WEBINAR

Testing of Bioprocess Residual Impurities in Gene Therapy Products

eurofins | BioPharma Product Testing

Register for our Live Webinar:

Thursday, November 7, 2019 | 11 am EST

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Event Overview

The manufacture of gene therapy products can be a complicated process. Multiple cell culture systems and a variety of process additives are often necessary to produce vector intermediates and the final bulk drug substance. To ensure the safety and efficacy of gene therapy products administered to patients, manufacturers are expected to measure and control impurities in drug substance, as well as manufacturing intermediates (where applicable), including host cell, vector components and process additives. Tracking the clearance of these residuals is also an essential part of process development and characterization. Due to the complex nature of gene therapy product manufacture, analytical method development and validation of these methods can be challenging. Furthermore, detailed regulatory guidance on acceptable limits are not available for all possible residuals.

During this presentation, you will learn:

- Typical residuals associated with the production of gene therapeutics
- Analytical approaches for residuals testing
- Challenges with platform method technology for residuals
- How to deal with matrix effect

Presenters:

Peter Schebler, Ph.D.
Group Leader III, Bio/Pharmaceutical Biochemistry
Eurofins BioPharma Product Testing

Robert Donatelli, MS
Manager, Molecular & Cell Biology - Method Development & Validation

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Eurofins BioPharma Product Testing Toronto, Inc.
1111 Flint Road, Unit 36, Downsview, Ontario,
M3J3C7, CANADA

https://www.eurofins.ca/en/services/pharmaceutical-testing/

pharma@eurofins.com