

GMP, GCP & QUALITY CONTROL

7th International Conference and Exhibition on

PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

September 25-26, 2017 Chicago, USA

Cleaning validation: Process life cycle approach

Paul Lopolito

STERIS Corporation, USA

The traditional cleaning validation approach has been used for over thirty years to define and validate manual and automated cleaning within GMP manufacturing. The life cycle approach includes three stages, (1) process design, (2) performance qualification and (3) continued process verification. The cleaning life cycle approach changes the emphasis from validation to design and monitoring of the cleaning process. Monitoring of the cleaning process and a better understanding of the design process (critical parameters) promotes continuous improvements and real-time scientific based decisions to OOS results and change management. Industry tools such as QbD, risk management and PAT provide the backbone to the life cycle approach. The easy-to-follow presentation provides a checklist for any organization to successfully migrate from a traditional validation model to the cleaning life cycle approach for new products or processes. The presenter will also cover some hot topics within cleaning validation, such as establishing health based limits, visual inspection, addressing non-routine cleaning residues and stainless steel maintenance.

Biography

Paul Lopolito is a Technical Services Manager for the Life Sciences Division of STERIS Corporation (Mentor, Ohio). He currently provides global technical support related to process research cleaners, stainless steel maintenance, and contamination control, which includes field support, site audits, training presentations and educational seminars. He has over 15 years of industry experience and has held positions as a technical services manager, manufacturing manager and laboratory manager. He is a frequent speaker at industry events including INTERPHEX, PDA, ISPE,ACHEMA, AALAS, and IVT. He has published several articles and book-chapters related to cleaning validation and contamination control. He earned a BA in Biological Sciences from Goucher College in Towson, MD.

paul_lopolito@steris.com

Notes: