Validation Documentation

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Validation Documentation

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Documentation: Agenda

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

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
Validation Documentation

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9 Withdrawn documents
The documentation format should be standardized, including:

- Layout
- Style
- Reference Numbering

Minimum requirements are:

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

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  - withdrawn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
Validation Documentation

Storage  GDP 4

- 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  GDP 5

- 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 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
## Functional Design Doc

<table>
<thead>
<tr>
<th>1</th>
<th>Management Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Summary of Functional Solution Approach</td>
</tr>
<tr>
<td>3</td>
<td>System Specification</td>
</tr>
<tr>
<td></td>
<td>- Product Usage Specification</td>
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<tr>
<td></td>
<td>- Process Specifications</td>
</tr>
<tr>
<td>4</td>
<td>Data Model Packet</td>
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<tr>
<td></td>
<td>- Logical Data Model</td>
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<tr>
<td></td>
<td>- Preliminary Physical Data Model</td>
</tr>
<tr>
<td>5</td>
<td>External Interface Specifications</td>
</tr>
<tr>
<td>6</td>
<td>Security and Control Requirements</td>
</tr>
<tr>
<td>7</td>
<td>Backup and Contingency Requirements</td>
</tr>
<tr>
<td>8</td>
<td>Technology Infrastructure</td>
</tr>
<tr>
<td>9</td>
<td>Data Conversion System Specifications</td>
</tr>
<tr>
<td>10</td>
<td>Acceptance Test Specification</td>
</tr>
<tr>
<td>11</td>
<td>Plan and Estimates</td>
</tr>
</tbody>
</table>

Appendix:
|
- Glossary
- Source Documents
- Other Documents

## 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
  - Planning and Reporting
  - Change Management
  - Security Management
  - Training
  - Vendor Assessment
- CSV Glossary

Guideline Contents

- Management Summary
- Purpose
- Scope
- Roles and Responsibilities
- Activities
- Timing
- Documentation

Always the same structure!
Validation Documentation

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