

Austrianova expands its operations to include sterility and endotoxin testing

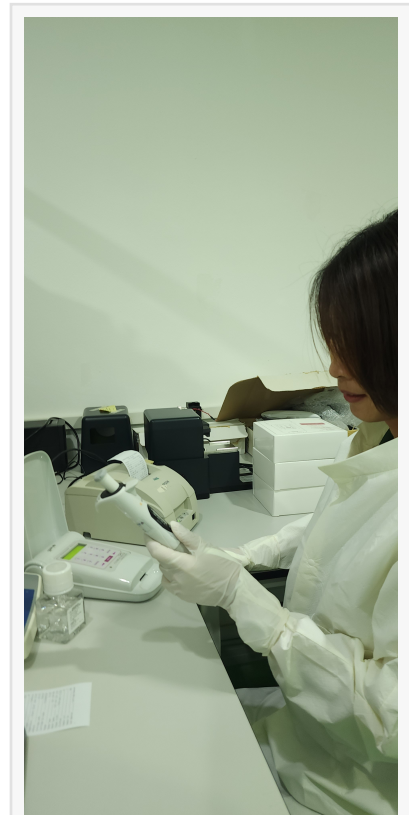
With this expansion of services, Austrianova is further solidifying its position in GMP cell encapsulation and related services.

SINGAPORE, SINGAPORE, October 24, 2024 /EINPresswire.com/ -- Austrianova, the cell encapsulation company, also provides a range of client services including cell banking. In an exciting evolution, the company has now extended its offerings to include standalone sterility and endotoxin testing services, all conducted in compliance with the latest ISO standards. This expansion signifies Austrianova's commitment to delivering comprehensive solutions to clients, ensuring top-notch quality and efficiency at every step.

By offering these services as a standalone service, the company is able to provide more tailored solutions to its clients and meet their specific needs. Additionally, by performing these tests in-house, Austrianova can ensure quicker turnaround times than classical testing services, and more efficient communication with clients regarding their test results. This level of control over the testing process also allows the company to maintain high quality standards and accuracy in its testing procedures.

As the biotech industry continues to evolve and grow, Austrianova's ability to adapt and expand its capabilities will be crucial in meeting the emerging needs of clients. By staying at the forefront of industry standards and technology, Austrianova is well-positioned to support the advancement and success of their clients in their research and development efforts.

Sterility is monitored using the BacT/Alert 3D microbial detection system (BioMerieux). This testing is a fully automated solution based on colorimetric technology that detects microbial growth by monitoring CO₂ production. There are several benefits to this technology, notably faster testing times with sample results available in less than 7 days compared to the 14-day incubation needed for traditional sterility tests. Bacteriostasis and fungistasis testing is also conducted alongside the sterility test to determine if the test article inhibits the growth of microorganisms. This testing is essential to validate the sterility findings and ensure that the test



Endosafe®-PTS™
endotoxin testing at
Austrianova

article does not have any antimicrobial properties that could impede the detection of microbial organisms during the sterility assessment.

For endotoxin testing, Austrianova utilizes a quick testing approach, the Endosafe®-PTS™ system (Charles River). This method utilizes kinetic chromogenic techniques with specific quantities of a known endotoxin (Limulus amoebocyte lysate), chromogenic substrate, and control endotoxin. The FDA approved cartridges are extremely sensitive and designed to detect very low levels of endotoxin (as low as 0.005 EU/mL). This testing method complies with the current bacterial endotoxin test outlined in the US Pharmacopeia. Moreover, both the British Pharmacopoeia Commission and the European Directorate for the Quality of Medicines and Health Care have confirmed that this test complies with the requirements outlined in the current harmonized test.



Austrianova Chief Production Officer, Rahul Pawa, said “Overall, this expansion in services showcases Austrianova's commitment to providing comprehensive solutions to its clients and continuing to expand its capabilities to meet the evolving needs of the biotech industry.”

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Rahul Pawa, Chief Production Officer

Brian Salmons, Austrianova CEO, added “State of the art testing with a rapid turnaround is the future of advanced therapeutic medicines (ATPs), allowing more rapid testing than by conventional means.”

About Austrianova

Austrianova (the SG Austria Group), is a biotech company with a global footprint and operations in Singapore, Thailand and Germany. Austrianova utilizes a novel and proprietary technology for the encapsulation of living mammalian (Cell-in-a-Box®) and bacterial (Bac-in-a-Box®)

cells. Cell-in-a-Box® protects the encapsulated cells from rejection by the immune system, allows cells to be easily transported, stored and implanted at specific sites in patients. The technology, which has been proven safe and efficacious in clinical trials carried out in Europe, allows companies to develop any kind of cells as a one-for-all living pharmaceutical. Bac-in-a-Box® is a

similar protective device adapted for encapsulation of probiotic bacteria where it has human food and animal feed applications as well as re-balancing the microbiome due to its ability to extend storage under lyophilized conditions and to protect encapsulated bacteria against destruction by stomach acid. Austrianova now also offers Pep-in-a-Box encapsulation of proteins and other small molecules for oral delivery featuring excellent protection against degradation by stomach acid, GMP4Cells that includes competitively priced Master Cell Bank and Working Cell Bank production, as well as “Fill and Finish” services for cell therapy products (such as stem cell therapies, biologics produced from cells e.g., vaccines, antibodies, enzymes, recombinant proteins, exosomes, etc.).

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Sterility testing using the BacT/Alert 3D microbial detection system

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