

How can CGT manufacturers ensure product safety with Microbial Solutions QC test methods?

Innovation forms the basis of every emerging technology. That is certainly the case with cell and gene therapies (CGTs), and the search for efficient quality control (QC) test methods continues to grow in this pharmaceutical sector. One of the most important factors to consider while deciding on a QC method for CGTs is the time to release a high-quality product, given that developing and manufacturing these therapies is already time consuming and complex.

QC TESTING VALIDATION is a mandatory step to meet strict regulatory requirements and routine inspections. Given the complex nature of cell and gene therapies (CGTs) and their unique manufacturing processes, certain challenges arise which require identifying the best QC testing support options available.

Charles River Microbial Solutions offers an extensive portfolio of products and services that are compliant with the current advanced therapy medicinal products (ATMPs) regulations. The following sections provide an understanding of the critical role these products and technologies play in reducing the time constraints and quality issues that may arise during and after manufacturing.

Endosafe® bacterial endotoxin testing solutions

Endotoxin contamination poses a serious threat to patient safety. Not surprisingly, it is vital to limit intrusion of these pyrogens into the manufacturing process. In the domain of CGT, with the use of growth promoting media and cell cultures, there are additional risks of contamination compared to traditional pharmaceutical manufacturing. Efforts must be made during the manufacturing process to monitor and respond to potential endotoxin contamination. Charles River Microbial Solutions offers rapid endotoxin testing systems backed by the innovative cartridge technology that is powered by *Limulus* amoebocyte lysate (LAL) and licensed by the US Food and Drug Administration (FDA).



Endosafe® nexgen-PTS™ provides accurate endotoxin test results within 15 minutes, leading to substantial improvements in turnaround time. In addition, its ease of use makes the system ideal for accelerating drug development processes.

Celsis Adapt™ for releasing short shelf-life products

CGTs need to be released to patients quickly. However, the use of living cells can limit shelf life. As an additional QC hurdle, the final product available for testing is often drastically reduced due to small-scale production in limited batches. As these emerging short shelf-life therapies continue to evolve, it is important to advance current QC techniques to provide faster results and reduce the risks of retesting. The Celsis Adapt™ rapid method platform is an innovative response to the fast-growing industry. The system works within the framework of compendial test methods to

provide short shelf-life product release results in as little as three days.

Accugenix® microbial identification services

Accurate microbial identification plays a pivotal role in determining the root cause of a contamination, so the accuracy of such testing systems cannot be taken for granted. Systems with limited libraries or technological challenges can yield incorrect identifications, sending your root cause investigation down a completely different path. Accugenix® DNA sequencing and matrix-assisted laser desorption/ionisation-time of flight (MALDI-TOF) technologies for microbial identification provides an optimal combination of accurate results, fast turnaround times and secure data. A comprehensive system library consists of validated microbial databases, and samples and trending data can be easily tracked via a personalised customer portal. ☒

To find out more, view on-demand the **Innovating Cell and Gene Therapy Quality Control Conference**, jointly organised by *European Pharmaceutical Review* and Charles River.

Learn from subject matter experts as they share their insights on the current trends and challenges faced in quality control methods for CGT industries. **Visit:** <https://bit.ly/3vr3vVK> or scan the QR code



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