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## **DRAVEN FLORES**

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Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals  
Technology Transfer  
Parenteral Drug Association (PDA). Presents the Parenteral Drug Association (PDA), a pharmaceutical science and technology association. Notes that the mission of the Association is to educate and exchange information about the art and science of sterile products manufacturing. Provides information about the PDA Training and

Research Institute. Offers access to discussion groups, documents to download, and a calendar of events. Includes information about membership, "PDA Journal," and worldwide chapters. Lists the board members. Posts contact information via mailing address, telephone and fax numbers, and e-mail.  
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Reprocessing of Biopharmaceuticals  
Rapid/automated ID Methods Survey  
A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry  
The Challenge of CMC Regulatory Compliance for Biopharmaceuticals  
"The greater our knowledge increases, the more our ignorance unfolds. " U. S. President John F. Kennedy, speech, Rice University, September 12, 1962  
My primary purpose for writing this book was much more than to provide another information

source on Chemistry, Manufacturing & Controls (CMC) that would rapidly become out of date. My primary purpose was to provide insight and practical suggestions into a common sense business approach to manage the CMC regulatory compliance requirements for biopharmaceuticals. Such a common sense business approach would need (1) to be applicable for all types of biopharmaceutical products both present and future, (2) to address the needs of a biopharmaceutical manufacturer from the beginning to the end of the clinical development stages and including post market approval, and (3) to be adaptable to the constantly changing CMC regulatory compliance requirements and guidance. Trying to accomplish this task was a humbling experience for this author! In Chapter 1, the CMC regulatory process is explained, the breadth of products included under the umbrella of biopharmaceuticals are identified, and the track record for the pharmaceutical and biopharmaceutical industry in meeting CMC regulatory compliance is discussed. In Chapter 2, while there are many CMC commonalities between biopharmaceuticals and chemically-synthesized pharmaceuticals, the significant differences in the way the regulatory agencies handle them are examined and the reasons for why such differences are necessary is discussed. Also, the importance of CMC FDA is stressed.

*Utilization of Statistical Methods for Production Monitoring*  
Springer Science & Business Media

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*Virus filtration* Parenteral Drug Association  
Presents the Parenteral Drug Association (PDA), a pharmaceutical science and technology association. Notes that the mission of the Association is to educate and exchange information about the art and science of sterile products manufacturing. Provides information about the PDA Training and Research Institute. Offers access to discussion groups, documents to download, and a calendar of events. Includes information about membership, "PDA Journal," and worldwide chapters. Lists the board members. Posts contact information via mailing address, telephone and fax numbers, and e-mail.

Rapid/automated ID Methods Survey

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Analytical Method Development and Qualification for  
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