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Accelerating Scientific Discovery

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cGMP compliance design of sterile/aseptic manufacturing facilities is a mandatory to meet qualification and validation requirements

This presentation will cover the cGMP design guidelines related to Sterile/Aseptic Manufacturing Facilities including layout, sanitary process equipment, clean utilities and pharmaceutical support systems, as well as the control quality, stability issues, quality system requirements and related procedures. This process will be supported by the inclusion of Risk Management strategies (see related ICH Q9 approach workshop) to meet qualification and validation requirements.

Such as reported by M. Kuwara, The speaker will cover:

- cGMP regulation requirements
- Reminder of URS / Clean Rooms
- Design of clean rooms
- Types of contaminants
- Code clothing & means of prevention
- Classifications of rooms vs standards & applications
- Types of segregation, of flow, of cascades
- Building construction and architectural finishes
- Design of HVAC systems for sterile products
- Design in the presence of High Potent products
- PPE, Personal Protective equipment
- Elements of Commissioning/Validation of Premises & HVAC
- Many case studies will be presented

Biography

Aziz Chraibi, eng., after having completed his studies in chemical & processes engineering with ENSIACET college of Toulouse (1986), and then a masters at the INP of Toulouse, followed by a thesis doctorate at the University of Perpignan (1990) which was postulated for the best thesis of CNRS award in 1990, began a career of more than 23 years in the pharmaceutical consulting, cGMP compliance and design review, audit and inspection to meet the good manufacturing practices (cGMP) from Health Canada, EMA/ANSM and FDA as well as standards such as ISO14644, ISO8573, ASME BPE 2012, USP797, USP, EuPh, JP, HSE, NFPA, ATEX, OSHA, ISO, ICH Q9, ASTM 2500, ISPE, etc. In 2007, he was admitted Health Canada Scientific Expert to carry out compliance audit of the facilities. It has in its assets more than 100 multidisciplinary projects made in Canada, but also in the international, involving, audit, compliance and design review, project management, conceptual design, basic (BOD) and detailed engineering, monitoring of "Commissioning and Benchmarking", FAT, installation & strat-up, SAT, and qualification as well.

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