

Validation Documentation



CONCEPT
HEIDELBERG

GMP Compliance for
Computerized Systems Validation
January 16 - 17, 2003 at Istanbul, Turkey

Validation Documentation

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Computerized Systems Validation
Dr. Guenter Generlich

Documentation 1

Documentation: Agenda

- Why documentation
- Good documentation practice
- Key documentation for validation

Computerized Systems Validation
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Documentation 2

Documentation Problems

- Nobody likes to document
- We don't have secretaries any longer
- IT speak is often difficult to understand
- We lack writing skills
- Only weak templates or samples
- Documentation often not read by intended audience

Documentation Objectives

- Generally improved credibility
- Reduced risk of misunderstanding
- Sound base for training
- Key information to decision makers
- Minimized impact of changes to project staff
- Eased system maintenance and system change
- Reference point for future efforts and improvements

Documentation Objectives

- Improved security of the system
- Sustain effective project monitoring
- Personal-independent access to information
- Protection of confidential documentation
- Comply with regulatory requirements
- Transparency is the partner of professionalism
- Last but not least: show what you've done

The Document Lifecycle

- Conceive Document
- Create ...
- Review
- Approve
- Issue
- Use
- Withdraw
- Archive
- Destroy
- Store
- Retrieve
- Backup
- Restore
- Change Format
- Change Content

Good Documentation Practice

Purpose:

To ensure that key documents are

- created
 - reviewed
 - approved
 - distributed
 - stored
 - archived
- in a controlled manner

Good Documentation Practices GDPs

- 1 Format & Layout
- 2 Version control
- 3 Master document file
- 4 Storage
- 5 Availability
- 6 Review
- 7 Signatures
- 8 Changes
- 9 Withdrawn documents



Documentation Format GDP 1

The documentation format should be standardized, including

- Layout
- Style
- Reference Numbering

Minimum requirements are

- Author (+ Owner)
- Title
- Date
- Location

Layout and 2nd Page GDP 1

 See sample pages at end of presentation

- Avoid abbreviations
- Consider an overall glossary
- Header and footer just 1 line
- Page numbering: page n of m pages
- Show company logo on all pages
- WinWord has a spell checker



Version Control GDP 2

- Documents should be under version control
- The status of a version should be identifiable, e.g.
 - draft
 - approved
 - released
 - effective
 - withdrawn
- A document should be clearly identified as *draft* prior to formal use

Master Document File GDP 3

- A Master Document File should be maintained with the master document copy and a document history or change log
- A Master Document Index should be retained, showing document reference, document title and document issue status

Storage GDP4

- Documentation and associated information should be stored safely and securely
- Documentation should be protected against accidental and malicious damage
- Documentation should be retrievable throughout the defined retention period



Availability GDP5

- Approved documents should be made available for use at required locations
- There should be safeguards against unintended use of unapproved or superseded documents
- If computerized distribution and archiving is used, printouts should state that the paper copy is not a controlled version

Review GDP 6

- Documents should be subjected to review from which identified problems or proposals should be documented
- Actions initiated by the review should be updated and verified for correctness by the document owner
- There may be different types of reviews, in which case the type of review conducted should be documented (technical, functional, ...)

Signatures GDP 7

- Approval should be documented by signing with formal signatures, including (in handwriting) the date of signing
- There should be a statement of what the approval implies
- Approval signatories should be identified by function and/or title in each document



Changes GDP 8

- Changes to documents should be reviewed and approved by the same functions / organizations that performed the original review and approval, unless specifically designated otherwise
- A change log should be kept, either as part of the document or in a separate record
- The change log should include a description of the change and an identification of the affected documents

Withdrawn Documents GDP 9

- Superseded and withdrawn documents should be archived in a clearly labeled separate file
- Such documents should be clearly identifiable as withdrawn

The KISS Principle

- Keep it simple, stupid
- Keep it short and simple
- Keep it simple and structured



The KISS Principle

- Value not how complicated you can make things sound, but how **simple**
- Often, people working on a project do not want what they are doing to sound **simple** and intelligible
- However, make things **simple to the reader** and the reader will love you for it
- Anyone can make complex things sound **confusing**
- It takes an expert to make complex things sound **simple**

Validation Documentation

... some Hints and Tips

- Start documenting from the very beginning
- Keep writing style clean and simple
- Show numerous examples
- Make use of visuals whenever possible and meaningful
- Use advance organizers and summaries
- Provide table of contents, indices, and glossaries
- Consider references, attachments, appendices
- Field-test early drafts
- Provide feedback mechanism to readers
- Use professional writers and copy editors
- Keep documenting throughout validation life cycle

Online Documentation

- Information is available when computer is available
- User don't need space to open printed manuals
- Manual updates are low cost
- Electronic indexing allow fast search of manual
- Multimedia help may be beneficial

Validation Documentation

Validation Documents (Configuration Items)

Application Software

- Standard Packages
- Custom developed Software
- Add-ons + Interfaces

+ A/S Documentation



Technology Products

- Hardware + Netware
- Operating Software
- Equipment + Peripherals

+ T/P Documentation



Other Documentation

- Life Cycle Documents
- Standards + Procedures (SOP)
- Logs



Personnel Matters

- People
- Organization
- Training



Live Cycle Documents

- Project Charter
- Project Plan
- Validation Plan
- Requirements
- Traceability Matrix
- Functional Design / Spec
- Business Models
- Technical Design / Spec
- Programs
- Testing
- Technical Procedures
- User Procedures
- Supplier Assessment
- Safety
- Training
- System Description
- Transition Plan
- Validation Report
- Review Plan

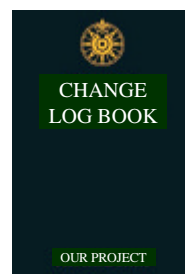
Validation Documentation

Functional Design Doc

- | | |
|---|---|
| 1 Management Summary | 8 Technology Infrastructure |
| 2 Summary of Functional Solution Approach | 9 Data Conversion System Spec |
| 3 System Specification <ul style="list-style-type: none">- Product Usage Specification- Process Specifications | 10 Acceptance Test Specification |
| 4 Data Model Packet <ul style="list-style-type: none">- Logical Data Model- Preliminary Physical Data Model | 11 Plan and Estimates |
| 5 External Interface Specifications | Appendix: <ul style="list-style-type: none">- Glossary- Source Documents- Other Documents |
| 6 Security and Control Requirem'ts | |
| 7 Backup and Contingency Rqmts | |

Logs

- Change Log
- Training Log
- Maintenance Log
- Risk Log



Standard Operating Procedures - SOPs (1)

- Business Change
- Documentation
- Archiving
- Change Management
- Testing
- Error Handling
- Job Description
- Training
- Ongoing / Periodic Review
- Logical & Physical Security
- Start-up & Shutdown
- Backup & Restore
- Maintenance & Repairs

All these can be
application
independent !

- System Support incl. Help Desk
- Assessments & Auditing (internal and external)
- Service Level Agreements (SLAs)

Standard Operating Procedures - SOPs (2)

- Application specific procedures 1
- Application specific procedures 2
- Application specific procedures 3
- Application specific procedures 4
-

Sample Standards / Master Validation Plan on Computerized System Validation

- CSV Policy and Appendix
- CSV Guidelines
 - Inventory and Master Planning
 - Specify and Design
 - Planning and Reporting
 - Build and Test
 - Change Management
 - Release and Use
 - Security Management
 - Infrastructure Validation
 - Training
 - Electr. Records + Signatures
 - Vendor Assessment
 - Documentation
- CSV Glossary

Guideline Contents

- Management Summary
 - Purpose
 - Scope
 - Roles and Responsibilities
 - Activities
 - Timing
 - Documentation
- Always the same structure!

Referenced Documents

- Organization IT global / local
- IT strategies, policies, standards (corporate, local)
- Infrastructure validation, incl. infrastructure development life cycle
- High level overviews and qualified status of computer rooms, servers, networks
- IT related inventories and configurations (detailed)
- Computer operations procedures
- Service delivery procedures
- Service support procedures

Document Related Technologies (DRT)

- Internet, Intranet and Extranet
- Document-, Workflow- and Knowledge Management
- E-commerce and Digital Signatures
- Document Input, Distribution and Storage
- OCR, ICR and Pattern Recognition
- Data Bases, Data Warehouses and Retrieval Engines
- Imaging and Multimedia
- Archival and Records Management
- Secure Communication and Unified Messaging
- Groupware and Office Solutions
- Forms and Output Management
- Middle and Component Ware
- Content Management and Content Distribution