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Hazardous Waste Measurements - Milagros S. Simmons - 1990-12-19
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Development and Validation of Analytical Methods - Christopher M. Riley - 1996-05-29
The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

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Advances in Robotics Research: From Lab to Market - Antoni Grau - 2019-09-17
In this book Part I presents first an overview of the ECHORD++ project, with its mission and vision together with a detailed structure of its functionalities and instruments: Experiments, Robotic Innovation Facilities and Public end-user Driven Technology Innovation PDTI. Chapter 1 explains how the project is born, the partners, the different instruments and the new concept of cascade funding projects. This novelty made ECHORD++ a special project along the huge number of research groups and consortia involved in the whole project. So far, it is the European funded project with more research team and partners involved in the robotic field. In Chapter 2, one of the instruments in ECHORD++ is explained in detail: RIF. Robotic innovation facilities are a set of laboratories across Europe funded with the project with the goal of hosting consortia involved in any experiment that have special needs when testing their robotic research. In the chapter the three different and specific RIFs will be described and analyzed. Chapter 3 explains an important instrument in ECHORD++: the Experiments. In this part, a big number of research groups have been involve in short time funded research projects. The chapter explains the management of such Experiments, from the call for participation, the candidate’s selection, the monitoring, reviews and funding for each of the 36 experiments funded for Echord. Chapter 4 is very special because it presents the innovation of funding public end-user driven technology, in particular, robotic technology. The robotic challenge is the key of such an instruments together with the management of the different consortia that participated competitively in the success of the robotic challenge proposed by a public entity, selected also with a very special and innovative process.

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Automation in blood transfusion - C.Th. Smit Sibinga - 2013-11-11
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Nadkarni - 1991

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High Throughput Screening - John P. Devlin - 1997-05-06
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