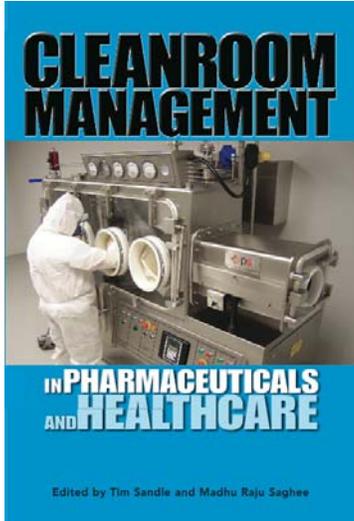


BOOK REVIEW



Cleanroom Management in Pharmaceuticals and Healthcare. Edited by Tim Sandle and Madhu Raju Saghee.

Book review by Victor Grayson, Sterility Assurance Office, Bio Products Laboratory

Cleanrooms are of great importance to the pharmaceutical industry: they are the envelope around which all critical operations take place. If this clean envelope has not been designed properly the product or process is at risk from contamination.

Although there are a range of different standards and regulatory missives, what has been missing for many years is a book which helps unravel the complexities of cleanroom operations. It also stands that books on cleanrooms are either focused on engineering or they simply cover environmental monitoring.

This has now changed for a comprehensive new book has appeared: "Cleanroom Management in Pharmaceuticals and Healthcare", edited by industry experts Tim Sandle and Madhu Raju Saghee.

The new book covers a number of dimensions relating to cleanrooms: engineering, risk assessment, microbiological aspects and management. There is no single volume on cleanrooms that contains these vitally important areas. Not only does the book embrace these concepts it weaves them together so that the engineering principles are related to the contamination risks and management strategies are presented which help cleanroom operators find solutions to overcome the risks.

To aid the reader, theoretical concepts are related to practical examples. What is also of use is the comparison of different standards and regulatory requirements. Never before have ISO, EU and US regulations been brought together and dissected in a way that makes them clear to the general reader.

The book is a heavy weight guide to cleanrooms and contamination control. It contains 26 chapters written by industry leads. The stand-out chapters are Cleanroom standards and GMP requirements, by Mark Hallworth, which weaves together the myriad of different cleanroom requirements; Air handling systems for the protection of pharmaceutical manufacturing processes by Hans Schicht, which clearly presents the science behind the contamination control principles of cleanroom use; and Environmental monitoring in cleanrooms by Tim Sandle and Madhu Raju Saghee, which introduces a clearly written risk based approach to the subject.

Other chapters of interest include one relating to airflow studies, an area often asked for but rarely described written by Tim Sandle, Marco Budini and T Rajesh; and a chapter on auditing cleanrooms which is very, very useful indeed.

The book is highly recommended for the shelf of any cleanroom manager, engineer, microbiologist or quality assurance manager. It is indeed the indispensable guide to cleanrooms and cleanroom management.

The book is published by Euromed Communications:

<http://www.euromedcommunications.com/publications/books/341-cleanroom-management-in-pharmaceuticals-and-healthcare>