Tools for the Pharma QA/QC: A Workflow Approach

Half Day Symposium hosted by Spectroscopy & Pharmaceutical Technology

Details

Date: Thursday, February 23, 2023

Time: 11am EST | 10am CST | 8am PST

Who Should Attend:

- R&D scientists
- QC scientists
- Lab managers
- Formulation development scientist
- Analytical scientists
- Department/group leads

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Event Overview

Spectroscopy and chromatography play key roles in the workflows of pharmaceutical and bioprocessing QA/QC labs. Understanding the importance of these tools in raw materials identification, content uniformity, and other workflows provides critical quality attributes (CQA) in a regulated environment. High-performance liquid chromatography (HPLC) is a proven tool for the analysis of critical process parameters (CPP) of biotherapeutics.

Key Learning Objectives

- Learn how to optimize dissolution testing
- The application of on-line HPLC to monitor and control CQA in bioprocessing
- Explore the use of Agilent's FTIR and spatially offset Raman spectrometers (SORS) for raw materials identification (RMID)
- Understand how transmission Raman spectroscopy can be used in drug discovery and development workflows

Agenda

Optimizing Dissolution Testing
Optimizing Dissolution Testing Integration of On-line HPLC as a PAT Tool for CQA Monitoring and Control in Bioprocessing
Raw Material Identification and Verification in Compliant Environments with FTIR and Raman Spectroscopy
Embracing the UV-Vis QA/QC Needs of a Pharma/BioPharma Laboratory

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Expanded Agenda

Optimizing Dissolution Testing

Ken Boda, Dissolution Product Specialist, Agilent Technologies

Dissolution is a key test to ensure that a drug is safe and effective and is the only test that can assess a formulation's performance. To have meaningful dissolution data, it is critical to ensure reproducibility of the dissolution apparatus and procedures. We will discuss optimizing the dissolution to bring about greater accuracy and precision, fewer dissolution failure investigations, and achieving higher throughput.

Optimizing Dissolution Testing Integration of On-line HPLC as a PAT Tool for CQA Monitoring and Control in Bioprocessing

Stacy Shollenberger, Senior Marketing Manager, Process Analytical Technologies, Millipore Sigma
Daniel Kutscher, Product Manager, Strategic Marketing, Agilent Technologies

High-performance liquid chromatography (HPLC) is a proven tool for the analysis of critical process parameters (CPP) and critical quality attributes (CQA) of biotherapeutics. Historically, HPLC has been performed off-line—a process that can take days or weeks to complete. By moving HPLC to the manufacturing floor as an on-line process analytical technology (PAT) tool, relevant data can be accessed in a matter of minutes. In this webinar, we highlight an initial use case demonstrating the utility of on-line HPLC to monitor and control antibody aggregation levels in bioprocessing. The implementation of PAT enables continuous manufacturing and empowers industry progress towards Bioprocessing 4.0.

Raw Material Identification and Verification in Compliant Environments with FTIR and Raman Spectroscopy

Yanqia Wang, Application Engineer, Molecular Spectroscopy, Agilent Technologies

Raw material identification (RMID) or verification is a common QA-QC practice in complaint environments with tremendous impact on customer safety as well as speed and cost of production. RMID has become an important application field of FTIR and Raman spectroscopy. Today's RMID can occur either in the field and in-lab, which raise new challenges. Agilent's compact portable FTIR and spatially offset Raman spectrometers (SORS) provide a great combination with versatile sampling interfaces and spectral process capabilities, which can offer great convenience, stability, and high-throughput solution to the RMID applications in compliant environments.

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Expanded Agenda, cont.

Embracing the UV-Vis QA/QC Needs of a Pharma/BioPharma Laboratory

Mark Fisher, Application Engineer, Molecular Spectroscopy, Agilent Technologies

The UV-Vis QA/QC needs of a pharma/biopharma laboratory range from the simple (an absorbance measurement at a single wavelength) to the complex (a thermal melt, also known as an absorbance verses temperature measurement). One of the challenges for a lab is deciding between a measurement-specific instrument or an instrument designed to perform a variety of measurements equally well. Agilent has two UV-Vis spectrophotometers that provide the pharma/biopharma the flexibility to meet their current and future needs even in a compliant environment.

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