

International Conference and Expo on **Parenterals & Injectables** August 17-19, 2015 Chicago, USA

Case studies of human flora and spore contamination in clean rooms

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Staying ahead of the curve in regard to Environmental Monitoring requires an understanding and an anticipation of the constantly changing microbial climate of the pharmaceutical manufacturing process. Knowing the characteristics of the environments in that process provides the benefit of allowing us to predict and solve potential future microbial control issues. This session will discuss pathways to use the data obtained from environmental monitoring to provide proactive and practical solutions for comprehending and managing everyday pharmaceutical microbiology challenges. The start up and control of cleanroom facilities will also be covered as well as meeting regulatory expectations. This presentation will cover case studies on human flora and spore contamination in clean room operations. Solutions will be discussed to proactively present future contamination issues. The seminar will cover the most common causes of contamination: Operators, items brought into the cleanroom, and degradation of the cleanroom over time. Case studies in operator borne contamination will be discussed as well as preventative long term solutions. Specific examples of aerobic and anaerobic vegetative bacteria will be highlighted and analyzed. Items brought into cleanrooms that can harbor fungal and bacterial spores will be discussed as well as specific case studies highlighting examples where sources were items brought into the cleanroom or in some cases other common causes. Fungal and bacterial spore structures as well as efficacy testing and specific test conditions will be briefly discussed. Solutions will be presented to prevent efficacy testing failures due to test method, recovery, and coupon porosity issues. Targeted long term solutions will be discussed regarding the spore case studies in a concerted effort to limit reoccurrences. The overall objective and scope of this seminar will be to discuss specific cases studies that have occurred in my years of experience in the industry. Specific and precision long term solutions will be conveyed to prevent reoccurrences and yield higher levels of control in the cleanroom operations.

Biography

Jim Polarine is a technical service manager at STERIS Corporation. He has been with STERIS Corporation for over fourteen years. His current technical focus is microbial control in cleanrooms and other critical environments. He has lectured in North America, Europe, Asia, and Latin America on issues related to cleaning and disinfection in cleanrooms. He is a frequent industry speaker and published several PDA book chapters and articles related to cleaning and disinfection and contamination control. He is currently co-authoring articles. He is active on the PDA task force on cleaning and disinfection and the PDA task force on Microbial Deviations and a co-author on the technical reports. He is a member of the PDA's Environmental Monitoring Group, Contamination Control Group, and Biotech Interest Group.

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