

## Powerflex 753 Drives Allen Bradley

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describes the methodologies and best practices of the sterile manufacture of drug products

thoroughly trained personnel and carefully designed operated and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice cGMP and preapproval inspection PAI requirements sterile processing of pharmaceutical products engineering practice validation and compliance in regulated environments provides up to date coverage of aseptic processing techniques and sterilization methods written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals topics include sanitary piping and equipment cleaning and manufacturing process validation computerized automated systems personal protective equipment PPE clean in place CIP systems barriers and isolators and guidelines for statistical procedure offering authoritative guidance on the key aspects of sterile manufacturing engineering this volume covers fundamentals of aseptic techniques quality by design risk assessment and management and operational requirements addresses various regulations and guidelines instituted by the FDA ISPE EMA MHRA and ICH provides techniques for systematic process optimization and good manufacturing practice emphasizes the importance of attention to detail in process development and validation features real world examples highlighting different aspects of drug manufacturing sterile processing of pharmaceutical products engineering practice validation and compliance in regulated environments is an indispensable reference and guide for all chemists chemical engineers pharmaceutical professionals and engineers and other professionals working in pharmaceutical sciences and manufacturing

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