

Electronic Batch Recording and Batch Release for Drugmakers

Table of Contents

About the Author

Introduction..... 5

Electronic Batch Recording and Batch Release..... 7

Strategic Goals and Deployment Possibilities of an EBR System 9

System Types by Extent of Automation..... 10

GMP-relevant Functions and Properties 12

Collecting and Classifying the Data 13

Designing an EBR Form Layout..... 14

Converting Paper Documentation to EBR 16

Appendices..... 17

- A. EU GMP Guide Chapter 4: Documentation
- B. EU GMP Guide Annex 16: Certification by a Qualified Person and Batch Release
- C. EU GMP Guide Annex 11: Computerised Systems
- D. 21 CFR Part 211 – Subpart J – Records and Reports
- E. 21 CFR Part 11 – Electronic Records; Electronic Signatures
- F. EU GMP Guide Chapter 1: Pharmaceutical Quality System
- G. EU GMP Guide Chapter 7: Outsourced Activities