CMAs), usability, regulatory expectations, and risk.

Requirements and compliance

Combination products are regulated by the agency overseeing the primary mode of action. For drug-led devices, CDER provides final product approval, while the device constituent must still comply with applicable CDRH requirements.

Risk (ICH Q9 and ISO 14971) and Quality by Design (ICH Q8) underpin design and design verification by encouraging a holistic view of the device and drug constituents across the product lifecycle.

Component level

Each configuration needs a tailored set of component-level assessments (e.g., primary and secondary containers) to confirm functionality and build a foundation that reduces primary-container risk. Standards and guidance, including ISO 11040-4/-6/-8, ISO 80369-20, ISO 11608-3, and USP <382> address elastomer performance, physio-chemical interactions between drug and package, container closure integrity, and standardized dimensions. Testing includes:

- Break-loose force
- Extrusion force
- Closure system liquid leakage
- Tip-cap pull off force
- Inherent integrity
- Needle self-sealing capacity

Assembled level

Assembling the primary container into the device constituent warrants additional assessment of the resulting combination product. Complex mechanical systems can fail due to manufacturing issues (e.g., injection molding processes), fitment problems, and assembly variability. Guidance and standards for assembled needle-based injection systems (e.g., ISO 11608-1, ISO 11608-5, FDA Guidance for Industry) emphasize mechanical, automated, and usability specifications, and provide data to support design verification.

Usability and human factors

Component performance can look acceptable in bench testing yet create real-world challenges for intended users that reduce usability and market viability. For example, excessive break-loose or cap-removal force may cause sudden release and physiologic hand rebound, increasing the risk of inadvertent needle exposure, accidental activation, or loss of control. If the force needed to overcome break-loose is too high, users may experience strain or injury, incomplete dose preparation, or unintentional medication loss.

At the assembled level, user-based testing should include early-stage, formative, and late-stage (end-stage) evaluations, since user performance can only be validated on the final finished product.

Conclusion

Safeguarding patient safety starts in the design phase and continues through the product lifecycle. Testing and inspection support this goal by helping deliver quality, user-friendly needle-based injection systems. Eurofins supports manufacturers by expanding our auto-injector testing footprint and onboarding universal test systems that can sequentially measure cap removal, activation force, deliverable volume, click detection, injection time, needle depth, and needle lockout. This approach can reduce sample quantity needs, lead times, and cost. For more information, contact us at: *Medical-Device@BPT.EurofinsUS.com*

EO Sterilization in transition – regulatory shifts & industry impact

Jessi Dōne, Sr. Director of Microbiology & Sterilization, Medical Device Services

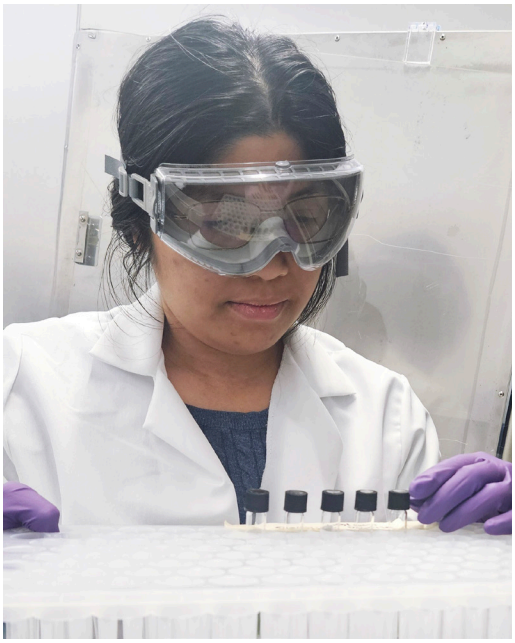
Ethylene oxide (EO) sterilization remains essential to the medical device industry, responsible for sterilizing nearly half of all devices. Its ability to penetrate complex geometries and sterilize heat- and moisture-sensitive materials makes it indispensable, despite increasing environmental and health concerns.

However, recent regulatory changes—including updates to NESHAP under the Clean Air Act, FIFRA, and evolving ISO standards—are significantly reshaping EO sterilization practices. Manufacturers must now reassess sterilization cycles, validate EO residuals, and work closely with service providers to maintain compliance, protect patient safety, and avoid delays or regulatory setbacks.

Stricter regulations reshape compliance - NESHAP & FIFRA updates

The EPA's March 2024 NESHAP amendments require EO sterilization facilities to achieve further emissions reductions through enhanced emissions capture, control technologies, and monitoring. Compliance timelines are phased, with most facilities expected to meet requirements by 2026–2027.

FIFRA introduces additional constraints, including a cap of 600 mg/L per sterilization cycle by 2035 unless otherwise justified, and a reduction in worker exposure limits from 1 ppm to 0.1 ppm. These changes are driving upgrades in ventilation and monitoring systems, longer aeration times, and widespread revalidation of sterilization cycles.



Impact for manufacturers

Manufacturers must evaluate existing sterilization cycles and processes to ensure compliance while maintaining sterility assurance. This includes reassessing validated products and implementing process adjustments to meet standards.

ISO standards add complexity - ISO 11135 and ISO 10993-7

Proposed updates to ISO 11135 and revisions to ISO 10993-7 introduce more rigorous expectations. ISO 11135 continues to guide the development, validation, and control of EO sterilization cycles, while ISO 10993-7 establishes updated EO residual limits using a more detailed, risk-based framework. Manufacturers will need to reassess cycle parameters, validate modified processes, and ensure EO residuals meet stricter limits—particularly for pediatric and sensitive populations. Residual calculations now incorporate body mass and device usage, increasing the need for robust documentation and risk assessments.

Evolving approach to EO cycle development

The proposed ISO 11135 revisions encourage a shift toward biologically based sterilization strategies. Rather than defaulting to traditional overkill methods, manufacturers are guided to tailor cycles based on actual microbial challenges and product characteristics. This enables optimized EO usage, reducing environmental impact and residuals while maintaining required sterility assurance levels. Additional emphasis is placed on:

- Design and selection of process challenge devices (PCDs)
- Standardization of biological indicators
- Packaging performance, including EO, moisture, and heat transfer characteristics

These factors are critical to ensuring effective sterilization and minimizing EO residuals.

Navigating revised EO residual limits

The updated ISO 10993-7 framework applies a risk-based approach to EO residuals, factoring in body mass, duration of use, and frequency of exposure. A standard adult body mass of 60 kg is now used, with lower values applied to children, infants, and neonates—often resulting in stricter residual limits.

The standard also introduces a concomitant exposure factor to account for multiple devices used simultaneously, as well as detailed calculations based on duration and frequency of use. These changes require comprehensive documentation, risk assessments, and testing strategies.

Gap assessments are critical to determine whether devices and packaging configurations meet new limits. Devices intended for lower body mass populations or specialized use cases, such as intraocular devices, require particularly stringent evaluation due to higher sensitivity to EO exposure.

Reevaluation and compliance strategy

Reevaluating EO sterilization processes requires a holistic review of product history, cycle performance, microbiological data, and prior EO residual results. Manufacturers must develop structured reevaluation plans, including protocol design, testing strategies, and validation updates.

Master change with Eurofins Medical Device Services

Given the scope of regulatory changes, manufacturers will need to reevaluate previously validated products and sterilization cycles. Eurofins Medical Device Services supports this transition with:

- EO cycle development and optimization
- Revalidation aligned with updated standards
- EO residual testing and risk-based assessments
- Regulatory guidance and documentation support

Through a collaborative and end-to-end approach, Eurofins partners with manufacturers to navigate complex requirements, maintain safety and quality standards, and avoid costly delays or supply disruptions—ultimately reducing risk and accelerating time to market. For more information, visit: *Eurofins.com/medical-device*

Engage with our experts

Visit our teams at these upcoming trade shows and find out how we can solve your medical device and consulting challenges.

thePACKout
May 11-14
Oxon Hill, MD

The MedTech Conference
Oct 18-21
Boston, MA

MedTech Strategist Innovation Summit
Nov (TBD)
San Diego, CA

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Need a testing partner for your biocompatibility, chemical characterization, and toxicological risk assessment needs?

Schedule a time with our Head of Regulatory Toxicology, Kimberly Ehman, PhD DABT, to discuss your biological test program. Kim has 20+ years of regulatory toxicology and medical device expertise. She and her team are here to help clients navigate dynamic regulatory environments and ensure compliance with the current versions of ISO 10993 as well as current FDA expectations.

Contact Kim at: *Kimberly.Ehman@bpt.EurofinsUS.com.*

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