



# BioPharma Services News

**BIO/PHARMA - MEDICAL DEVICES - COSMETICS - BIOCIDES**

## Next Generation Sequencing revolutionises adventitious virus detection

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Adventitious virus detection is an integral part of safety testing of biopharmaceutical products. Viral detection methods currently considered as industry standard generally fall into two categories: (1) broad spectrum screening assays such as cell culture (*in vitro*) and animal (*in vivo*) based testing and transmission electron microscopy (TEM); (2) target specific assays (typically qPCR). While broad spectrum screening assays are able to detect a wide range of viruses, some may remain undetected due to diverse viral physiology and limitations in assay sensitivity. Target specific qPCR methods on the other hand are often highly sensitive, but can only detect pre-defined/known target(s). These target specific approaches are therefore used more often as tools to aid the investigation after a positive result has been identified during the broad screening assays.

Recently, Next Generation Sequencing (NGS) technology has revolutionised genome sciences. In recent years, NGS has been successfully adopted for the purpose of adventitious virus detection. NGS allows deep sequencing of all nucleic acids present in a given sample. When coupled with powerful bioinformatics, this has the potential to overcome the existing practical challenges and to provide a universal platform for not only detecting, but also identifying viruses with high sensitivity. Currently, the BioPharm industry continues to make ongoing efforts to optimise the assay and identify best practices for the full leverage of the many advantages NGS can offer to adventitious virus testing.

To this end, Eurofins Lancaster Laboratories and Eurofins Genomics (Ebersberg) have partnered and performed several successful NGS studies where contaminating viruses were quickly identified in biopharmaceutical samples of various matrices. With a turnaround time of preliminary results as quick as within one week, the findings have helped clients quickly identify the root cause of the contamination and implement appropriate corrective and preventative actions. It is also interesting to note that in a few cases, NGS was able to confirm that putative positive results were not related to viral contamination but rather false positive results due to the nature of sample/sample matrix, therefore allowing clients to avoid unnecessary and costly rejection of the manufactured materials. In addition to offering NGS testing services to our clients, Eurofins Lancaster Labs and Eurofins Genomics are also active members of the Advanced Virus Detection Technologies Interest Group (AVDTIG), a task force coordinated by PDA and joined by regulatory and industry experts. For more information, visit:

[www.eurofins.com/biopharma](http://www.eurofins.com/biopharma);  
[www.eurofins.com/genomic-services/our-services/next-generation-sequencing/](http://www.eurofins.com/genomic-services/our-services/next-generation-sequencing/)

## Eurofins Scientific celebrates 30<sup>th</sup> Anniversary

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Eurofins Scientific was founded in 1987 as a small start-up with just four employees, based on the SNIF-NMR<sup>®</sup> method developed by Dr. G. and M. Martin at the University of Nantes in France. The method was used initially to detect the addition of sugar during winemaking to increase its alcohol content, called chaptalisation.

In 2017, Eurofins is 30 years young, and we believe that's a good reason to celebrate. We're recognising what we've achieved over the past three decades and the difference we make every day. We're paying tribute to all the remarkable people who have contributed to our success story. And we're celebrating the vision of a healthy and safe life for everyone on earth.

Over the last 10 years, Eurofins has donated to many charities around the world. As a Group, we support various social projects and charitable works throughout



the year as part of our continuous commitment to contribute to the improvement of health and protection of the environment.

On the occasion of this 30<sup>th</sup> Anniversary, Eurofins has also decided to donate 1 million Euro on behalf of all employees to 40 charitable organisations across all continents. These charities have been chosen because their work is consistent with Eurofins' DNA: better nutrition, improved health, protecting the environment, social entrepreneurship and supporting local communities.

Today, Eurofins Scientific has grown to become a leading international Group of laboratories, providing a unique range of analytical testing services to the bio/ pharmaceutical, food, environmental and consumer products industries and to governments with more than 30,000 employees and 400 sites in 41 countries.

## Eurofins' commitment to alternative methods for Medical Device Testing

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Skin irritation is considered an essential endpoint for the biological evaluation of medical devices. Reconstructed human epidermis (RhE) are widely used to assess skin effects for chemical and cosmetic products while the current version of ISO 10993-10 "Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitisation" still includes *in vivo* tests.

Two Eurofins Medical Device Testing laboratories in Milano and Munich, along with 17 other laboratories were involved in an international Round Robin Study aimed to evaluate the RhE method for determination of skin irritant potential of medical device extracts.

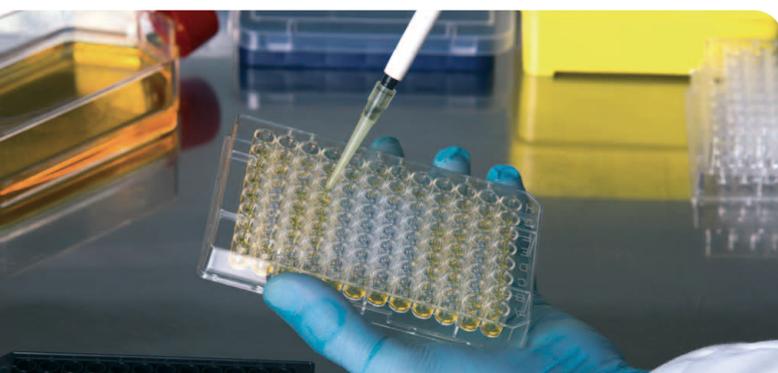
Two models (MatTek EpiDerm<sup>™</sup> and SkinEthic<sup>™</sup> RHE) were used during this study.

Four irritant and three non-irritant polymers were specifically prepared and used as positive and negative samples. The samples were extracted according to ISO 10993-12 "Biological evaluation of medical devices - Part 12: Sample preparation and reference materials," using a surface/volume ratio of 3cm<sup>2</sup>/ml or weight/volume ratio of 0,2g/ml, at a temperature of 37±1°C for 72±2 hours under agitation with saline and sesame oil. 100µL of these extracts were dosed on the tissues.

After 18 hours (EpiDerm<sup>™</sup>) and 24 hours (SkinEthic<sup>™</sup> RHE) of incubation at 37°C, 5% CO<sub>2</sub>, 95% humidified atmosphere, the viability of the tissues was determined. The viability was based on cellular reduction of MTT (methylthiazolyldiphenyl-tetrazolium bromide) and subsequent conversion to a purple formazan salt that is quantitatively measured by a spectrophotometer.

The cell viability reduction was calculated comparing treated tissue with negative control tissue. A sample was considered irritant in case of a cell viability reduction greater than 50%. All data showed that both the two RhE models were able to correctly identify irritant materials.

The results indicate that RhE tissue models can detect strong skin irritants at low levels in extracts of medical devices and these models are suitable replacements for *in vivo* irritation tests. For more information, visit: [www.eurofins.com/medical-device/](http://www.eurofins.com/medical-device/)



## Eurofins Pharma Bioanalytical Services launches new Consulting Business

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Capitalising on a growing client need for access to high levels of large molecule GLP expertise for special, often short-term, consults when it is not feasible to utilise in-house experts, Eurofins Pharma Bioanalytical Services has established a new service line to provide the quality and regulatory expertise and experience required in conducting and reporting new drug clinical study results to regulatory agencies in both the US and EU. Backed by 15 years of experience, Eurofins Bioanalytical Consulting offers a wide range of consulting services in support of proposed and ongoing large molecule bioanalysis.

Eurofins provides on-site or remote scientific resources to meet in-house bioanalytical needs or to resolve issues. The team can develop a comprehensive bioanalytical programme for drug candidates, provide method troubleshooting services, monitor and review method validation and sample analysis activities, perform pre-qualification and final study data audits. Working in tandem

with clients, Eurofins Consulting strives to ensure that bioanalytical methods, processes and data are scientifically sound, accurate, and suitable for regulatory submission.

Delivering scientific expertise, training to improve assay ruggedness and increase laboratory efficiencies, Eurofins is dedicated to meet clients' rigorous needs with an emphasis on the design of large molecule bioanalytical programmes, preparation of protocol synopses, and development of reports at various levels of detail summarising findings. Combining technical knowledge, capacity, regulatory expertise and global presence, Eurofins Consulting is uniquely qualified to provide clients with the reliability they can trust. For more information, visit [www.eurofins.com/biopharma-services/bioanalysis/](http://www.eurofins.com/biopharma-services/bioanalysis/)



## Biopesticides: Eurofins supports analytical regulatory registration in EU and US-EPA

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The increase in the numbers and types of microbial pesticides and their uses as plant protection and biocidal products has come about as a result of innovation in the industry and of the need to



produce more targeted and sustainable products.

Microbial pesticides specifically include any microbiological entity, including lower fungi and viruses, cellular or non-cellular, capable of replication or of transferring genetic material (in accordance with the definition used in the EU Regulation (EC) No 1107/2009).

The properties of living microbial pesticides differ from the properties of chemical pesticides, not least because microorganisms have the capability of propagation. Based on these differences, the type and level of

regulatory requirements for microbial pesticides can be challenging.

In particular, the characterisation of microbial pesticides involve many different types of expertise. Genotyping to identify the active ingredient at strain level is normally required as well as a sound experience in classical microbiology and microbial method validation to quantify the active ingredient content and the microbial pathogenic impurities in the formulation itself and different matrices (for instance, drinking water).

Furthermore, OECD *in vivo* technical guidelines for chemicals should be evaluated, and proposals for adaptation to microorganisms should be made in different ways, including parameters such as growth temperature, O<sub>2</sub> and CO<sub>2</sub> concentration and so on.

Alternative methods and their results should also be taken into account, such as US EPA 885 technical guidelines, specifically validated for microbial pests.

With comprehensive Biopest expertise, Eurofins BioPharma Product Testing has responded to the growing market needs and established global laboratory teams specifically dedicated to the study of microbial pests to support manufacturers with their successful submissions of their innovative and beneficial products to the EU and US highly regulated markets. For more information, visit: [www.eurofins.com/biopharma](http://www.eurofins.com/biopharma)



## Eurofins Scientific expands Contract Development & Manufacturing (CDMO) global footprint

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Eurofins Scientific recently enhanced its leadership in biopharmaceutical services and expanded its Contract Development and Manufacturing (CDMO) offering with several strategic acquisitions, including:

**Eurofins Alphora (Alphora Research Inc.)** is a premier, full-service contract research, development and manufacturing organisation (CDMO) for complex and niche small molecule active pharmaceutical ingredients (APIs). Based in Mississauga, Ontario, Canada, with more than 145 employees and facilities totaling more than 5,500 m<sup>2</sup>, Alphora offers a full spectrum of complex API development, testing and manufacturing services, including extensive capabilities in multi-step syntheses, as well as the development of cytotoxic and highly potent APIs.

**Eurofins Advinus (Advinus Therapeutics)** is a leading preclinical contract research company for Safety Assessment, DMPK, and CMC services, offering end-to-end solutions in the areas of preclinical toxicology testing, API process development and scale up, analytical R&D, drug metabolism and pharmacokinetics, as well as long-term nonclinical toxicology testing, including carcinogenicity studies. The company also supports early clinical development through multi kilo scale API synthesis under cGMP. With over 25 years of GLP compliance and certification, Eurofins Advinus has more than 380 staff and operates

a state-of-the art 20,000 m<sup>2</sup> facility in Bangalore, India.

**Eurofins Amatsigroup (Amatsigroup)** is one of the leading CDMOs in Europe providing high-quality, customised drug development solutions for specialty and biopharma clients, including bioprocess development, biomanufacturing, analytical studies, formulation development and manufacturing (Fill & Finish capacities) of clinical or small commercial batches, as well as complementary services such as preclinical studies, bioanalysis and clinical trial supply. GLP & GMP certified, Eurofins Amatsigroup employs 400 staff and operates eight sites in France, two sites in Belgium and one site in the US, totaling more than 28,000 m<sup>2</sup>.

With the addition of these acquisitions into Eurofins' existing sterile and non-sterile manufacturing sites in the US and Europe, Eurofins is able to support biopharmaceutical companies from the preclinical phase through to commercialisation of niche products. Further, Eurofins can address a wide array of development challenges with a full spectrum of complex drug substance and drug product development, testing and manufacturing services. Globally, Eurofins is well-positioned to support the growing R&D outsourcing needs throughout the North American, European and Asia-Pacific regions. For more information visit: [www.eurofins.com/biopharma](http://www.eurofins.com/biopharma)

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