XTALKS PRESS RELEASE FOR Nitto Avecia Pharma (April 17/18 webinar)

HEADLINE:

Cell-Based Assays in a CGMP Environment: Approaches for Clinical and Commercial Stability Studies, New Webinar Hosted by Xtalks

SUB-HEADLINE:

Presentation to highlight the approaches used in developing consistent cell-based potency assays meeting regulatory expectations (USP <1032> and <1033>) and are suitable for CGMP stability testing

SUMMARY:

Potency of biotherapeutics, often determined by cell-based assays, is one of the most important critical quality attributes. Potency must be monitored throughout the entire drug development cycle as it measures drug activity and provides a direct link to clinical efficacy. An ideal potency assay should represent a drug's mechanism of action (MOA), as well as be specific and sensitive enough to detect changes and degradations of the product. Cell-based potency assays are intrinsically complex and may present challenges during development, validation, transfer and implementation.

This presentation will highlight the approaches used in developing consistent cell-based potency assays meeting regulatory expectations (USP <1032> and <1033>) and are suitable for CGMP stability testing. In addition, a phase appropriate potency method development and qualification/validation strategy will be discussed. Practices in support of successful cell-based assay transfer and long-term maintenance of the assay in the QC laboratory will be presented.

The discussion including a Q&A session with the audience, will benefit biopharmaceutical/biotechnology industry professionals involved in quality assurance/quality control and regulatory affairs for biologics, as well as validation specialists and outsourcing professionals.

Key topics include:

- Challenges in establishing a robust cell-based potency assay
- Routine assay performance monitoring
- Analyst training and qualification requirements
- Analytical working cell bank generation and characterization
- Cell maintenance and growth tracking
- Bridging studies for critical reagents

On Tuesday, April 17, 2018 at 2pm EDT, join experts from to Avecia Pharma Services Aryo Nikopour, Senior Vice President of Scientific and Technical Services, and Ming Li,

Principal Scientist/Team Lead for Biopharmaceutical Development, for an informative session.

For more information about this complimentary event, visit: Cell-Based Assays in a CGMP Environment: Approaches for Clinical and Commercial Stability Studies.

ABOUT XTALKS

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