INSIDE STORY

Eurofins Scientific (Brussels) may be an unfamiliar company to many U.S. device manufacturers – but maybe not for long. Eurofins is an international laboratory services company that provides an array of testing services, annually performing more than 150 million tests to establish the safety, composition, traceability, and purity of chemical and biological substances, components, and manufactured products. The company's network of more than 250 laboratories in 39 countries includes a new business unit – Eurofins Medical Device Testing – that has already become an emerging force in lifecycle testing for medical products worldwide. To find out more about the expertise that Eurofins brings to this area, and the company's plans for expansion into the United States, *Medical Design Briefs* recently spoke with Christopher Scott, vice president of Eurofins Medical Device Testing.

***MDB*: In Europe, Eurofins laboratories have performed analytical testing for a wide range of industries. How has this experience contributed to the company's acknowledged expertise in testing for life sciences companies?**

Scott: The core competencies that Eurofins has demonstrated in supporting these other industries provide a strong basis for its increasing focus on medical device testing. With more than 120 experienced PhDs specializing in bioengineering, chemistry, microbiology, and toxicology across 16 facilities, each of our laboratories contributes an element of technical expertise and capability that strengthens the overall network, and in-depth knowledge of the local operating and regulatory environments specific to the medical device industry.

***MDB*: What opportunities led Eurofins to launch its new business unit focused on medical devices, and why was the United States selected for its headquarters?**

Scott: The device industry is becoming more global. For example, a device company based in the United States might manufacture its product in Asia, and seek CE marking in Europe. In order to address logistical and local regulatory considerations, clients require a qualified testing partner that operates in all of those regions. With many of the world's largest device manufacturers located in the United States, it was a logical decision to headquarter Eurofins Medical Device Testing at our state-of-the-art 71-acre campus in Lancaster, PA.

***MDB*: What types of testing services offered by Eurofins will be most in demand by medical device manufacturers?**

Scott: FDA recognizes more than 1,000 consensus standards as relevant to medical devices, with some standards comprising well over a dozen individual tests. Additionally, innovative product designs require many customized test methods. With core strengths in analytical chemistry, biocompatibility, mechanical and electrical testing, and microbiology, Eurofins is uniquely capable of addressing a wide range of needs for this industry.

***MDB*: Let's talk about a few of these areas in more detail. Physiochemical analyses are often a company's first line of defense against improperly formulated materials and components. What kinds of tests does Eurofins perform in this area?**

Scott: Eurofins Medical Device Testing can perform the full range of ASTM, ISO, and USP tests to thoroughly characterize the physiochemical properties of a raw material or finished device. These tests are necessary for meeting the verification requirements for a new product design, including assessments of the effects of sterilization techniques, long-term aging, and *in vivo* stability. This type of testing is also relevant for qualifying new raw materials suppliers, or for ongoing product release testing.

***MDB*: Biocompatibility has always been a major concern for medical products – and especially for implantable devices. What kinds of services does Eurofins offer in this area, and what kinds of testing are involved?**

Scott: As described in the series of standards for the biological evaluation of medical devices compiled by the International Organization for Standardization (ISO 10993), the general workflow for biocompatibility begins with a full chemical characterization, including extractables and leachables testing, followed by a toxicological risk assessment to determine what additional animal testing may be necessary.

***MDB*: For many types of devices, including implantables, microbiology and sterility testing are essential for product release. But validation of package integrity for maintaining sterility is just as important. What types of testing does Eurofins perform in these areas?**

Scott: The connection between package and sterility testing is critical when validating any device that is shipped sterile to the end-user. Confirmation of appropriate dosing for a terminally sterilized product must be combined with a robust testing program to ensure that the packaging design will enable the product to survive the rigors of the entire distribution chain with its sterile barrier intact.

Eurofins has a state-of-the-art package testing facility capable of assessing the entire range of packaging, from primary sterile-seal integrity through full pallet-level transit testing, and integrity testing for unique device identifier labeling. Additionally, with nearly 200,000 ft^3 of continuously monitored environmental chambers, we offer tremendous capacity for accelerated and real-time shelf-life studies.

To find out more about Eurofins Medical Device Testing, visit the full-length version of this interview, available online at ***www.medicaldesignbriefs.com/InsideStory0217.***