

Technology-Enhanced Pharmaceutical Discovery (TEPD)

SEMINAR SERIES 2024/2025

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12:15p.m.

GUEST SPEAKER

**Dr. Shaolong Zhu, Principal
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“The application of biochemical, biophysical, and mass spectrometry methods to the control, characterization, and investigational testing of protein-based vaccine antigens”

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The development of protein-based vaccines requires the application of biochemical, biophysical, and mass spectrometry methods to the control and characterize the identity, purity, content and stability of the purified antigen drug substances and the formulated antigen drug products. To illustrate some of the methods routinely applied as part of release and characterization of protein-based vaccines as well as applied for investigations, three examples will be presented. First, an E. coli-expressed bacterial antigen exhibiting atypical reverse phase chromatographic behaviour was investigated with a variety of methods and determined to have a site-specific post-translational modification (PTM). Second, an E. coli-expressed antigen that was expressed as partially truncated was compared to a purified version of the major reverse phase chromatographically truncated form, to understand the properties of the truncate. Finally, a soluble version of the highly glycosylated Covid-19 spike protein antigen expressed using baculovirus from an insect cell expression system was characterized using reverse-phase for purity and host cell protein (HCP) profile in addition to mass spectrometry to probe antigen microheterogeneity, HCP identity, structural dynamics. These examples will illustrate how a broad range of analytical methods can be applied to the challenges of developing vaccine antigens for clinical release and licensure.

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