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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Validation of Chromatography Data Systems: Ensuring Data Integrity, Meeting Business and Regulatory Requirements, 2nd Edition
By R. D. McDowall

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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.

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