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Control microorganism contamination and understand the implications on batch certification/release

The presentation will shed light on the current industrial issues as the objectionable microorganism definition and the regulation requirements on objectionable microorganism contamination control. Also, will identify the common microorganisms found in the cleanrooms and the pharmaceutical grade water systems that would potentially be in contact with the production batches. In addition, the presentation will focus on the ways to proactively limit bacterial and mold spore contamination from incoming items into cleanrooms, limit other sources of contamination and implement an effective cleaning and disinfection program. Moreover, through case studies, the implication of objectionable microorganism contamination on batch certification and release will be understood. Finally, why “211.113-Control of microbiological contamination” was at the top of the most observed FDA deficiencies during FY14 will be shared. The attendees will understand how to pro-actively avoid microorganism contamination in manufacturing systems and the implications of microorganism contamination on batch certification and release.

Biography

Walid El Azab is a Technical Services Manager for the Life Sciences Division of STERIS Corporation. He currently provides technical support related to cleaning chemistries, disinfectants and sterility assurance products and their application and validation. His areas of expertise include both upstream and downstream biopharmaceutical operation and validation. He has held various positions including Project Manager, Inspection Readiness Manager, Quality and Regulatory Manager and Qualified Person (QP). His responsibilities and experience have also included handling deviations and complaints, releasing raw materials and drug products, conducting external audits of suppliers and leading customer and regulatory (FDA, EMA, etc.) audits. He earned a Master's degree in Industrial Pharmaceutical Sciences from the University of Liège, Belgium and is a certified Lean Six Sigma green belt. He also gives Industrial Pharmaceutical Sciences Master courses at the University of Liège, Belgium. Finally, he is an Active Member of the PDA, ISPE, Pharmaprocess, ECA, A3P and is Secretary of the Belgium Qualified Person (UPIP-VAPI) Association.

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