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News

BIO/PHARMA - MEDICAL DEVICES - COSMETICS - BIOCIDES

Detection of mycobacterium species in qPCR as a consideration for cell banking testing in support of cell & gene therapy manufacturing

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Cell and gene therapies (CGT) are one of the fastest-growing areas of therapeutics and are at the very core of healthcare innovation. Production of cell and gene therapies, often use mammalian cells (cell banks), including human donor/patient cells. Mammalian cells are subject to contamination by viruses, microbes, fungus, or other agents and by mycobacterium. Mycobacterium causes tuberculosis in humans. According to the World Health Organization (WHO) (*www.who.int/news-room/fact-sheets/detail/tuberculosis*), it is estimated that 10 million people globally developed tuberculosis in the year 2020.

Mycobacterium has been a concern in the vaccine industry for many years and now is also becoming a concern among those in the gene therapy industry. Testing for the absence of these organisms is outlined in various regulatory documents, including the Food and Drug Administration (FDA) 2010 Vaccine Guidance as well as WHO's Annex 3 for the Evaluation of Animal Cell Cultures. As per FDA's guidance, if the species from which cells are derived is susceptible to infection with Mycobacterium species, an appropriate test should be performed.

Eurofins BioPharma Product Testing has optimised and validated a platform real-time PCR method to test for the presence of mycobacterium species in cell lines used for vaccine and cell and gene therapy production. The assay has the ability to detect *Mycobacterium tuberculosis complex (MTBC) DNA, including M. bovis, M. tuberculosis, M. microti, M. caprae, M. pinnipedi, M. africanum, and M. canetti* (species pathogen affecting human and animals). Validation was based on FDA ICH Harmonised Tripartite Guideline, Q2 (R1), and the standard testing is conducted under current Good Manufacturing Practices (cGMP). The PCR method has a detection limit (LOD) of 16 copies of nucleic acid per PCR reaction and does not require extensive suitability/interference testing. Matrix interference evaluation is included in standard sample testing with a control included in each assay performed. This rapid, standard assay has very quick turnaround time (one week or less).

Historical mycobacterium test methods utilised an *in vitro* approach. With the speed the CGT industry is moving, innovative approaches will be needed to address TAT required as well as increased testing volumes. The Eurofins BioPharma Product Testing mycobacterium complex PCR detection method only requires 1-2mL of sample and the certificate of analysis can be issued in 10 days or less.

In addition to mycobacterium, microbial testing (sterility), mycoplasma testing, and viral adventitious agent testing are all required to ensure a cell line is safe to be used for viral vector and vaccine production. Eurofins BioPharma Product Testing can provide the full GMP biosafety testing package for global clients working to meet regulatory requirements and ensure product safety for their clinical trials and/or commercial molecules. ***Contact us*** to learn more.

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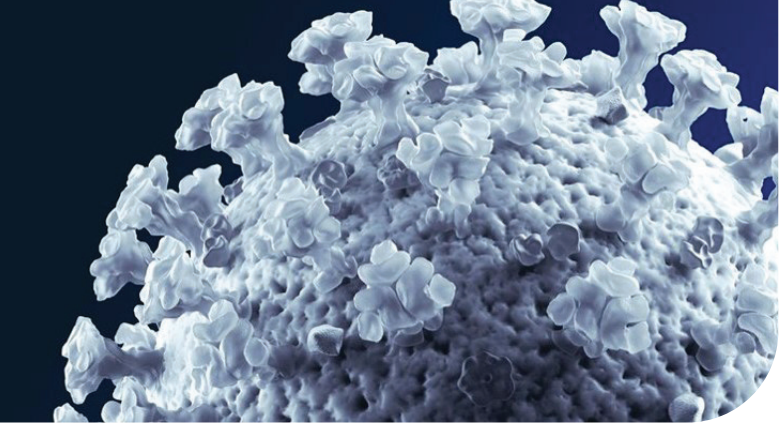

Eurofins enhances vaccine development services

Sandra Hageman, Director of Marketing, Eurofins BioPharma Services, Laboratory Testing, SandraHageman@eurofins.com

Vaccine development has historically been a long, complex process, requiring evaluation of immunogenicity, safety and protective efficacy. Given this complexity, many factors can affect the probability of licensure and ultimately, public health impact. The COVID-19 pandemic has shifted understanding of what's possible in terms of fast-track vaccine development to address the public health emergency whilst maintaining standards of quality, safety and efficacy.

As experts in infectious disease assays, Eurofins Viracor BioPharma Services offer a broad array of testing solutions for biomarker detection, immunogenicity, and other safety and efficacy assessments to support anti-viral and clinical vaccine candidate programmes. Eurofins Viracor BioPharma supported the assay development, validation and testing of the Moderna mRNA-1273 COVID-19 vaccine candidate.

Eurofins Vaccine Development Services is comprised of Eurofins Viracor BioPharma Services, Eurofins Central Laboratory, Eurofins Bioanalytical Services and Eurofins CDMO; each company collaborates with each other and brings a unique set of capabilities to the mix to support vaccine development programmes from pre-clinical to human pharmacology studies (phase I trials), therapeutic exploratory studies (phase II), clinical vaccine efficacy and safety studies (phase III) and post authorisation surveillance studies (phase IV).

Further, Eurofins CDMO supports the development and manufacturing process of vaccine candidates for clinical trials worldwide.

Eurofins Vaccine Development Services supports multi-center, multi-country studies in over 85 countries worldwide. With large sample numbers distributed across many locations, the need for expert global logistics support to maintain specimen integrity, quick turnaround time of results and globally combinable data is key, and Eurofins companies are the go-to partners to support global vaccine development programmes. For more information, visit: *www.eurofinscentrallaboratory.com/vaccine-development/*

Simplifying the audit process for drug manufacturers

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Drug manufacturers must comply with the stringent regulatory requirements of GxP in order to develop and provide safe drugs to the market. Compliance is determined through regular audits of suppliers. Over the past number of years, the amount of supplier audits has drastically grown due to increasingly stringent regulations, which has led to an added challenge for suppliers to host many audits and for audit sponsors who accrue higher costs.

To smoothen the supplier auditing process, Eurofins Healthcare Assurance, as a 3rd party GxP and quality assurance audit provider, proposes:

- Shared audits
- Access to an extensive audit report library

How shared audits can simplify

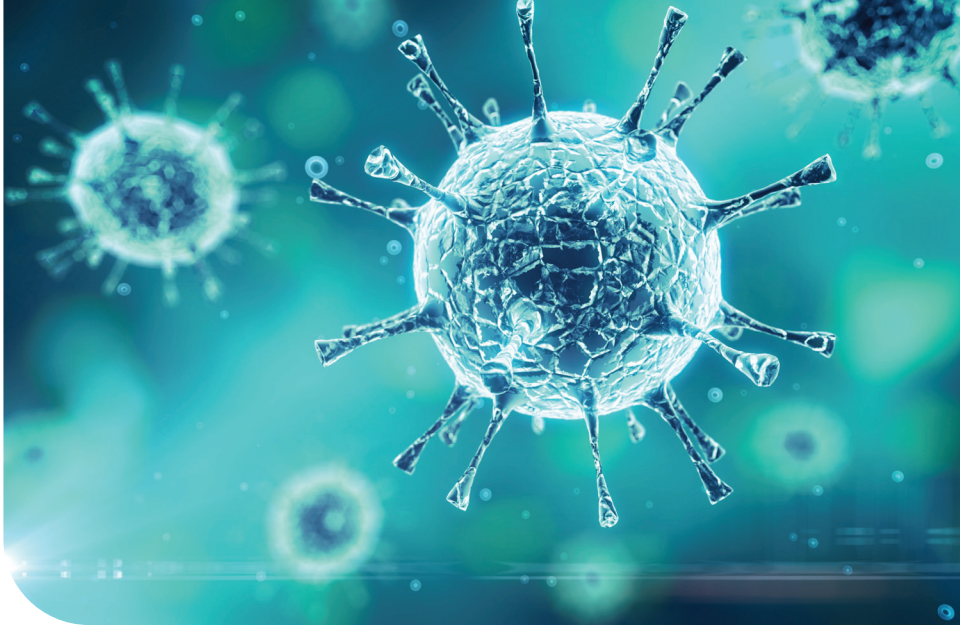
A shared audit is auditing one supplier site on behalf of several drug manufacturers. This means that the cost of the audit is shared by the manufacturers and that the audited supplier sites will have to host only one audit instead of several.

As a 3rd party audit provider, Eurofins Healthcare Assurance will take care of the whole audit organisation, which results in smooth audit scheduling and lower costs for manufacturers. It also lowers the burden for the audited sites to welcome auditors. Audits manufacturers' names are kept confidential and are provided a final report that contains specific information about material of interest for each one of them.

Benefits of our audit report library

For drug manufacturers who require immediate access to an audit outcome and insights, existing audit reports are made available in our extensive library, which contains more than 700 reports, validated within the last three years or less. Every purchase request is treated with the highest level of confidentiality, and reports are only shared with the agreement of the audited site. Our unique report library is accessible here: *www.eurofins.com/pharmasharedaudits*.

Eurofins Healthcare Assurance experts have more than 20 years of experience in the healthcare industry and can support manufacturers with the highest level of quality, in a cost-effective and time efficient manner.



Eurofins BPT Italy expands efficacy testing capacity and capabilities against viruses

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During the SARS-CoV-2 pandemic, market demand for testing the virucidal efficacy of hand hygiene products, surface sanitizers and disinfectants as well as articles treated with permanent antiviral coatings against coronaviruses, reached an unprecedented historical peak.

The effects of the COVID-19 pandemic can still be felt today, with many healthcare institutions paying significant attention to and interest in emerging and re-emerging viral pathogens, in order to preempt and be prepared for future public health challenges.

Considering this market need, Eurofins BioPharma Product Testing Italy has increased its testing capacity with a new dedicated laboratory area, and has continued developing its viral library with new viral models (e.g., respiratory viruses such as influenza viruses H1N1 and H3N2, or RSV) in order to support customers to test for both seasonal epidemic events and new emerging viruses, with validated and internationally recognised test methods.

Testing capability is not just limited to a large viral library but also includes different product typologies, such as:

- Liquid products for disinfection of hands, surfaces and surgical instruments
- Nebulised airborne products for disinfection of hospital rooms, canteens, public spaces
- UV devices used to mitigate viruses on surfaces (e.g. reusable PPEs, public toilettes)
- Treated articles (porous and non-porous articles) with antiviral properties.

Eurofins BioPharma Product Testing Italy provides a broad spectrum of antiviral and virucidal tests, and contributes to the development of new and effective means to support the safety of products and people across the globe. For further information, contact us at *InfoBiocides@eurofins.com* or visit: *www.eurofins.it/virucidal-efficacy-testing/*

Testing for rouge metals can help make pharmaceutical water and final drug products safer for patients

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Rouging is a corrosion phenomenon that occurs on stainless steels. It is commonly observed in compendial water, pure steam production, water distribution installations, and in manufacturing equipment. Although this problem is fairly frequent, its causes have not been completely elucidated and pharmacopeias have not given any recommendations. Therefore, users have to troubleshoot this widespread and complex phenomenon.

Rouge is the general term used to describe a variety of discolorations on surfaces caused by variations in hydration agents and the formation of metallic iron oxides/ hydroxides (generated by external sources, or by alteration of the chromium-rich passive layer). This passive layer - normally just a few nanometers thick - consists primarily of chromium oxide, a mixture of iron oxide and iron hydroxide, and small quantities of nickel hydroxides.

The Pharmaceutical industry and regulatory authorities are increasingly aware of the need to test for trace metals in pharmaceutical water used in the production of large molecule and other pharmaceuticals. This analysis could better reveal the presence of unwanted metals that could transfer to the final product during the production process.

Rouge metals (Cr, Mn, Fe, Ni, Mo) can also be found in finished products, having a catalytic effect that induces degradation of the product or the API, potentially leading to harmful consequences on patients.

Inductively Coupled Plasma Mass Spectrometry (ICP-MS) is the preferred and most sensitive method for the determination of trace metals in ultra-pure water / steam systems in the pharmaceutical industry. This analysis also supports the ICHQ3D risk assessment.

Eurofins BPT Les Ulis, France, has the experience to help support pharmaceutical companies test for Rouge in water, API and final products. For more information, please contact : SalesFR_EBPT@eurofins.com

Ready for MDR? Last chance to identify and close gaps in your documentation

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The transitional provisions under Regulation (EU) 2017/745 (MDR), which are applicable for legacy devices already marketed under 93/42/EEC (MDD), will cease no later than 26 May, 2024. By this date, technical documentation for these devices must comply with the new requirements in order for the products to maintain CE certification. To close any gaps in technical documentation, Eurofins BioPharma Services Consulting Munich offers a new service that supports manufacturers by performing gap analyses of their entire technical documentation, and provides strategies and/or documentation to close the identified gaps.

Eurofins Consulting Munich further offers more detailed gap analyses regarding the existing documentation on biocompatibility (ISO 10993 series), packaging (ISO 11607 series) and reprocessing (ISO 17664). In addition, Eurofins Consulting Munich's experts evaluate changes to existing devices in terms of raw materials used, processing or suppliers and their impact on the biological risks of the final devices. Validity of studies conducted under previous versions of biocompatibility standards can also be evaluated. Based on our regulatory expertise, required biocompatibility testing can be reduced through identification of efficiencies resulting in lower costs and reduced time for the overall evaluation of legacy devices.

Besides gap analyses and change assessments for existing devices, Eurofins Consulting Munich also supports medical device manufacturers throughout the complete development of new devices. This includes planning of appropriate testing strategies and the determination of chemical characterisation parameters appropriate for individual devices and their clinical application. The proposed testing strategies are not only based on relevant ISO standards, but also take into account recommendations from a variety of additional guidance documents published by regulatory authorities, for example the US FDA. Corresponding biological evaluation plans, toxicological evaluations of leachable and extractable profiles and biological risk assessments can be prepared for a wide range of different medical devices (e.g. dental products, implants, blood contacting devices).

For more information about medical device documentation and evaluation, visit: *www.eurofins.de/medical-device-consulting/*

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