



Training Course Agenda

PDA 444.1 Technical Report No. 30: Parametric Release of Pharmaceutical and Medical Device Products Sterilized with Moist Heat

DAY 1

15 min Welcome and Introductions

75 min Definitions and History of Parametric Release
Issues/Limitation of the Sterility Test

15 min Break

60 min Sterilization Science: Microbiology and Engineering

15 min Wrap-Up / Q&A

DAY 2

15 min Day 1 Recap / Q&A

75 min Parametric Release Program Elements and Fundamentals

15 min Break

60 min Sterility Assurance Risk Management and Submission Documentation

15 min Wrap-Up / Q&A