



アルベルト ゴンザレス

Takeda

Global Sterility Assurance Associate Director

Alberto Gonzalez is a pharmacist with 15+ years of multinational experience in pharma and biotech. He is part of Takeda's Global Sterility Assurance and Microbiology team. His expertise centers on Aseptic Process Simulations (APS), Contamination Control Strategies (CCS) and Quality Risk Management (QRM). Within PDA, Alberto serves as Co-Chair for Technical Report 90 'Contamination Control Strategy' Part 2. He speaks regularly at conferences and teaches sterility assurance in postgraduate programmes.

10月22日(木) 17:10 講演

APS の課題と解決策

APS Design Challenges and Proposed Solutions

Designing an aseptic process simulation (APS) involves interpreting regulatory requirements and making risk-based decisions.

In this presentation, I will examine three recurring APS design challenges:

1. Do I need to simulate every intervention, or can I group them and then simulate only the selected representative interventions?
2. Can I remove an intervention from the APS if it is no longer performed in routine commercial production?
3. In a campaign APS, how many batches must use media rather than product or water?

I will explore these questions from the perspectives of Annex 1, PDA Technical Report 22, and current industry practices. I will also propose practical approaches grounded in science.