

Book Reviews

Clean-In-Place for Biopharmaceutical Processes. Edited by Dale A. Seiberling. Informa Healthcare: New York. 2008. 391 pp. \$229.95, £115.00 (Hardcover). ISBN: 10:0-8493-4069-1

Clean-in-place (CIP) technology originated nearly 60 years ago in the dairy and beverage industries, but in the last two decades it has been increasingly applied in pharmaceutical and biopharmaceutical plants. A CIP procedure avoids the time-consuming disassembly/reassembly steps associated with traditional manual cleaning, and its automated nature provides greater consistency of performance, which in turn aids the validation of a cleaning process. However, in order to achieve these benefits it is important to design the processing equipment to be “CIPable”, rather than attempt to retrofit CIP elements into an existing reactor or plant.

The editor of the present volume has been involved with CIP since its inception in the late 1940s, and has assembled an experienced team of authors to explain the detailed engineering and procedural aspects of these complex systems. It is thus highly recommended reading for chemists and engineers with particular responsibilities for the development of cleaning procedures, even if they do not employ CIP, as the book provides detailed insight into commonly encountered cleaning problems and practical solutions to them.

After an introduction (itself fairly detailed) and historical perspective, subsequent chapters consider Project Planning, Water Requirements, Composition of Cleaning Agents, and Cleaning Cycle Sequences. There then follow a series of chapters concerned with engineering aspects such as System

Components and Configurations, Instrumentation and Controls, Cleaning Agent Injection Systems, Spray Device Design and Application, Distribution Piping Systems, Cleanable In-Line Components, Materials of Construction and Surface Finishes. (Although, the only material really considered here is stainless steel—a reflection of the book’s primary emphasis on formulation processes.)

Three chapters consider the particular cleaning requirements for Liquids Processing Equipment, Solids Processing Equipment, and API Processing Equipment. It is this latter chapter that process chemists will want to study with particular attention; it discusses the problems and inefficiencies associated with traditional boil-up methods and considers the cleaning challenges presented by reactor systems, isolation equipment, and dryers.

The final chapters deal with Troubleshooting, Waste Treatment, and the important regulatory aspects of Commissioning and Qualification, Cleaning Validation Strategies, and the applicable International Regulations.

Equipment cleaning is not a topic likely to inspire many chemists; but few would deny its importance, and this book collates all the information a process chemist or engineer is ever likely to require on the subject.

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