

VALIDATION TIMELINE AND SOFTWARE DEVELOPMENT



Start with Commitment by Management to build Quality into Software Development Process

- ▶ Top Level Management
- ▶ Local Management
 - ▶ Plan
 - ▶ Resources
 - ▶ Training
 - ▶ Document
 - ▶ Internal Audits
 - ▶ Certification

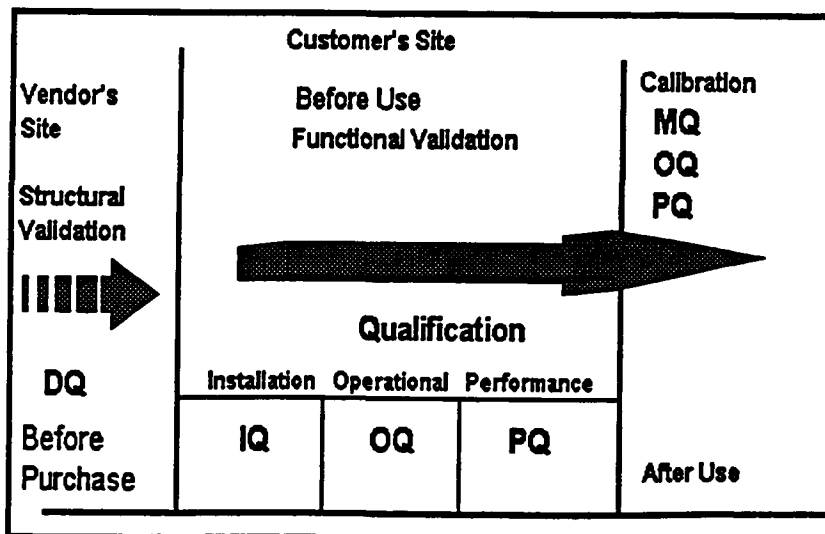


Build Quality System Support for:

- | | |
|-------------------------------|----|
| 1. Design Qualification | DQ |
| 2. Installation Qualification | IQ |
| 3. Operational Qualification | OQ |
| 4. Performance Qualification | PQ |
| 5. Maintenance Qualification | MQ |



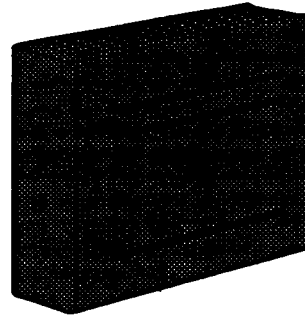
Software Validation Time Line



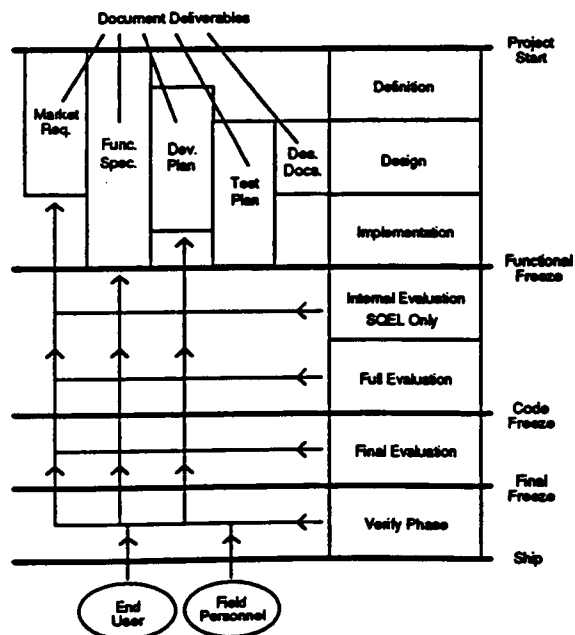
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DESIGN QUALIFICATION

- ▶ Structural Integrity
- ▶ Documented Evidence of SDLC
 - ▶ Requirements
 - ▶ Specifications
 - ▶ Plans
 - ▶ Schedules
 - ▶ Testing
 - ▶ Results
 - ▶ Qualification Protocols



Waters Software Life Cycle



Software Life Cycle Provides:

- ✓ Documented evidence to exit the Milestones
- ✓ Records of Pass/Fail Criteria
- ✓ Acceptance Testing
- ✓ Continuous improvement
- ✓ Collaborative effort
- ✓ Leads to good Structural Validation

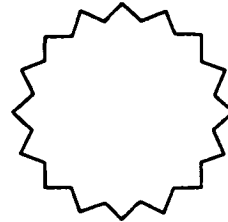


Structural Validation

- ▶ Code Review
- ▶ Design Documents
- ▶ Code Documentation
- ▶ Input/Output Specification
- ▶ Test Cases/Results
- ▶ Pass/Fail Criteria
- ▶ Acceptance Testing
- ▶ Exit Criteria Milestones

Vendor Deliverable DQ

- ▶ **Certificate of Software Validation**
 - ▶ Assurance of Structural Integrity
 - ▶ Marketing Requirements Definition
 - ▶ Functional Specification
 - ▶ Software Quality Plan
 - ▶ Test Plan
 - ▶ Test Summary Reports
 - ▶ Source Code Documentation
 - ▶ Hardware Testing Configurations



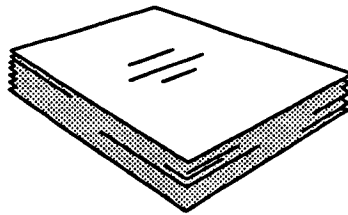
INSTALLATION QUALIFICATION

- ▶ **Provided by Vendor User Knows Software Installed Correctly:**
 - ▶ List of files installed
 - ▶ CRC - Cyclic Redundancy Check
 - ▶ Size and Date
 - ▶ Changes based on custom installation
 - ▶ Configuration Management Control



Vendor Deliverable IQ to Customer:

- ▶ Program to run checksum/CRC
- ▶ Document with Vendor Results
or
- ▶ Document of files and locations
- ▶ Optional - Forms for sign off



OPERATIONAL QUALIFICATION

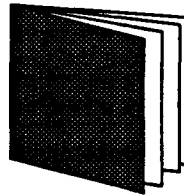
- ▶ A subset of tests used by vendor run at Customer Site - Data Set NOT Acquisition
- ▶ Waters Data set provides:
 - ▶ External Standard or
 - ▶ Internal Standard
 - ▶ Integration
 - ▶ Calibration
 - ▶ Reports
- ▶ Must be run before any Instrument OQs



Vendor Deliverable OQ

► OPTIONAL

- Data Set or conditions to exercise the code
- Subset of tests
- Will not exercise all code
- Configuration Management Control
- Forms or "Qualification Workbook" user can incorporate
- Run at Customer Site



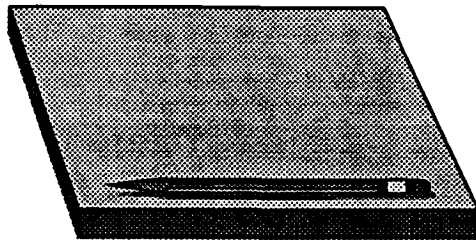
Performance Qualification

- Done after IQ and OQ successful
- Customer Method Validation
- System performance
 - CPU/Software
 - Pump/Injector/Detector



Vendor Deliverable PQ

- ▶ Provided by Vendor Under Configuration Management Control
- ▶ "Qualification Workbook"
- ▶ Certified Validation Specialists
- ▶ NIST Traceable Standards



Maintenance Qualification

- ▶ Done after set period of time (6 or 12 mos)
- ▶ Done after a major repair
- ▶ Done just to prove the system still works (FDA)



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- ▶ Vendor before Sale
 - ▶ Develops
 - ▶ Documents
 - ▶ Creates IQ, OQ , PQ, MQ for user

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Customer Site

- ▶ User evaluates against
 - ▶ Supplied IQ
 - ▶ Supplied results (OQ)
 - ▶ Validates Performance against Method
 - ▶ Perform routine Maintenance

**"Good
Enough Is
Never
Good Enough"**