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life sciences

Computer System Validation Basics

By Praxis Life Sciences

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Validation Center™
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VALIDATION CENTER

Computer System Validation Basics

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Your Praxis Facilitator

- Debra Bartel, MBA, CQA, PMP
- Principal, Praxis Life Sciences
- 25+ years experience specializing in software quality assurance, validation and regulatory compliance, Information Systems project management, and process design.
- Prior to joining Praxis, held management positions in the pharmaceutical industry in both Quality Assurance and Information Systems organizations
- Active member of American Society for Quality (ASQ), Northeastern Illinois Section, Software Division

How We Help

VALIDATION CENTER

Follow us!

Target Audience

Industries
- Pharmaceutical & Biologics
- Medical Device
- Clinical Studies
- Blood Products

Regions
- Operating in the US
- Selling to the US Market

Personnel
- IT Personnel and Managers
- Quality Personnel and Managers
- Auditors and Audit Managers

Webinar Outline

1. CSV Regulatory Requirements
2. CSV Purpose & Benefits
3. CSV Methodology
4. CSV Scope
5. CSV Failure Consequences
6. CSV Program Implementation

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CSV Regulatory Requirements

Part 1

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CSV Regulatory Requirements

Computer System Validation is require 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

USA

FDA 21 CFR 11 *Electronic Record; Electronic Signatures*

Subpart B--Electronic Records, Sec. 11.10

Controls for closed systems.

Such procedures and controls **shall include** the following: (a) **Validation of systems** to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

21 CFR 820 *Quality System Regulation*

Subpart C Design Controls, Sec. 820.30(g)

Design validation **shall include software validation** and risk analysis, where appropriate

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

When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall **validate computer software for its intended use** according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

USA

FDA 21 CFR 211 *Current Good Manufacturing Practice for Finished Pharmaceuticals*

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

Input to and output from the computer or related system of formulas or other records or data **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)

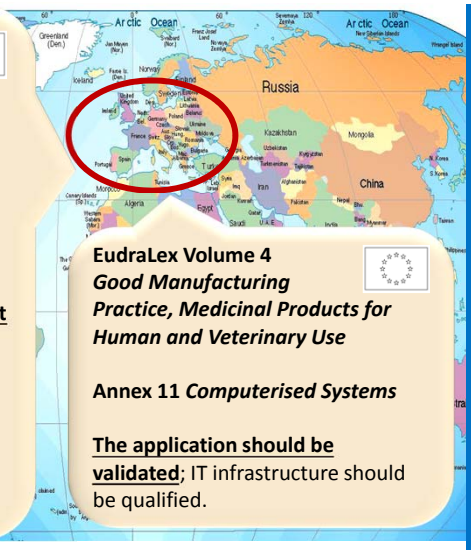
You must validate the performance of computer software for the intended use, and the performance of any changes to that software for the intended use, if you rely upon the software to comply with core CGTP requirements and if the software either is custom software or is commercially available software that has been customized or programmed (including software programmed to perform a user defined calculation or table) to perform a function related to core CGTP requirements.

European Union

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.

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom

Brazil

Brazilian ANVS *Good Practices of Medicament Manufacturing*

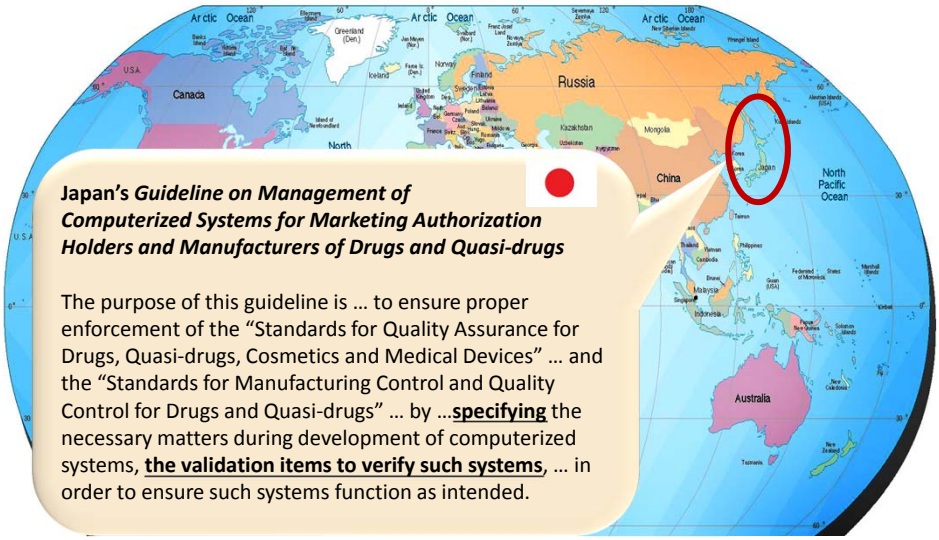
TITLE VIII GOOD PHYTOTHERAPIC MEDICAMENTS MANUFACTURE PRACTICES, CHAPTER IV VALIDATION, Art. 18.

Any aspect of operation, including significant changes in the facilities, location, **computer systems**, equipment or processes that can affect product quality, directly or indirectly, **must be qualified and / or validated**.

TITLE VII, COMPUTER INFORMATION SYSTEMS, Art. 573.

Validation shall be considered **part of the computer system's life cycle**, which includes the planning, specification, scheduling, test, documentation, operation, monitoring, maintenance and change stages.

Japan



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

The purpose of this guideline is … to ensure proper enforcement of the "Standards for Quality Assurance for Drugs, Quasi-drugs, Cosmetics and Medical Devices" … and the "Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs" … by …**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

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.

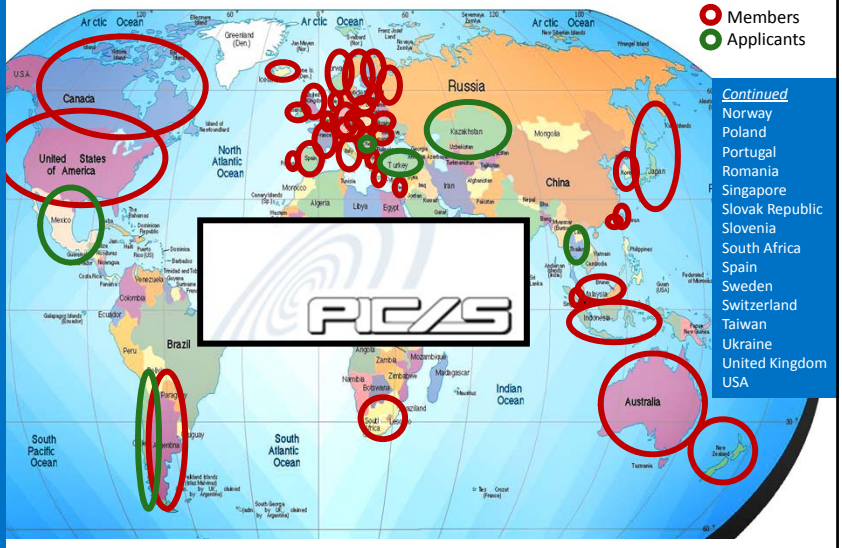
ICH E6 *Good Clinical Practice*

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

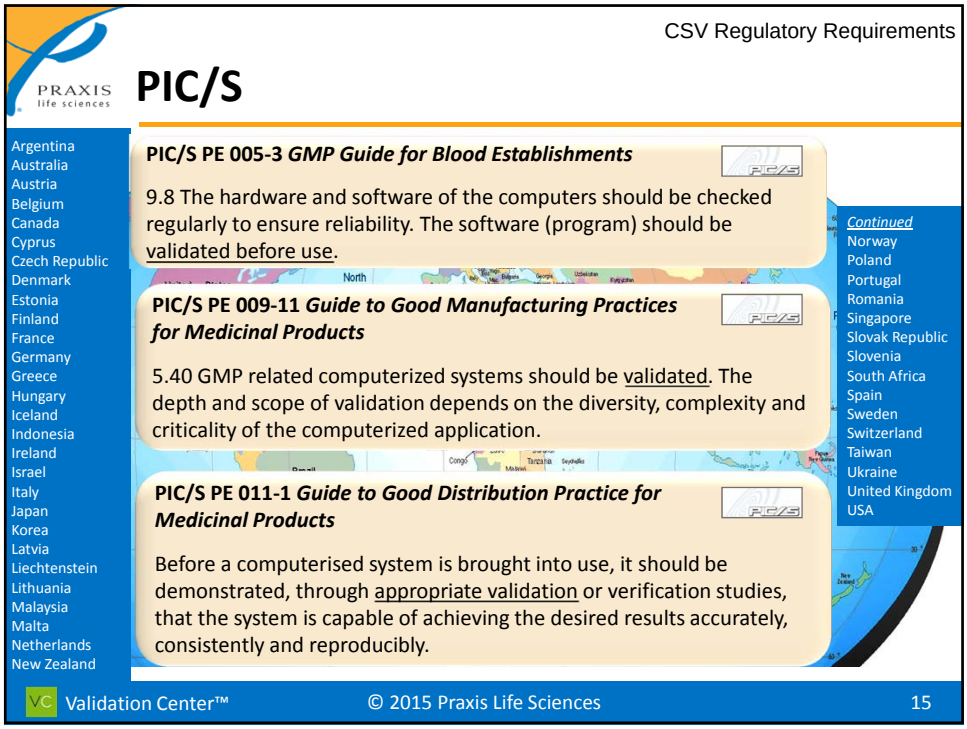
- Ensure and document that the electronic data processing system(s) conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation)

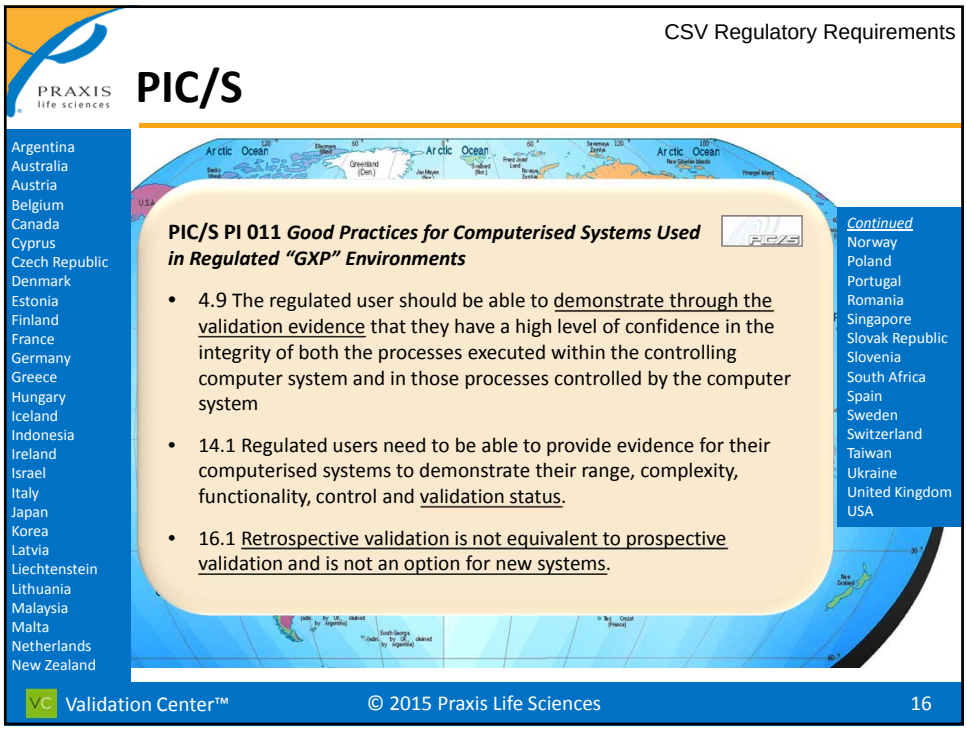
PIC/S

Argentina
Australia
Austria
Belgium
Canada
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Indonesia
Ireland
Israel
Italy
Japan
Korea
Latvia
Liechtenstein
Lithuania
Malaysia
Malta
Netherlands
New Zealand



Continued
Norway
Poland
Portugal
Romania
Singapore
Slovak Republic
Slovenia
South Africa
Spain
Sweden
Switzerland
Taiwan
Ukraine
United Kingdom
USA





WHO

WHO *Specifications for Pharmaceutical Preparations*

6.3 Critical computerized systems should be validated before use.

World Health Organization

WHO *Good Manufacturing Practices for Pharmaceutical Products: Main Principles*

4.11 Particular attention should be paid to the validation of analytical test methods, automated systems and cleaning procedures.

World Health Organization

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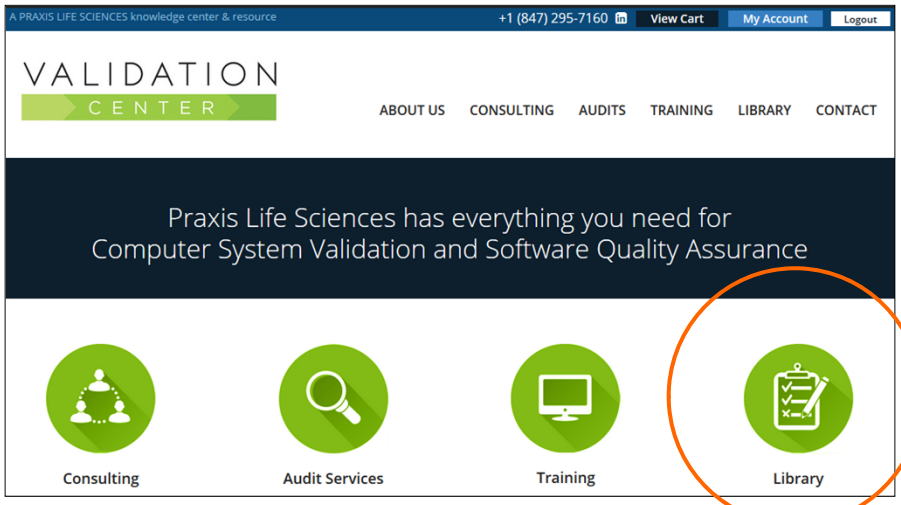

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CSV Purpose and Benefits

Part 2

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CSV Purpose and Benefits

Effectiveness

Safety

Integrity

Accuracy

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CSV Methodology

Part 3

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CSV Methodology

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FDA Definitions

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

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

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

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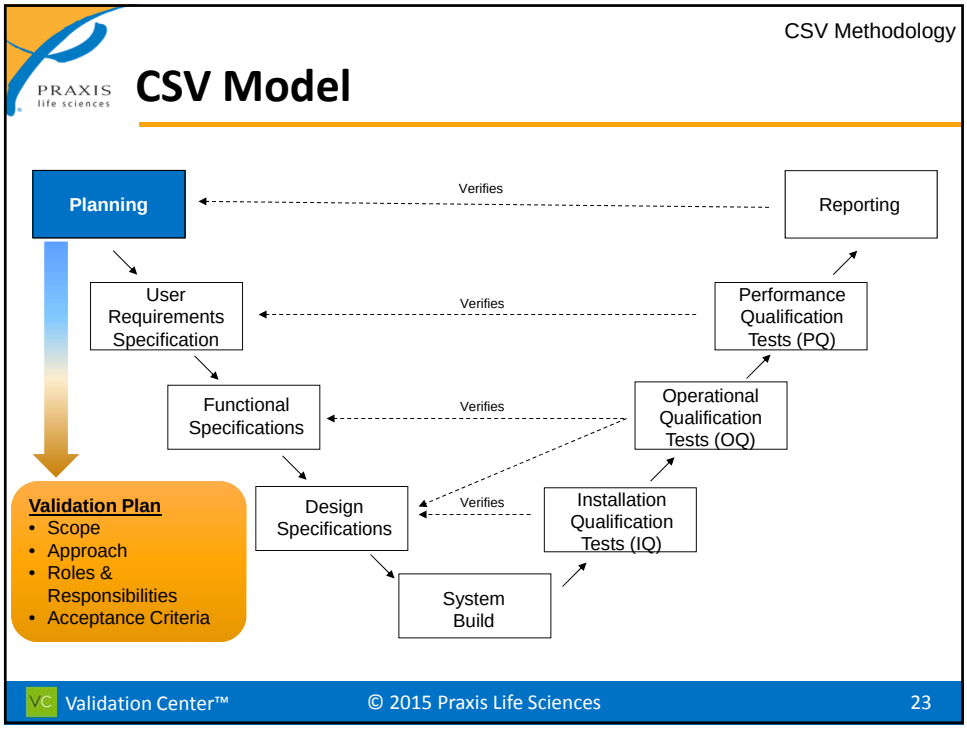
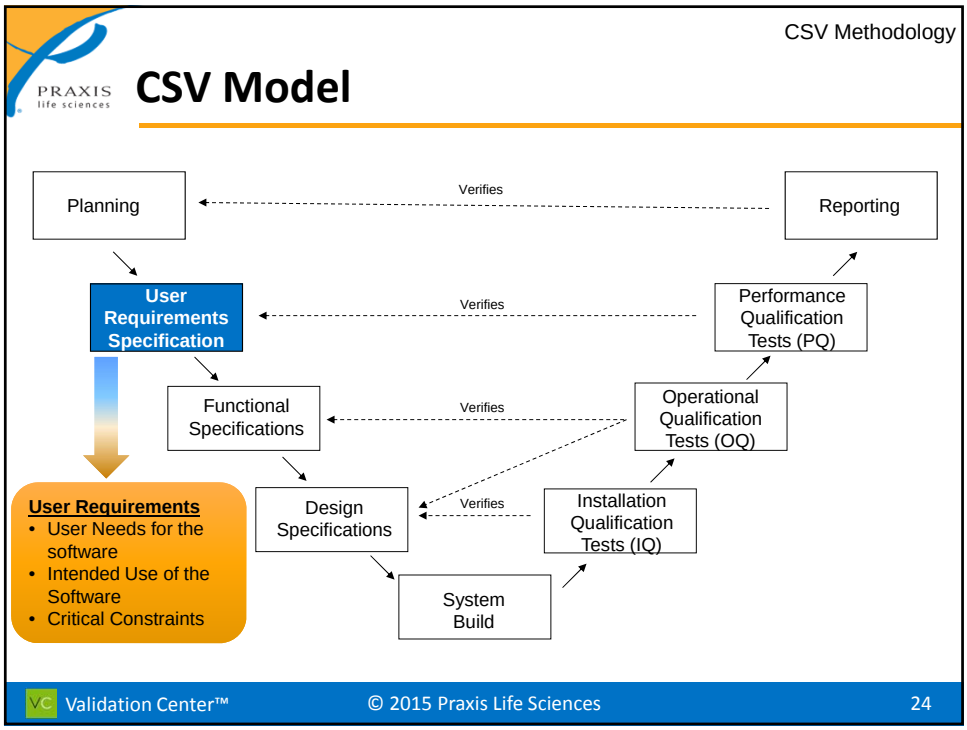
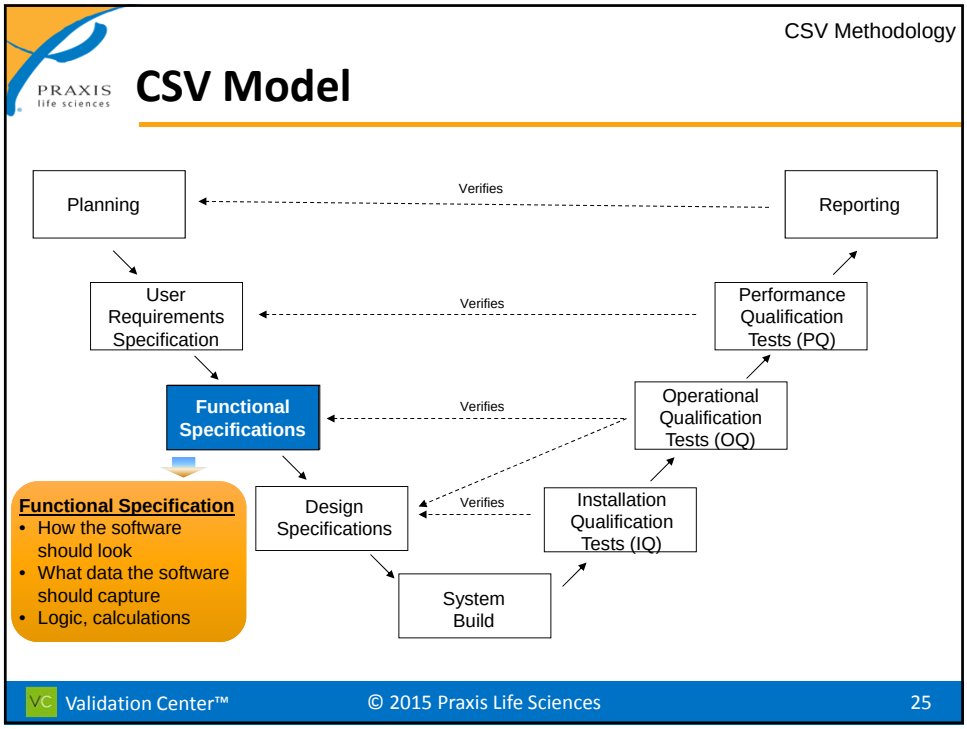
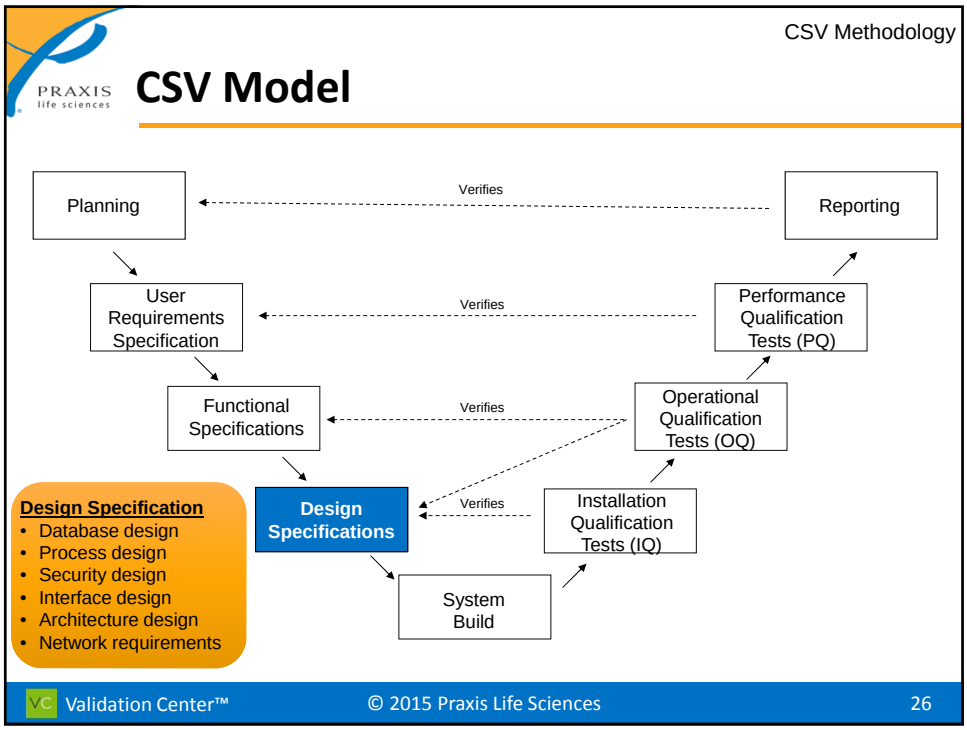
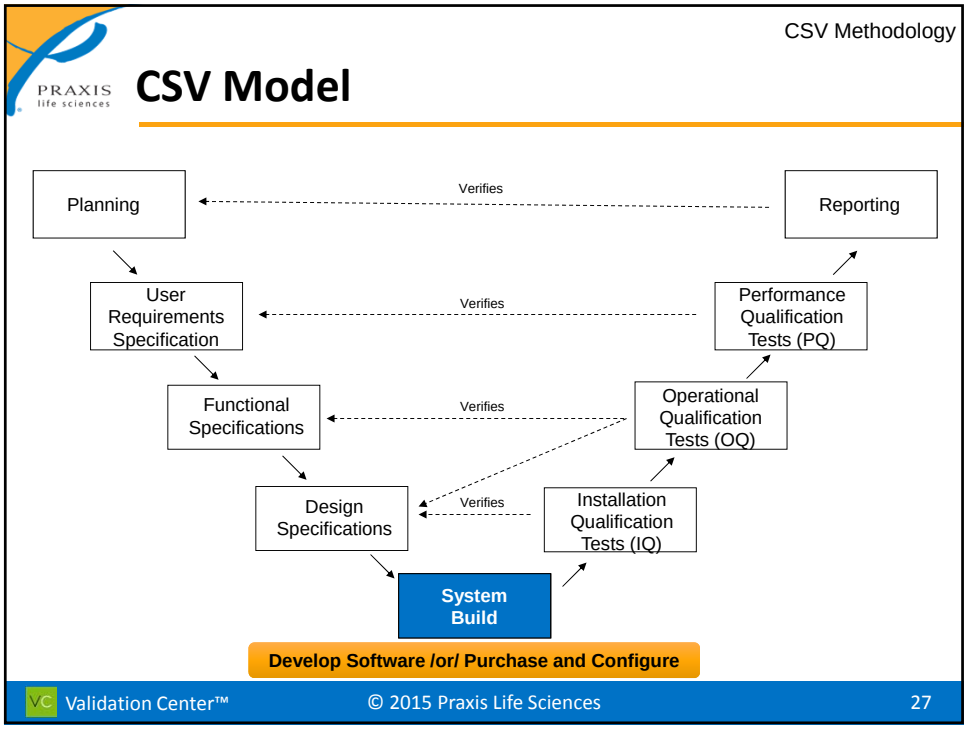
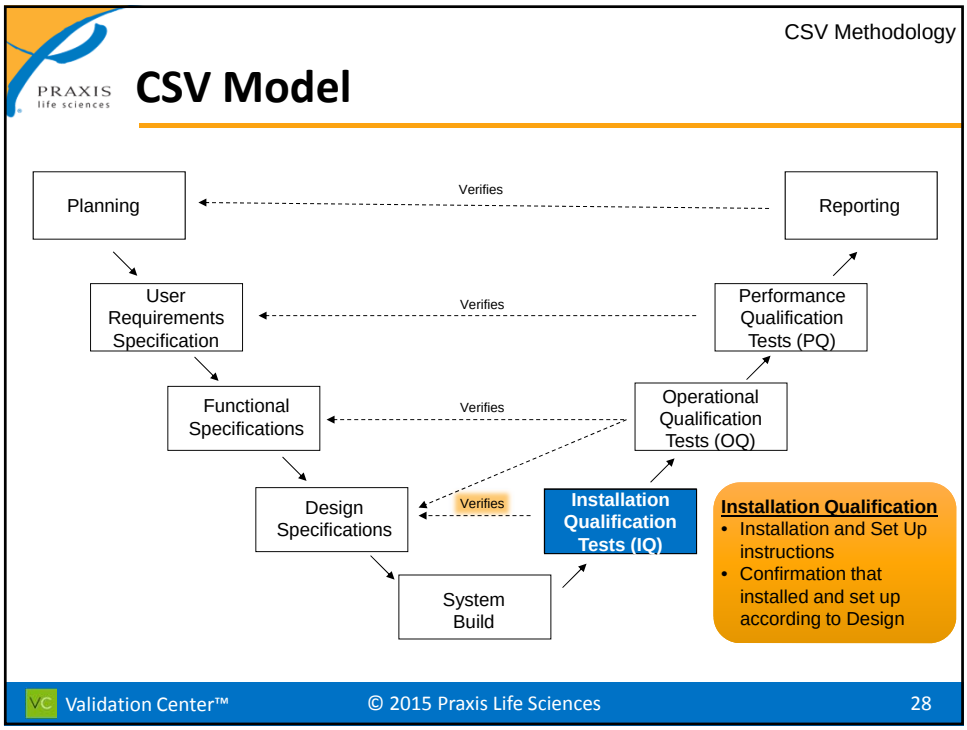


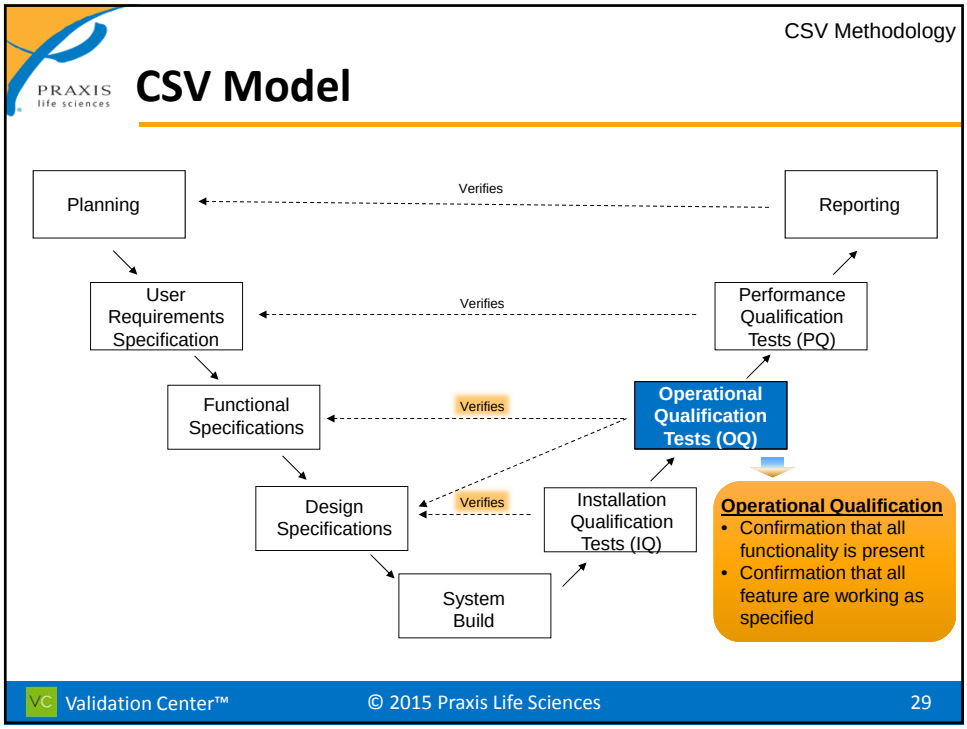


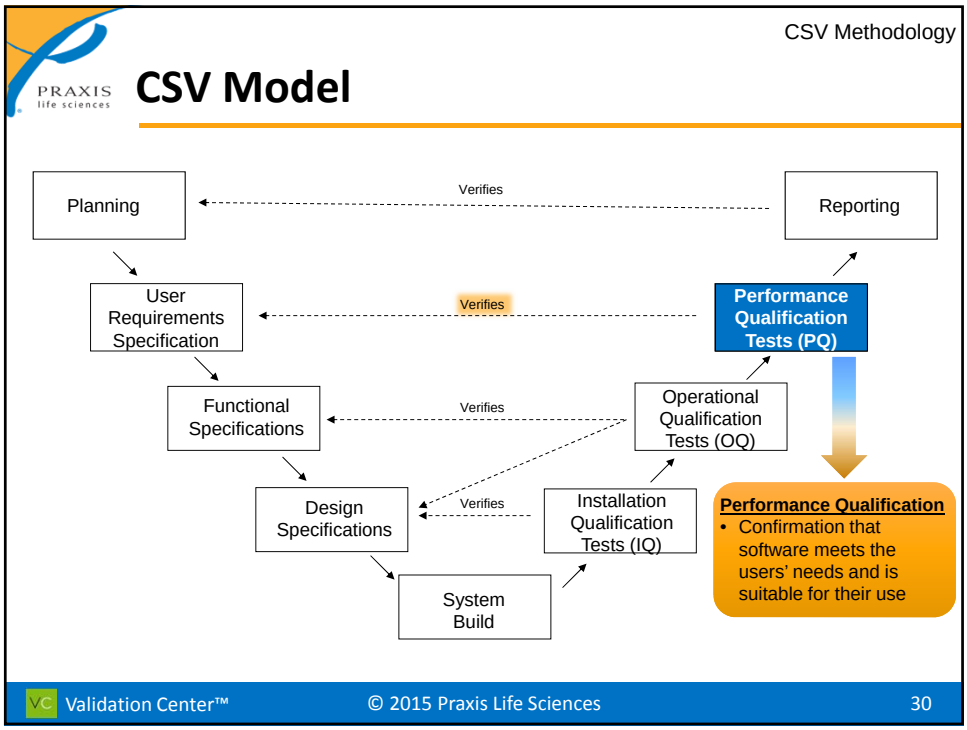




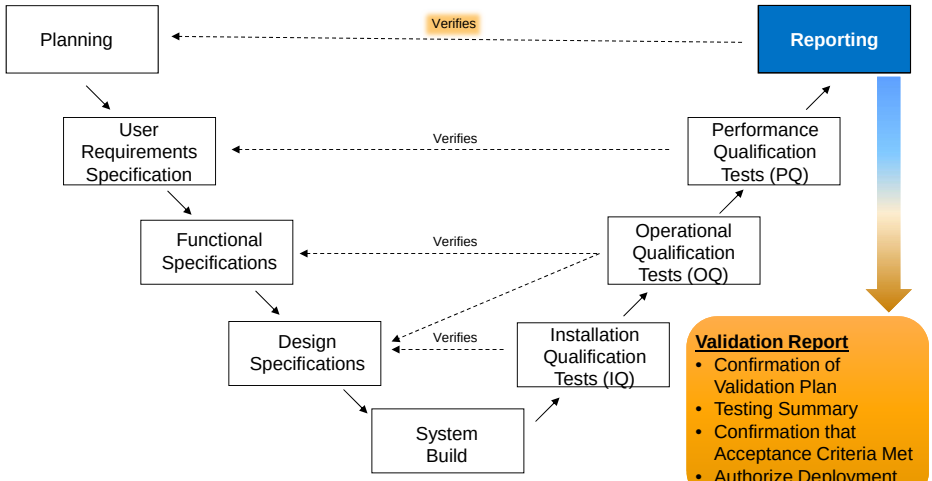








CSV Model



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. [FDA]

VERIFICATION
Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated. [FDA]

QUALIFICATION
Formal testing to demonstrate that the software meets its specified requirements. [IEEE]

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
- Validation Report
- Performance Qualification
- Operational Qualification
- Installation Qualification
- SOP Review
- Training Review

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

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CSV Scope

Part 4

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

What Types of Computer Systems and Software Require Validation?

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.

Blood Supply Management Software	Radiation Treatment Control Software	Infusion Pump Software	Heart Arrhythmia Detection Software
Blood Donor Management Software	Defibrillator Software	Patient Monitoring Software	Injury Treatment Machine Software
Medical Imaging System Software	Laser Treatment Software	Robotic Surgery Software	Hospital Bed Software
Laboratory Diagnostics Software	Oxygen Regulating Software	Pacemaker Software	Wheelchair and Scooter Software

What Software Requires Validation?

What Types of Computer Systems and Software Require 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?

What Types of Computer Systems and Software Require 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

Change Control Software	Calibration Software	Document Management Software	Non-Conformance Tracking Software
Inventory Control Software (e.g., ERPs)	Preventive Maintenance Management	Device History Software	Deviation Tracking Software
Product Returns Management Software	Quality Trending Software	Specification Management Software	CAPA Software
Product Recall Management Software	Internal Audit Tracking Software	Specification Setting Software	Complaints Software

What Software Requires Validation?

What Types of Computer Systems and Software Require 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

Software for FDA-Regulated Records
- Software used to create, modify, maintain, archive, retrieve, or transmit FDA-required records. And electronic records submitted, per FDA requirement.

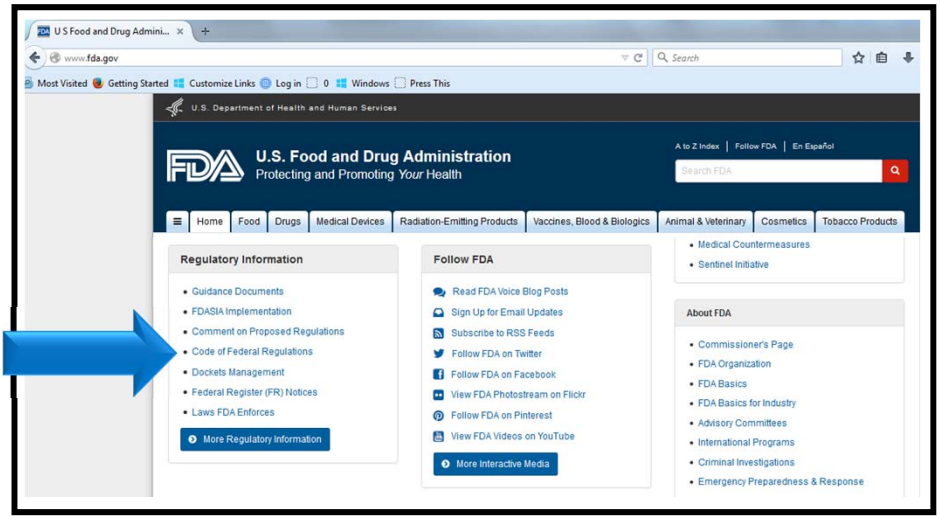
Sources: General Principles of Software Validation: Final Guidance for Industry and FDA Staff
Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application

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.

Electronic Submissions Software	IRB Records Software	Training Records Software	Prescription Order Fulfilment Software
Adverse Event Reporting Software	Clinical Trial Records Software	Learning Management Software	Distribution Records
MDR Reporting Software	Service Records Software	Supplier Approval Records	Warehouse Management Software
Organ / Tissue Donor Records	Call Center Records Software	Validation Records	Product Rework Records

FDA Regulations



FDA Regulations

Topic	Part	Title
Clinical Trials	21 CFR 50	Protection of Human Subjects
Clinical Trials	21 CFR 56	Institutional Review Boards
Nonclinical Lab Studies	21 CFR 58	Good Laboratory Practice for Nonclinical Laboratory Studies
Drugs	21 CFR 210	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General
Finished Pharmaceuticals	21 CFR 211	Current Good Manufacturing Practice for Finished Pharmaceuticals
Drugs	21 CFR 312	Investigational New Drug Application
Drugs	21 CFR 314	Application for FDA Approval to Market a New Drug
Biological Products	21 CFR 600	Biological Products: General
Blood & Components	21 CFR 606	Current Good Manufacturing Practice for Blood and Blood Components
Medical Devices	21 CFR 803	Medical Device Reporting
Medical Devices	21 CFR 806	Medical Devices: Reports of Corrections and Removals
Medical Devices	21 CFR 820	Quality System Regulation
Cells and Tissue Products	21 CFR 1271	Human Cells, Tissues, and Cellular and Tissue-Based Products

CSV Scope

FDA Regulations

Topic	Part
Clinical Trials	
Clinical Trials	
Nonclinical Lab Studies	
Drugs	2
Finished Pharmaceuticals	2
Drugs	2
Drugs	2
Biological Products	2
Blood & Components	2
Medical Devices	2
Medical Devices	2
Medical Devices	2
Cells and Tissue Products	2

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 820 QUALITY SYSTEM REGULATION

Subpart A--General Provisions
§ 820.1 - Scope.
§ 820.3 - Definitions.
§ 820.5 - Quality system.

Subpart B--Quality System Requirements
§ 820.20 - Management responsibility.
§ 820.22 - Quality audit.
§ 820.25 - Personnel.

Subpart C--Design Controls
§ 820.30 - Design controls.

Subpart D--Document Controls
§ 820.40 - Document controls.

Subpart E--Purchasing Controls
§ 820.50 - Purchasing controls.

Subpart F--Identification and Traceability
§ 820.60 - Identification.
§ 820.65 - Traceability.

Subpart G--Production and Process Controls
§ 820.70 - Production and process controls.
§ 820.72 - Inspection, measuring, and test equipment.
§ 820.75 - Process validation.

Subpart H--Acceptance Activities
§ 820.80 - Receiving, in-process, and finished device acceptance.
§ 820.86 - Acceptance status.

Subpart I--Nonconforming Product
§ 820.90 - Nonconforming product.

Subpart J--Corrective and Preventive Action
§ 820.100 - Corrective and preventive action.

Subpart K--Labeling and Packaging Control
§ 820.120 - Device labeling.
§ 820.130 - Device packaging.

Subpart L--Handling, Storage, Distribution, and Installatio
§ 820.140 - Handling.
§ 820.150 - Storage.
§ 820.160 - Distribution.
§ 820.170 - Installation.

Subpart M--Records
§ 820.180 - General requirements.
§ 820.181 - Device master record.
§ 820.184 - Device history record.
§ 820.186 - Quality system record.
§ 820.198 - Complaint files.

Subpart N--Servicing
§ 820.200 - Servicing.

Subpart O--Statistical Techniques
§ 820.250 - Statistical techniques.

CSV Scope

FDA R

Topic	
Clinical Trials	
Clinical Trials	
Nonclinical Lab Studies	
Drugs	2
Finished Pharmaceuticals	2
Drugs	2
Drugs	2
Biological Products	2
Blood & Components	2
Medical Devices	2
Medical Devices	2
Medical Devices	2
Cells and Tissue Products	2

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C--DRUGS: GENERAL

PART 211 CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart A--General Provisions
§ 211.1 - Scope.
§ 211.3 - Definitions.

Subpart B--Organization and Personnel
§ 211.22 - Responsibilities of quality control unit.
§ 211.25 - Personnel qualifications.
§ 211.28 - Personnel responsibilities.
§ 211.34 - Consultants.

Subpart C--Buildings and Facilities
§ 211.42 - Design and construction features.
§ 211.44 - Lighting.
§ 211.46 - Ventilation, air filtration, air heating and cooling.
§ 211.48 - Plumbing.
§ 211.50 - Sewage and refuse.
§ 211.52 - Washing and toilet facilities.
§ 211.56 - Sanitation.
§ 211.58 - Maintenance.

Subpart D--Equipment
§ 211.63 - Equipment design, size, and location.
§ 211.65 - Equipment construction.
§ 211.67 - Equipment cleaning and maintenance.
§ 211.68 - Automatic, mechanical, and electronic equipment.
§ 211.72 - Filters.

Subpart E--Control of Components and Drug Product Containers and Closures
§ 211.80 - General requirements.
§ 211.82 - Receipt and storage of untested components, drug product containers, and c
§ 211.84 - Testing and approval or rejection of components, drug product containers, ar
§ 211.86 - Use of approved components, drug product containers, and closures.
§ 211.87 - Retesting of approved components, drug product containers, and closures.
§ 211.89 - Rejected components, drug product containers, and closures.
§ 211.94 - Drug product containers and closures.

Subpart F--Production and Process Controls
§ 211.100 - Written procedures; deviations.
§ 211.101 - Charge-in of components.
§ 211.103 - Calculation of yield.
§ 211.105 - Equipment identification.
§ 211.110 - Sampling and testing of in-process materials and drug products.
§ 211.111 - Time limitations on production.
§ 211.113 - Control of microbiological contamination.
§ 211.115 - Reprocessing.

Subpart G--Packaging and Labeling Control
§ 211.122 - Materials examination and usage criteria.
§ 211.125 - Labeling issuance.
§ 211.130 - Packaging and labeling operations.
§ 211.132 - Tamper-evident packaging requirements for over-the-counter (OTC) human d
§ 211.134 - Drug product inspection.
§ 211.137 - Expiration dating.

Subpart H--Holding and Distribution
§ 211.142 - Warehousing procedures.
§ 211.150 - Distribution procedures.

Subpart I--Laboratory Controls
§ 211.160 - General requirements.
§ 211.165 - Testing and release for distribution.
§ 211.166 - Stability testing.
§ 211.167 - Special testing requirements.
§ 211.170 - Reserve samples.
§ 211.173 - Laboratory animals.
§ 211.176 - Penicillin contamination.

Subpart J--Records and Reports
§ 211.180 - General requirements.
§ 211.182 - Equipment cleaning and use log.
§ 211.184 - Component, drug product container, closure, and labeling records.
§ 211.186 - Master production and control records.
§ 211.188 - Batch production and control records.
§ 211.192 - Production record review.
§ 211.194 - Laboratory records.
§ 211.196 - Distribution records.
§ 211.198 - Complaint files.

What About …

- **Off-The-Shelf (OTS) Software?**
- **Configured Applications?**
- **Software as a Service (SAAS) Applications?**
- **Systems in the Cloud?**

1

Validation scope can be limited to the features that will be used by the regulated company

For example, a device manufacturer who chooses not to use all the vendor-supplied capabilities of the software only needs to validate those functions that will be used and for which the device manufacturer is dependent upon the software results as part of production or the quality system

FDA, *General Principles of Software Validation*

What About …

- **Off-The-Shelf (OTS) Software?**
- **Configured Applications?**
- **Software as a Service (SAAS) Applications?**
- **Systems in the Cloud?**

2

Validation must be specific to the regulated company's planned and documented use of the application

The acceptance of vendor-supplied validation data in isolation of system configuration and intended use is not acceptable. In isolation from the intended process or end user IT infrastructure, vendor testing is likely to be limited to functional verification only, and may not fulfil the requirements for performance qualification.

MHRA, *GMP Data Integrity Definitions and Guidance*

What About …

- **Off-The-Shelf (OTS) Software?**
- **Configured Applications?**
- **Software as a Service (SAAS) Applications?**
- **Systems in the Cloud?**

3

Vendor documentation can be used as the starting point for validation

If the vendor can provide information about their system requirements, software requirements, validation process, and the results of their validation, the medical device manufacturer can use that information as a beginning point for their required validation documentation.

FDA, *General Principles of Software Validation*

Documentation supplied with commercial off-the-shelf products should be reviewed by regulated users to check that user requirements are fulfilled

Eudralex Annex 11, *Computerised Systems*

What About …

- **Off-The-Shelf (OTS) Software?**
- **Configured Applications?**
- **Software as a Service (SAAS) Applications?**
- **Systems in the Cloud?**

4

The regulated company needs to audit the vendors of critical applications and services – depending on risk

The audit should demonstrate that the vendor's procedures for and results of the verification and validation activities performed for the OTS software are appropriate and sufficient for the safety and effectiveness requirements …

FDA, *General Principles of Software Validation*

The competence and reliability of a supplier are key factors when selecting a product or service provider. The need for an audit should be based on a risk assessment.

Eudralex Annex 11, *Computerised Systems*

What About …

- **Off-The-Shelf (OTS) Software?**
- **Configured Applications?**
- **Software as a Service (SAAS) Applications?**
- **Systems in the Cloud?**

5

Formal agreements are required to document responsibilities

When third parties (e.g. suppliers, service providers) are used e.g. to provide, install, configure, integrate, validate, maintain (e.g. via remote access), modify or retain a computerised system or related service or for data processing, formal agreements must exist between the manufacturer and any third parties, and these agreements should include clear statements of the responsibilities of the third party.

Eudralex Annex 11, *Computerised Systems*

CSV Failure Consequences

Part 5

FDA Enforcement Tools

- Warning Letter
- Injunction
- Product seizure
- Import restrictions
- Clinical hold
- Delay in approval of new products or facilities
- Consent decree
- Rejection of application data
- Disqualification of clinical investigators
- Debarment
- Criminal prosecution

Warning Letter Statistics

Nearly 200 Warning Letter citations in the last 3 years (2012-2014) for software and computer system issues

Over 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

Consequences

Warning Letter Example

Company	German manufacturer of endoscopic grasping/cutting instruments
System	Purchased, configured ERP used for production planning and quality records. NOTE: Software vendor performed installation and upgrades
Warning Letter Excepts	• There are no procedures that describe the qualification and maintenance of the Majesty Enterprise Resource Planning (ERP) software for production planning and maintenance of quality records. • There are no records documenting that the Majesty system is validated or meets user needs and intended uses. • There are no documents that define the system's features and functions, operating environment, or hardware requirements. • The procedure which addresses vendor selection qualification and requalification of suppliers, has not been not implemented. There is no documentation that the supplier of Majesty software, was qualified or re-qualified as a supplier.

Consequences

Warning Letter Example

Company	California manufacturer of wound bio-engineered alternative tissue devices
System	Spreadsheet used for calculations
Warning Except	• Your firm did not validate use of an Excel spreadsheet used to calculate the Moisture Vapor Transmission Rate (MVTR)
Company	New Jersey manufacturer of medical devices
System	SharePoint used for document management
Warning Excepts	• Off-the-shelf software (Microsoft SharePoint) is being used to manage quality system documents for document control and approval. However, firm has failed to adequately validate this software to ensure that it meets your needs and intended uses. • There were two different versions of your CAPA & Customer Complaint procedure; however, no revision history was provided on the SharePoint document history. Your firm has failed to validate the SharePoint software to meet your needs for maintaining document control and versioning.

Warning Letter Example

Company	Idaho manufacturer of radiopharmaceuticals
System	Custom developed system for batch records, calculations, and label generation
Warning Letter Except	• Firm's custom software for Master Batch Production record has not been validated. This software is responsible for generating the batch production record, performing calculations to produce varying concentrations of drug product, and generating label information for customer vials and lead pigs.
Company	Italian manufacturer of laser devices
System	Custom developed system for tech calls, complaints, and service records
Warning Letter Excepts	• The software developed by your firm to record, evaluate, investigate, correct and repair incoming technical assistance calls, complaints, and service records was implemented in 2012, and has not been validated. • No validation documentation was available for an established protocol, any testing data, or a finished report for the validation of this system. system.

Warning Letter Example

Company	German manufacturer of sterile and non-sterile needles and sutures
System	Software controlling the machinery making needles
Warning Letter Except	• Your firm uses custom automatic machines in the needle production process. Your firm stated that it performed software validation for the automatic machines and that the software protocol was tested, but these validation activities were not documented.
Company	Kentucky medical center
System	Blood management
Warning Letter Except	• Your firm went live with version 2.0.0 of the Hemocare Lifeline (HCLL) Donor Module; however, the validation of Module 15, Product Labeling, was incomplete in that it was not reviewed, accepted, or signed off by a responsible individual.

PRAXIS life sciences

CSV Program Implementation

Part 6

PRAXIS life sciences

CSV Program Implementation

Procedure Examples
- How to validate
- How to perform risk assessment
- How to audit vendors

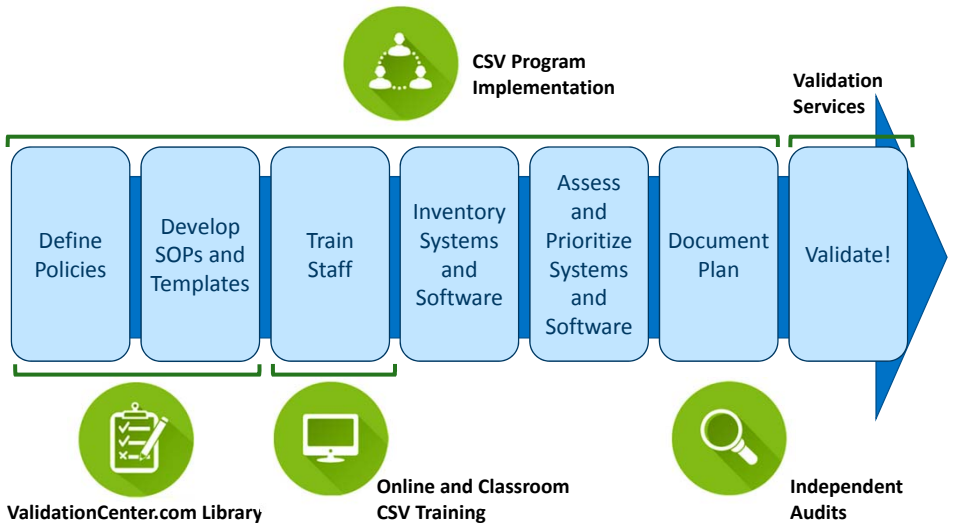
CAPA (if out of compliance)
Validation Master Plan
- Policies, Procedures
- Inventory
- Validation Timeline

Define Policies → Develop SOPs and Templates → Train Staff → Inventory Systems and Software → Assess and Prioritize Systems and Software → Document Plan → Validate!

Policy Examples
- Which systems and software require validation?
- When does validation occur?
- When do vendors need to be qualified? Audited?

Example
- Which systems and software require validation?
- What is the risk level of each?
- What is the priority for validating each system?

CSV Program Implementation



Thank You!

Thanks for your interest in Computer System Validation

Any questions about what we have discussed today?
Please, feel free to contact me:

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