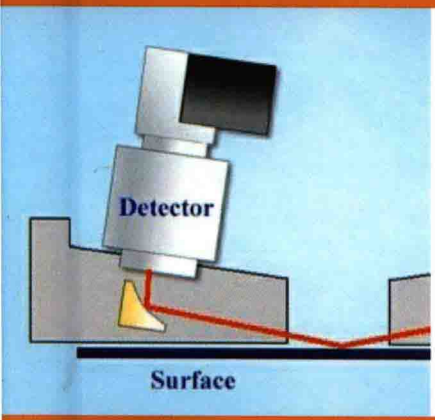
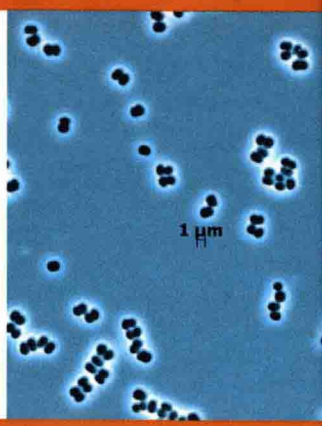
Developments in Surface Contamination and Cleaning

Cleanliness Validation and Verification





Volume Seven

Edited by
Rajiv Kohli and K.L. Mittal

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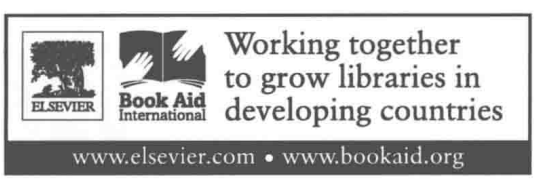

Developments in Surface Contamination and Cleaning

Developments in Surface Contamination and Cleaning Series

Series Editors

Rajiv Kohli and K.L. Mittal

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Preface

The purpose of the book series *Developments in Surface Contamination and Cleaning* is to provide a continuous state-of-the-art critical look at the current knowledge of the behavior of both film-type and particulate surface contaminants. The first six volumes, published in 2008, 2010, 2011, 2012, and 2013 (Volumes 5 and 6), respectively, covered various topics dealing with the fundamental nature of contaminants, their measurement and characterization, and different techniques for their removal. The present book is the seventh volume in the series.

The individual contributions in this book provide state-of-the-art reviews by subject matter experts on contamination sources and cleanliness validation.

Contaminants are ubiquitous. The most common types of surface contaminants are particles; thin film or molecular contamination that can be organic or inorganic; ionic contamination; and microbial contamination. Surface cleanliness levels are defined for each of these contaminant categories by consensus standards that aim to help control and mitigate the deleterious effects of contaminants. In his contribution, *Rajiv Kohli* provides an overview of the sources of these contaminants and mechanisms of their generation and discusses some of the impacts of the contaminants. This can assist in developing remediation solutions for these types of contaminants.

Mid-IR spectroscopy, performed at grazing angle and in direct reflectance mode, provides a convenient tool for surface analysis and cleanliness validation. *Mary Thomson* describes the method in detail and discusses a wide range of qualitative, semiquantitative, and fully quantitative applications in surface concentration ranges that are relevant to pharmaceutical cleaning validation in particular. This method can be used to identify and measure organic contaminants down to submicrogram levels, and it provides a direct, near-real-time result without the need for subsequent laboratory analysis.

The chapter by *Mantosh Chawla* presents a thorough treatise of optically stimulated electron emission (OSEE), also known as photoelectric effect. The OSEE technique is very well suited to thin film contamination detection and monitoring. The chapter discusses the theory of the technique, the factors affecting the technique, and the most common applications of the technique for the study, measurement, and evaluation of the changes in the surface state of almost any substrate. Specific examples of the vast array of applications are also presented spanning all types of industries. This chapter is intended as a practical

and a useful reference tool for anybody involved in surface cleanliness monitoring/measuring or detection, control, and/or elimination of surface contamination in various industries.

Successful cleaning of medical devices and instruments requires both careful selection of materials and consistent monitoring of the procedures used to process them. Chemical characterization of residues that may be adsorbed onto surfaces and mechanical testing to ensure functionality should provide sufficient information to evaluate the potential success of cleaned and disinfected/sterilized medical devices. By using a combination of chemical and mechanical analysis techniques, both manufacturing and decontamination processes can be optimized to ensure a safe and effective product. Choosing the optimal testing protocols, interpreting results, selecting the appropriate chemistries, and implementing rugged, reliable processes require experienced advice and input. It is important to note that no test, however foolproof its design, can ever be considered a definitive predictor of clinical performance. The chapter by *David Albert* examines various kinds of contaminants associated with medical devices and explores various analytical techniques to detect their presence or absence. The use of toxicological risk assessment as a way to set residue limits and as a method to evaluate the overall biological safety of any remaining or detected contaminants left on medical devices is discussed.

Pharmaceutical products and active pharmaceutical ingredients (APIs) can be contaminated by other pharmaceutical products or APIs, by cleaning agents, by microorganisms, or by other materials, such as airborne particles, dust, lubricants, raw materials, intermediates, and auxiliaries. To avoid contamination of the product, adequate cleaning procedures are essential. In their chapter, *S. Lakshmana Prabu*, *T. N. K. Suriya Prakash*, and *R. Thirumurugan* discuss cleaning validation and its regulatory aspects in pharmaceutical manufacturing. The purpose of cleaning validation is to prevent contamination and cross-contamination in pharmaceutical dosage forms. Cleaning validation describes proper application of cleaning procedures for the removal of contaminants associated with the previous products, residues of cleaning agents, as well as the control of potential microbial contaminants and significantly reduces the amount of actives, excipients, and cleaning agents to a concentration within defined acceptance limits.

The contributions in this book provide a valuable source of information on the current status and recent developments in the respective topics on the impact, characterization, and removal of surface contaminants. The book will be of value to government, academic, and industry personnel involved in research and development, manufacturing, process and quality control, and procurement specifications in microelectronics, aerospace, optics, xerography, joining (adhesive bonding), and other industries.

We would like to express our heartfelt thanks to all the authors in this book for their contributions, enthusiasm, and cooperation. Our sincere appreciation goes to our publishers Peter Gane and Matthew Deans, who have strongly

supported the publication of this volume, in particular, and this series, in general. Melissa Read and the editorial staff at Elsevier have been instrumental in seeing the book to publication. Rajiv Kohli would also like to thank the staff of the STI library at the Johnson Space Center for their efforts in locating obscure and difficult-to-access reference materials.

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About the Editors

Dr. Rajiv Kohli is a leading expert with The Aerospace Corporation in contaminant particle behavior, surface cleaning, and contamination control. At the NASA Johnson Space Center in Houston, Texas, he provides technical support for contamination control related to ground-based and manned spaceflight hardware, as well as for unmanned spacecraft. His technical interests are in particle behavior, precision cleaning, solution and surface chemistry, advanced materials, and chemical thermodynamics. Dr. Kohli was involved in developing solvent-based cleaning applications for use in the nuclear industry, and he also developed an innovative microabrasive system for a wide variety of precision cleaning and microprocessing applications in the commercial industry. He is the principal editor of this book series *Developments in Surface Contamination and Cleaning*; the first six volumes in the series were published in 2008, 2010, 2011, 2012, and 2013 (Volumes 5 and 6), respectively, and the present book is the seventh volume in the series. Previously, Dr. Kohli coauthored the book *Commercial Utilization of Space: An International Comparison of Framework Conditions*, and he has published more than 250 technical papers, articles, and reports on precision cleaning, advanced materials, chemical thermodynamics, environmental degradation of materials, and technical and economic assessment of emerging technologies. Dr. Kohli was recently recognized for his contributions to NASA's Space Shuttle Return to Flight effort with the Public Service Medal, one of the agency's highest awards.

Dr. Kashmiri Lal "Kash" Mittal was associated with IBM from 1972 to 1994. Currently, he is teaching and consulting in the areas of surface contamination and cleaning and in adhesion science and technology. He is the founding editor of the new journal *Reviews of Adhesion and Adhesives* which made its debut in 2013. He cofounded the *Journal of Adhesion Science and Technology* and was its editor-in-chief until April 2012. Dr. Mittal is the editor of more than

120 published books, many of them dealing with surface contamination and cleaning. He was recognized for his contributions and accomplishments by the worldwide adhesion community which organized in his honor on his 50th birthday the 1st International Congress on Adhesion Science and Technology in Amsterdam in 1995. The Kash Mittal Award was inaugurated in his honor for his extensive efforts and significant contributions in the field of colloid and interface chemistry. Among his numerous awards, Dr. Mittal was awarded the title of doctor *honoris causa* by the Maria Curie-Sklodowska University in Lublin, Poland, in 2003. In 2014 two books entitled *Recent Advances in Adhesion Science and Technology* and *Surfactants Science and Technology: Retrospects and Prospects* were published in his honor.

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