



Mr Fredrick Sundberg
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Level 6 Boardroom

Host: Dr Zhang Wei

Seminar Abstract

A thorough understanding of how the bioprocess parameters impact critical quality attributes (CQAs) of drug products is essential for confident decision-making. Establishing well-characterized biological products for complex modalities is a significant challenge for the industry. Implementation of a control strategy with information-rich technologies has the potential to significantly improve both characterization and overall productivity. One technology that is expanding rapidly in quality control applications due to its speed, precision and high-quality binding kinetics is surface plasmon resonance (SPR). This presentation will provide an overview of novel assays from R&D to QC including process analytical technology (PAT) trends and how novel protein analysis tools have been implemented for better comparability assessment including FDA-approved release testing. It will also cover the latest regulatory strategies for meeting current health authority expectations and review the latest SPR Validation Guideline.

About the Speaker

As Global Director Strategic Technologies at Cytiva, Fredrik is responsible for working with the biopharmaceutical industry to improve current workflows with innovative analytical solutions. He also advises on R&D projects and business development activities. Fredrik is author of several publications on drug discovery and biosimilar strategies. He is also member of an EMEA Pharmaceutical Industry Expert Panel, and he regularly lectures and discusses regulatory issues with government officials and health authorities.