Abstract

Decontamination system is a system that sterilization or disinfecting process. This system comprises Autoclave which is sterilized by Moist Steam Sterilization or Moist Heat Sterilization and Hot air oven which is sterilized Dry Heat Sterilization, which Tools and equipment is used in analysis for quality control of medicinal products must be performance qualification and verification to confirm that tools and equipment is reliable. There is performance qualification of decontamination system for quality control laboratory that is appropriate to the process and can guarantee the product quality. The procedures must start from the risk assessment of working process and the identity of the decontamination system to identify steps crisis. The result of risk assessment can be designed preventive maintenance plan, calibration plan and prepared performance qualification of decontamination system (autoclave & hot air oven) for quality control laboratory protocol. The results study of the empty chamber heat distribution and load chamber heat distribution, heat penetration and microbiological challenge with Biological Indicator showed all tests complied with acceptance criteria. This project has expanded to include the development of GMP compliant documentation for quality control that the production of biopharmaceutical and proteins for medical, both in terms of development system and personnel are scarce. The benefits from these developers can continue to use as the model for creating new knowledge in risk assessment and performance qualification of the machines these given the other private and public sector organizations, to accommodate the needs of the pharmaceutical industry.

Keywords: Decontamination system, Performance Qualification (PQ), Risk Assessment