Taking the Mystery out of Computer System Validation

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Introductions

• Deb Bartel, MBA, CQA, PMP
• Praxis Life Sciences
Outline

1. Why Validate Systems?
2. Which Systems Need Validation?
3. How Do You Validate Systems?
Why Validate Systems?

Part 1
FDA 21 CFR 11 *Electronic Record; Electronic Signatures*

Subpart B--Electronic Records, Sec. 11.10

... procedures and controls **shall include** the following: (a) **Validation of systems** ...

FDA 21 CFR 211 *cGMP for Finished Pharmaceuticals*

Subpart D--Equipment, Sec. 211.68(b)

**Input to and output from the computer** .... **shall be checked for accuracy.**

21 CFR 1271 *Human Cells, Tissues, and Cellular and Tissue-Based Products*

Subpart D Current Good Tissue Practice, Sec. 1271.160(d)

**You must validate the performance of computer software for the intended use, ...**

21 CFR 820 *Quality System Regulation*

Subpart C Design Controls, Sec. 820.30(g)

Design validation **shall include software validation** ...

Subpart G Production and Process Controls, Sec. 820.70(i)

... the manufacturer shall **validate computer software for its intended use ....**
Warning Letter Statistics

Over 200 Warning Letter citations in a 3 year period (2013-2015) for software and computer system issues

Nearly 1/3 of these were for validation issues

A majority of the validation issues were for simply failing to validate the software or computer system

EC COUNCIL
DIRECTIVE 93/42/EEC

ANNEX I
ESSENTIAL REQUIREMENTS

12.1a For devices which incorporate software or which are medical software in themselves, the software must be validated according to the state of the art taking into account the principles of development lifecycle, risk management, validation and verification.

EudraLex Volume 4
Good Manufacturing Practice, Medicinal Products for Human and Veterinary Use

Annex 11 Computerised Systems

The application should be validated; IT infrastructure should be qualified.
Brazilian ANVS
**Good Practices of Medicament Manufacturing**

... computer systems .. must be qualified and / or validated.

Validation shall be considered part of the computer system’s life cycle, ....

Japan’s Guideline on Management of Computerized Systems for Marketing Authorization Holders and Manufacturers of Drugs and Quasi-drugs

**specifying** the necessary matters during development of computerized systems, **the validation items to verify such systems**, ... in order to ensure such systems function as intended.
ICH Q7A, *Good Manufacturing Practice for Active Pharmaceutical Ingredients*

GMP related **computerized systems should be validated.** The depth and scope of validation depends on the diversity, complexity, and criticality of the computerized application.

ICH E6 *Good Clinical Practice*

When using electronic trial data handling and/or remote electronic trial data systems, the sponsor should:

**Ensure and document that the electronic data processing system(s) conforms to the sponsor’s established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation)**
9.8 The hardware and software of the computers should be checked regularly to ensure reliability. **The software (program) should be validated before use.**

**5.40 GMP related computerized systems should be validated.** The depth and scope of validation depends on the diversity, complexity and criticality of the computerized application.

Before a computerised system is brought into use, it should be demonstrated, **through appropriate validation** or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.

4.9 The regulated user should be able to **demonstrate through the validation evidence** that they have a high level of confidence in the integrity of both the processes executed within the controlling computer system and in those processes controlled by the computer system.
CSV Purpose and Benefits

- **Effectiveness**
- **Safety**
- **Integrity**
- **Accuracy**
Which Systems Need Validation?
Part 2
Computer System Validation is required for companies that …

Activities
- Design
- Develop
- Conduct clinical trials
- Manufacture
- Package
- Label
- Store
- Distribute
- Install
- Service

Products
- Pharmaceuticals
- Biologicals
- Medical Devices
- Blood and Blood Components
- Human Cell and Tissue Products
- Infant Formula
What Software Requires Validation?

**Medical Device Software**
- Software used as a component, part, or accessory of a medical device
- Software that is itself a medical device

---

Sources: General Principles of Software Validation: Final Guidance for Industry and FDA Staff
Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application
Examples: Medical Device Software

Medical Device Software
Software used as a component, part, or accessory of a medical device. And, software that is itself a medical device.

<table>
<thead>
<tr>
<th>Blood Supply Management Software</th>
<th>Radiation Treatment Control Software</th>
<th>Infusion Pump Software</th>
<th>Heart Arrhythmia Detection Software</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Donor Management Software</td>
<td>Defibrillator Software</td>
<td>Patient Monitoring Software</td>
<td>Injury Treatment Machine Software</td>
</tr>
<tr>
<td>Medical Imaging System Software</td>
<td>Laser Treatment Software</td>
<td>Robotic Surgery Software</td>
<td>Hospital Bed Software</td>
</tr>
<tr>
<td>Laboratory Diagnostics Software</td>
<td>Oxygen Regulating Software</td>
<td>Pacemaker Software</td>
<td>Wheelchair and Scooter Software</td>
</tr>
</tbody>
</table>
What Software Requires Validation?

**Medical Device Software**
- Software used as a component, part, or accessory of a medical device
- Software that is itself a medical device

**Production Software**
- Software used in the production of the FDA regulated product

Sources: General Principles of Software Validation: Final Guidance for Industry and FDA Staff
Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application
Examples: Production Software

Production Software
Software used in the production of the FDA regulated product

- Manufacturing Automation Software
- Production Monitoring Software
- Laboratory Instrument Software
- Batch Release Software
- Programmable Logic Controllers (PLCs)
- Bill of Material Software
- Laboratory Management Software
- Product/Part Inspection Software
- Computer Numerical Controls (CNCs)
- Material Control Software
- Laboratory Calculations (e.g., spreadsheets)
- Product Testing Software
- Building Management Systems
- Work Order Management Software
- Yield Calculations
- Labeling Software
What Software Requires Validation?

**Medical Device Software**
- Software used as a component, part, or accessory of a medical device
- Software that is itself a medical device

**Production Software**
- Software used in the production of the FDA regulated product

**Quality Management Software**
- Software used to implement the FDA-required quality management system

Sources: General Principles of Software Validation: Final Guidance for Industry and FDA Staff
Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application
### Examples: Quality Management Systems

**Quality Management Software**
Software used to implement the FDA-required quality management system

<table>
<thead>
<tr>
<th>Change Control Software</th>
<th>Calibration Software</th>
<th>Document Management Software</th>
<th>Non-Conformance Tracking Software</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inventory Control Software (e.g., ERPs)</td>
<td>Preventive Maintenance Management</td>
<td>Device History Software</td>
<td>Deviation Tracking Software</td>
</tr>
<tr>
<td>Product Returns Management Software</td>
<td>Quality Trending Software</td>
<td>Specification Management Software</td>
<td>CAPA Software</td>
</tr>
<tr>
<td>Product Recall Management Software</td>
<td>Internal Audit Tracking Software</td>
<td>Specification Setting Software</td>
<td>Complaints Software</td>
</tr>
</tbody>
</table>
## What Types of Computer Systems and Software Require Validation?

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medical Device Software</strong></td>
<td>• Software used as a component, part, or accessory of a medical device</td>
</tr>
<tr>
<td></td>
<td>• Software that is itself a medical device</td>
</tr>
<tr>
<td><strong>Production Software</strong></td>
<td>• Software used in the production of the FDA regulated product</td>
</tr>
<tr>
<td><strong>Quality Management Software</strong></td>
<td>• Software used to implement the FDA-required quality management system</td>
</tr>
<tr>
<td><strong>Software for FDA-Regulated Records</strong></td>
<td>• Software used to create, modify, maintain, archive, retrieve, or transmit FDA-required records. And electronic records submitted, per FDA requirement.</td>
</tr>
</tbody>
</table>

*Sources: General Principles of Software Validation: Final Guidance for Industry and FDA Staff Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application*
### Examples: Records Software

**Software for FDA-Regulated Records**

Any software used to create, modify, maintain, archive, retrieve, or transmit FDA-required records. And, electronic records submitted, per FDA requirement.

<table>
<thead>
<tr>
<th>Software for FDA-Regulated Records</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic Submissions Software</td>
<td>Adverse Event Reporting Software</td>
</tr>
<tr>
<td>IRB Records Software</td>
<td>Clinical Trial Records Software</td>
</tr>
<tr>
<td>Training Records Software</td>
<td>Learning Management Software</td>
</tr>
<tr>
<td>Prescription Order Fulfilment</td>
<td>Distribution Records</td>
</tr>
<tr>
<td>Software</td>
<td>MDR Reporting Software</td>
</tr>
<tr>
<td></td>
<td>Service Records Software</td>
</tr>
<tr>
<td></td>
<td>Supplier Approval Records</td>
</tr>
<tr>
<td></td>
<td>Warehouse Management Software</td>
</tr>
<tr>
<td></td>
<td>Organ / Tissue Donor Records</td>
</tr>
<tr>
<td></td>
<td>Call Center Records Software</td>
</tr>
<tr>
<td></td>
<td>Validation Records</td>
</tr>
<tr>
<td></td>
<td>Product Rework Records</td>
</tr>
</tbody>
</table>
How Do You Validate Systems?

Part 3
The FDA defines software validation as...

**Confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled**

The examination needs to confirm that the software will work in all anticipated situations.

Document all validation activities and test results.

Define what the user needs to do with the software and how they will use the software.

Examine the software to confirm that it functions as defined in requirements and it will be suitable for the intended use.

Define how the software needs to work to enable the intended use.

Source: General Principles of Software Validation: Final Guidance for Industry and FDA Staff
CSV Model

Planning

User Requirements Specification

Verifies

Functional Specifications

Design Specifications

System Build

Verifies

Installation Qualification Tests (IQ)

Installation Qualification Tests (IQ)

Verifies

Operational Qualification Tests (OQ)

Performance Qualification Tests (PQ)

Verifies

Reporting

Verifies
CSV Model

Planning

User Requirements Specification

Functional Specifications

Design Specifications

System Build

Installation Qualification Tests (IQ)

Operational Qualification Tests (OQ)

Performance Qualification Tests (PQ)

Reporting

Verifies

User Requirements
- User Needs for the software
- Intended Use of the Software
- Critical Constraints

User Requirements Specification

• User Needs for the software
• Intended Use of the Software
• Critical Constraints

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## User Requirement, examples

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.0</strong></td>
<td>The system shall provide the capability for managing the training requirements for each job</td>
<td><strong>2.0</strong></td>
</tr>
<tr>
<td><strong>14.0</strong></td>
<td>The system shall restrict user access to authorized personnel</td>
<td><strong>15.0</strong></td>
</tr>
<tr>
<td><strong>25.0.</strong></td>
<td>The system shall provide reports of employee training status</td>
<td><strong>26.0.</strong></td>
</tr>
</tbody>
</table>
## Risk Assessment, example

<table>
<thead>
<tr>
<th>Requirement or Feature</th>
<th>What is the risk to patients, products, data integrity?</th>
<th>What is the likelihood of failure?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.0</strong> The system shall provide the capability for managing the training for each employee</td>
<td><strong>Medium:</strong> A defect or error in tracking employee training could impact product quality if employee performs task incorrectly as a result</td>
<td><strong>Low:</strong> Out of the box feature thoroughly tested by software vendor and confirmed during vendor audit</td>
</tr>
<tr>
<td><strong>26.0.</strong> The system shall provide reports of training charges by department</td>
<td><strong>Low:</strong> A defect or error in training charges will not impact patients, products, or the integrity of associated data</td>
<td><strong>High:</strong> Custom-developed functionality built with a new report building tool</td>
</tr>
</tbody>
</table>
**CSV Model**

**Planning**
- User Requirements Specification
  - Verifies

**Functional Specifications**
  - Verifies

**Design Specifications**
  - Verifies

**Installation Qualification Tests (IQ)**

**Performance Qualification Tests (PQ)**

**Reporting**

**Validation Plan**
- Scope
- Approach
- Roles & Responsibilities
- Acceptance Criteria

**System Build**

**System Build**

**Planning**

**Reporting**
**CSV Model**

**Planning** -> **Verifies** -> **Functional Specifications**

**User Requirements Specification** -> **Verifies** -> **Performance Qualification Tests (PQ)**

**Functional Specifications**

**Functional Specification**
- How the software should look
- What data the software should capture
- Logic, calculations

**Design Specifications**

**Verifies** -> **Installation Qualification Tests (IQ)**

**System Build**

**Verifies** -> **Operational Qualification Tests (OQ)**

**Reporting**
## User Requirement 2.0
The system shall provide the capability for managing the training for each employee.

<table>
<thead>
<tr>
<th>Functional Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 The system shall require that each employee is assigned to a</td>
</tr>
<tr>
<td>2.1.1 Job ID</td>
</tr>
<tr>
<td>2.1.2 Department.</td>
</tr>
<tr>
<td>2.2 For each employee, the system shall require entry of</td>
</tr>
<tr>
<td>2.2.1 the employee’s e-mail address</td>
</tr>
<tr>
<td>2.2.2 the supervisor’s e-mail address.</td>
</tr>
<tr>
<td>2.3 The system shall send an email notification to employees assigned to a Job ID for any new of revised training courses assigned to the Job ID.</td>
</tr>
<tr>
<td>2.4 The system shall send assigned trainees an email training notification reminder every day until training is complete.</td>
</tr>
<tr>
<td>2.5 For overdue training, the system shall send the assigned trainee’s supervisor an email training notification reminder every day until training is complete.</td>
</tr>
</tbody>
</table>
Design Specification
- Database design
- Process design
- Security design
- Interface design
- Architecture design
- Network requirements
Design Element, examples

Hardware

<table>
<thead>
<tr>
<th>Application Server Requirements</th>
<th>Component Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processor</td>
<td>Intel Xeon E5506 Nehalem-EP 2.13 GHz 4 x 256 KB L2 Cache 4 MB L3 Cache LGA 1366 80W 64-bit</td>
</tr>
<tr>
<td>Memory</td>
<td>8 GB (30 GB Available)</td>
</tr>
<tr>
<td>HDD Configuration</td>
<td>300.0 GB 10K RAID 5</td>
</tr>
<tr>
<td>Operating System</td>
<td>Windows Server 2012</td>
</tr>
</tbody>
</table>

Configuration

<table>
<thead>
<tr>
<th>Access Configuration</th>
<th>Job Data</th>
<th>Doc. Data</th>
<th>Course Data</th>
<th>Audit Trails</th>
</tr>
</thead>
<tbody>
<tr>
<td>M: Add, Change, Inactivate</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>V</td>
</tr>
<tr>
<td>V: View only</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>V</td>
</tr>
<tr>
<td>X: No Access</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>V</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component Specification</th>
<th>Job Data</th>
<th>Doc. Data</th>
<th>Course Data</th>
<th>Audit Trails</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Admin</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>V</td>
</tr>
<tr>
<td>Training Manager</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>V</td>
</tr>
<tr>
<td>Training Personnel</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>V</td>
</tr>
<tr>
<td>Laboratory Supervisor</td>
<td>V</td>
<td>V</td>
<td>V</td>
<td>X</td>
</tr>
<tr>
<td>Laboratory Personnel</td>
<td>X</td>
<td>V</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Database Structure

Customization

Technology: Develop CLASS/SAP interface in JAVA v7.1 and AIP AT.

<table>
<thead>
<tr>
<th>Data Mapping</th>
<th>CLASS Field</th>
<th>AIP AT Field</th>
<th>Transformation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Course Identifier</td>
<td>Course ID</td>
<td>Expense</td>
<td>Reference 1</td>
</tr>
<tr>
<td>Training Date</td>
<td>Expense</td>
<td>Reference 2</td>
<td></td>
</tr>
<tr>
<td>Department Identifier</td>
<td>Expense</td>
<td>Department</td>
<td>AIP AT: look-up GL-Dept value associated with xxxx in D-XREF-GL Table</td>
</tr>
<tr>
<td>Cost</td>
<td>Expense</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Failure Notifications must be sent in the following situations:
- Interface job fails to complete within 15 minutes
- No value found in table D-XREF-GL
CSV Model

Planning

User Requirements Specification

Verifies

Functional Specifications

Design Specifications

Installation Qualification Tests (IQ)

Installation Qualification
- Installation and Set Up instructions
- Confirmation that installed and set up according to Design

Operational Qualification Tests (OQ)

Performance Qualification Tests (PQ)

Reporting

System Build

Verifies

Verifies

Verifies
## IQ, examples

### Hardware

<table>
<thead>
<tr>
<th>Step</th>
<th>Element</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Processor</td>
<td>Intel Xeon E5506 Nehalem-EP 2.13 GHz 4 x 256 KB L2 Cache 4 MB L3 Cache LGA 1366 80W 64-bit</td>
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</tr>
<tr>
<td>3</td>
<td>HDD Configuration</td>
<td>300.0 GB 10K RAID 5</td>
</tr>
<tr>
<td>4</td>
<td>Operating System</td>
<td>Windows Server 2012</td>
</tr>
</tbody>
</table>

### Customization

#### Section 1.0  Installation of CLASS/SAP Interface version 1

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Executor Initial/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Move object “CL-SP-098-VS” to folder D:/Interface/Prod/Program</td>
<td>Object “CL-SP-098-VS” exists in folder D:/Interface/Prod/Program</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Set permission for object “CL-SP-098-VS” to Security Level ADMIN-ONLY</td>
<td>Permission for object “CL-SP-098-VS” is Security Level ADMIN-ONLY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Move the following files to folder D:/Interface/Prod/Data</td>
<td>The following files are in folder D:/Interface/Prod/Data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>•  D-XREF-098</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>•  MSG-098-V1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Operational Qualification**

- Confirmation that all functionality is present
- Confirmation that all features are working as specified

**Planning**

- User Requirements Specification

**Verifies**

- Functional Specifications

**Verifies**

- Design Specifications

**Verifies**

- System Build

**Verifies**

- Installation Qualification Tests (IQ)

**Verifies**

- Performance Qualification Tests (PQ)

- Operational Qualification Tests (OQ)

**Verifies**

- Reporting
Data Setup

<table>
<thead>
<tr>
<th>Step</th>
<th>Description/Action</th>
<th>Verifier Initial/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Employees 3010, 3011, and 3012 are assigned to complete training on Document QLY-003</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Employee 2010 is the supervisor for Employees 3010, 3011, and 3012</td>
<td></td>
</tr>
</tbody>
</table>
| 3.   | Employee has completed training on Document QLY-003  
Employees 3010 and 3011 have not completed training on Document QLY-003 |                      |

End of Data Setup

Test Case 3

<table>
<thead>
<tr>
<th>Step</th>
<th>Description/Action</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Tester Initial/Date</th>
</tr>
</thead>
</table>
| 3.3  | On the day after the Training Due Date recorded in step 1.9, launch email application for Employee 3010.  
- Capture Screen Shot of the Overdue Training email | An Overdue Training email notification for Document QLY-003 was received. |                |          |                    |
| 3.4  | On the day after the Training Due Date recorded in step 1.9, launch email application for Employee 2010.  
- Capture Screen Shot of the Overdue Training email | An Overdue Training email notification for Document QLY-003 was received for employee 3010 |                |          |                    |
| 3.5  | On the day after the Training Due Date recorded in step 1.9, launch email application for Employee 3012... | No Overdue Training email notification for Document QLY-003 was received... |                |          |                    |
CSV Model

Performance Qualification
- Confirmation that software meets the users' needs and is suitable for their use
## Data Setup

<table>
<thead>
<tr>
<th>Step</th>
<th>Description/Action</th>
<th>Verifier Initial/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Employees 3010, 3011, and 3012 are assigned to complete training on Document QLY-003</td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Employee 2010 is the supervisor for Employees 3010, 3011, and 3012</td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Employee has completed training on Document QLY-003</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Employees 3010 and 3011 have not completed training on Document QLY-003</td>
<td></td>
</tr>
</tbody>
</table>

End of Data Setup

## Test Case 3

<table>
<thead>
<tr>
<th>Step</th>
<th>Description/Action</th>
<th>Expected Result</th>
<th>Actual Result</th>
<th>Pass/Fail</th>
<th>Tester Initial/Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>On the day after the Training Due Date recorded in step 1.9, launch email application for Employee 3010. - Capture Screen Shot of the Overdue Training email</td>
<td>An Overdue Training email notification for Document QLY-003 was received.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4</td>
<td>On the day after the Training Due Date recorded in step 1.9, launch email application for Employee 2010. - Capture Screen Shot of the Overdue Training email</td>
<td>An Overdue Training email notification for Document QLY-003 was received for employee 3010</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.5</td>
<td>On the day after the Training Due Date recorded in step 1.9, launch email application for Employee 3012...</td>
<td>No Overdue Training email notification for Document QLY-003 was received...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>User Requirement</td>
<td>Verification</td>
<td>Functional Requirement</td>
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<td><strong>2.0</strong> The system shall provide the capability for managing the training for each employee</td>
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<td>2.5</td>
<td>OQ 2 Test Case 3</td>
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<td><strong>3.0</strong> The system shall track completion of employee training</td>
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<td>PQ 4 Test Case 1</td>
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**Terminology**

**VALIDATION**

Confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.

**VERIFICATION**

...consistency, completeness, and correctness of the software and its supporting documentation, ...

- URS Approval
- FS Approval
- Design Review
- Code Walkthrough
- Unit Testing
- Trace Matrix

**QUALIFICATION**

Formal testing to demonstrate that the software meets its specified requirements.

- Performance Qualification
- Operational Qualification
- Installation Qualification
- SOP Review
- Training Review
Thank You!

Thanks for your interest in Computer System Validation

Any questions?
Please, feel free to contact me:

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