

Electronic Document Management Systems for Drugmakers

Table of Contents

About the Author

- Introduction..... 5**
- Documentation and Document Management..... 7**
 - Knowledge and Information Management 7
 - Project Management 8
 - Training Management..... 9
 - DMS Integration in the Company..... 9
 - GMP-relevant Documentation and Processes 10
 - System Landscape 16
 - Adjacent Systems 17
 - Basic Principles of a DMS 17
 - Example: SOP Management 19
 - Basic Functions and Key Concepts 22
 - Defining Master Document 22
 - Electronic Signatures..... 23
 - Check in and Check out 23
 - Managing Header and Footer Information..... 24
 - Miscellaneous 25
 - Validating a DMS 25
- Appendices..... 27**
 - A. EU GMP Guide, Chapter 4: Documentation
 - B. ICH Q10: Pharmaceutical Quality System
 - C. EU GMP Guide, Chapter 7: Outsourced Activities
 - D. EU GMP Guide Annex 11: Computerised Systems