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Review on ICH Guideline for Aseptic Laboratory

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Abstract: *ICH Guidelines were created by The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH).ICH aims to provide uniform standards for technical requirements for pharmaceuticals for human use. They are developed by regulatory and pharma industry authorities. The purpose of ICH guidelines is to ensure safe, effective and high-quality medicines are developed and registered efficiently. ICH guidelines are a set of guidances to ensure safe, effective and high-quality medicines are developed and registered efficiently. These guidelines have been adopted by regulatory authorities throughout the world. Aseptic manufacturing is used in cases, where the drug substance is instable against heat, hence sterilisation in the final container closure system is not possible. Aseptic manufacturing means that the used drug substance and excipients were sterilised appropriately and all materials, equipment and container closure systems were used only after sterilisation. All working steps were performed in so called clean areas to avoid contamination. Therefore high standards have to be established concerning the manufacturing room, the personnel, the equipment and the supply systems (air system, water for injection, sterile gases used in the working process; for example compressed air, nitrogen etc.).*

Keywords: ICH Guideline, Aseptic Condition, Sterilization

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