

Preface

Why read or even buy this book?

If you are using a chromatography data system (CDS) in the regulated areas of the pharmaceutical, medical device, active pharmaceutical ingredient and contract research organisations, you will need to validate the system.

This book will be your guide through the regulations and jargon. It provides practical advice that can be used directly by you to meet regulatory requirements and allow a sustainable validation effort for your chromatography data system throughout its operational life.

However, computer validation is more than just a means of meeting regulatory requirements. It is a strategic business tool.

- How much money has your organisation wasted on computer systems that fail to meet initial expectations or do not work? If used correctly, validation is a means of implementing the right system for the right job. Computer validation is quite simply good business practice, that, if followed provides regulatory compliance for no additional cost.
- In addition, implementing electronic signatures with electronic ways of working will allow a laboratory to exploit tangible business benefits from regulatory compliance. This requires more time spent mapping and analysing the current working process and practices but the payback is reduction of tedious tasks such as checking for transcription errors in the laboratory and tangible time and resource savings.

This book is intended to help the reader to validate their CDS in the current risk based regulatory climate and is written by a chromatographer with extensive experience of validating many different computerised systems in many different organisations since 1986.

The principles and practices of validation outlined in this book are also applicable to other types of computerised systems used in laboratories.

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