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Walid El Azab, J Develop Drugs 2016, 5:4(Suppl)
http://dx.doi.org/10.4172/2329-6631.C1.020

International Conference and Expo on

Generic Drug Market & Contract Manufacturing

November 07-09, 2016 Barcelona, Spain

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STERIS Corporation, Belgium

EU GMP changes: Impact on cleaning and process validation

The presentation will shed light on the current European GMP changes and how these changes are now linked to each other. The presentation will also detail and explain the changes of recently effective and draft documents as the annex 15, annex 16, chapter 2, chapter 3, chapter 5 and finally the EMA guidance on setting limit. Following that the presentation will explain the impact of these changes on cleaning, process validation and how senior management and the qualified person need to ensure compliance. In addition, the presentation will deep dive on how to assess setting limits in cleaning validation and explain the difference with the ISPE and EMA guidance. Finally, the presentation will share common questions asked by manufacturers on cleaning and process validation in Europe and what regulatory agencies are expecting to be in place.

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, A3P - ECA / QGP and is Secretary of the Belgium Qualified Person (UPIP-VAPI) Association.

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