



Steam Sterilization: A Practitioner's Guide

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This book contains pragmatic details on how to accomplish the tasks necessary for a sterility assurance program for steam sterilization processes. Each chapter author is a subject matter expert and has a minimum of 10 years of hands-on experience in the topics discussed. The authors use this experience to identify practical ways to perform research, development, validation, and production activities associated with steam sterilization. Here is a complete collection of practical instructions covering: sterilization processes, design specifications, commissioning, installation qualification, operational qualification, cycle development, special considerations for development of cycles for plastic containers, performance testing and qualification, parametric release, on-going monitoring, biological indicators, handling aberrant sterilization cycles, issues related to foreign inspections of sterilization processes, and packaging considerations. The book also contains tremendously useful sample procedures, protocols, and documents to use as templates in your facility.

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