



ブレント リーファーズ

Cytiva

Senior Director, Innovation Advocacy

Brent is currently the Sr. Director of Innovation Advocacy, having joined Cytiva in 2022 as the general manager for the company's Aseptic Filling business. He has over 30 years of extensive experience in the pharmaceutical industry, from API manufacture through to fill/finish, in operations ranging from small clinical to large commercial scale production. Driving technological innovation in drug product manufacturing, Brent is an advocate for outcome-based regulatory compliance based on QRM/QbD, robust risk assessment, accurate real-world data and scientific rationale with the ultimate goal of improving patient safety.

10月23日(金) 10:20 講演

PDA / ANSI Standard 03-2025 Standard Practice for Quality Risk Management of Aseptic Processes

A Holistic Approach to Quality Risk Management for Aseptic Manufacturing

The recently-released PDA/ANSI standard provides a lifecycle approach using a holistic evaluation of contamination control systems with layers of protection designed to prevent contamination during aseptic processing and ultimately ensure the safety of the products when delivered to the patient.

This presentation will provide an overview of the standard including how it can be a more appropriate methodology offering advantages over some commonly employed tools for performing risk assessments around complex and innovative critical aseptic operations such as gloveless robotic isolators with real-time viable particle monitoring.