RSC Chromatography Monographs

Validation of Chromatography Data Systems

Ensuring Data Integrity, Meeting Business and Regulatory Requirements

R. D. McDowall

ROYAL SOCIETY OF CHEMISTRY

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2nd Edition

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Preface to the First Edition

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

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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.

Bob McDowall
Bromley, UK

Preface to the Second Edition

The importance of validation of laboratory computerised systems operating in regulated laboratories has not changed and is indeed become more important since the publication of the first edition of this book. Since 2005, there has been detection of increased fraud and falsification involving chromatography data systems, as evidenced in FDA warning letters and citations by other regulatory authorities. Coupled with this, are poor data management practices that have also resulted in increased regulatory scrutiny of these systems as often chromatographic analysis can constitute up to 100% of a GXP regulated laboratory's workload. This results in the detailed examination of the system: the validation, change control as well as the integrity of the electronic records/raw data generated.

In addition, there have been many regulatory changes since the first edition:

- A United States Pharmacopeia general chapter <1058> in 2008 on analytical instrument qualification (AIQ) and a new version published in USP XXXX 1st Supplement.
- The Food and Drug Administration (FDA) has produced guidance including an updated compliance program guide for pre-approval inspections where one of the three objectives is a detailed examination of the laboratory data contained in a regulatory submission as well as data integrity guidance.
- In Europe, EU GMP 8 of the 9 main chapters of Part 1 have been revised plus Annex 11 on computerised systems and Annex 15 on qualification and validation.
- Data integrity guidance has been published by the UK regulatory agency (Medicines and Healthcare Products Regulatory Agency), the World Health Organisation, the FDA, PIC/S and EMA.

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- GAMP Forum have published the second edition of the good practice guide on risk based validation of laboratory computerised systems and an updated electronic records and data integrity guidance.

All of these documents have resulted in changes to validating and operating computerised systems in general and chromatography data systems in particular as well as the way of managing the electronic records that these systems generate and process.

As a result of regulatory changes, the second edition of this book has grown from 25 to 37 chapters, (about three times the size of the first edition) and the content of each chapter is greatly expanded with more practical detail to help the reader in their task of validation and operational control of a chromatography data system. Moreover, the sub-title of the book has been amended to reflect the current regulatory interest in data integrity.

As with the first edition of this book, the principles and practical approaches described here are applicable to other computerised systems in regulated laboratories.

Bob McDowall
Bromley, UK

Biography

Bob McDowall is an analytical chemist with over 45 years of experience. After graduating from the University of Newcastle-upon-Tyne in 1972 he completed his PhD at the Department of Forensic Medicine, London Hospital Medical College, University of London in 1977. Then, he worked for two major international pharmaceutical companies working in bioanalysis for 15 years. In 1990 he was a co-chair of the first Bioanalytical Methods Validation meeting that was co-organised by the American Association of Pharmaceutical Scientists and the Food and Drug Administration. He was a co-author of the subsequent publication that was a major input into the FDA's Guidance for Industry on the subject issued a few years later.

In 1993 he set up his consultancy practice. Initially, this was McDowall Consulting but this entity was replaced by R. D. McDowall Limited, founded in 1998.

Bob's interests are process improvement, laboratory informatics, computerised system validation including Part 11 and data integrity, quality software development, interpretation of GXP regulations and laboratory automation. He is also a trained auditor working in the GLP, GMP and GCP areas.

He has published widely for over 40 years including editing the first book on LIMS in 1987 and for his work in training and advancement of the subject he was presented with the 1997 LIMS Award by the LIMS Institute. Bob has written the Questions on Quality column in LC-GC Europe since 1993 and the Focus on Quality column in Spectroscopy since 2000. He is also a presenter and trainer giving many presentations and short courses in his subject areas.

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He has been a contributor to the GAMP Good Practice Guides for IT Compliance (2005) and Control and Risk Based Validation of Laboratory Computerised Systems second edition (2012). Bob was a co-author of a stimulus to the revision process of United States Pharmacopoeia general chapter <1058> in January 2012 and the final version will be published in USP XXXX 1st Supplement in 2017.

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I would like to thank Neil Lander, Heather Longden, Loren Smith and Paul Smith for their help in obtaining figures used in this book. In addition, I appreciate the review and comment by Chris Burgess and Mark Newton during the preparation of the text.

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