



BPE Code Week Workshops – Raleigh, NC (Oct 2010)

TITLE: Design for Bioburden Control in Biologics Manufacturing

DATE: October 12, 2010, Tuesday, 8:00am – 10:00am

LOCATION: The Marriott at RTP

PRESENTER: David M. Marks, Chair, BPE Subcommittee on Design

SESSION DESCRIPTION:

The control of bioburden and other process contaminants is a critical requirement for biologics manufacturing. This requirement has a significant impact on the design of GMP facilities and process systems. In this session we will examine some of the unique challenges and technology solutions for bioburden control in bioprocess facilities. The seminar will focus on best practice to reduce contamination risks in bioprocess equipment design, including bioreactor pure culture processing. We will review case studies and strategies for investigating and determining root cause of contamination incidents. The prevention and control of bioburden contamination is a key element in the quality risk management process and development of an effective product protection control strategy. This session will review design considerations for new facilities, as well as strategies for remediation of existing facilities to reduce the risk of product contamination.

TARGET AUDIENCE:

This workshop is an essential resource for engineers, scientists and other personnel involved in the design of bioprocessing equipment including suppliers, end-users, contracts and component suppliers.

INSTRUCTOR BIO:

David M. Marks is president and founder of DME Alliance Incorporated. He has over 25 years of experience in the specification, design and implementation of process systems. He is a frequent author, speaker and consultant on bioprocess technology, facility/equipment design & compliance topics. His professional experience is concentrated in the design and implementation of bioprocess systems for FDA-licensed facilities, having served many of the leading international biotech and pharmaceutical firms since 1989.

Prior to founding DME Alliance in 1998, David managed the engineering department for Associated BioEngineers and Consultants. He is active on the ASME Bioprocess Equipment (BPE) standard main committee, serves on the polymers subcommittee and is currently Chair of the BPE Subcommittee on Design. A graduate of Lafayette College, David holds a BS in Chemical Engineering and is a registered Professional Engineer.