propharma

VALIDATION CENTER

Best-in-Class Documentation for Computer Systems Validation (CSV) Program

VC v.1

1

Today's Presenter

- Esra Guven, BScEE, PMP, ASQ SSGB
- Associate Director, Computer Systems Validation and Data Integrity ProPharma Group
- 23+ years of experience in IT Quality and Computer Systems Validation within the Pharmaceutical Industry.
- Expert on:
  - Computer Systems Validation (CSV)
  - Computer Software Assurance (CSA)
  - Data Integrity (DI)
  - IQ Quality and Compliance
  - Electronic Records and Signatures
  - Agile / Lean CSV

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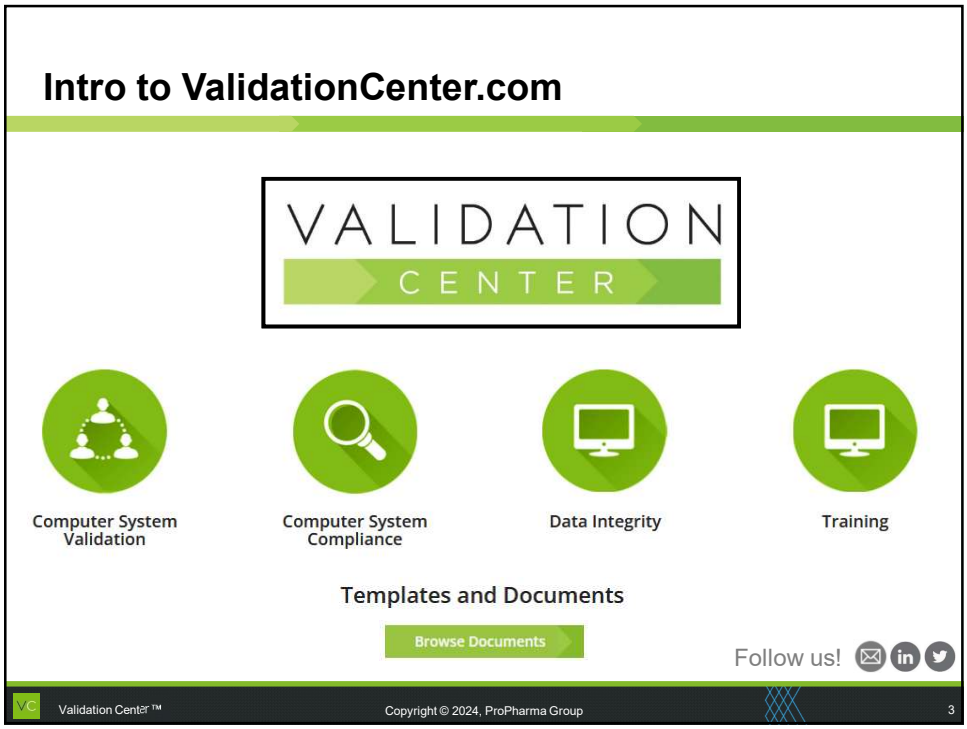

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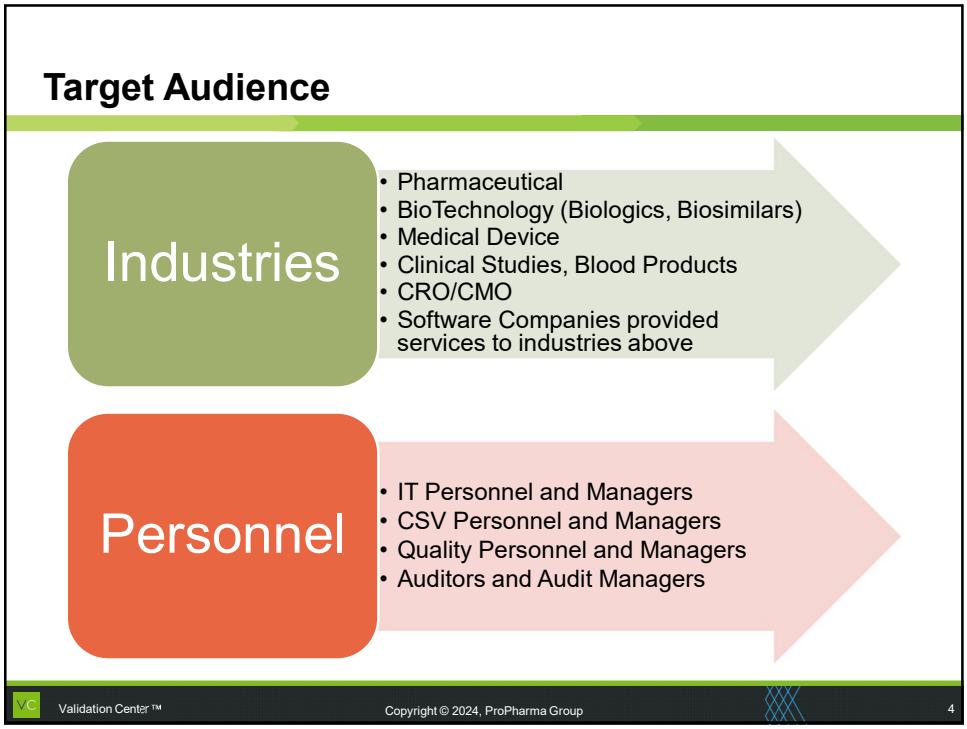

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Objectives

By the end of the training, you will be able to:

- Establish and structure an effective CSV Program
- Identify required SOPs
- Create best-in-class CSV deliverables, SOPs, and templates

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Webinar Outline

1. CSV Program
2. High Quality CSV SOPs
3. High Quality CSV Templates
4. Conclusion

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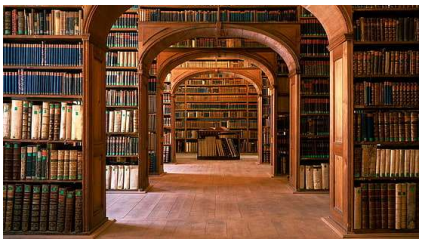

CSV Program

Part 1

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CSV Program

- Section Overview
  - Structure of CSV Program Documents and Tools
  - Global Policies
  - Computer Systems Validation Master Plan

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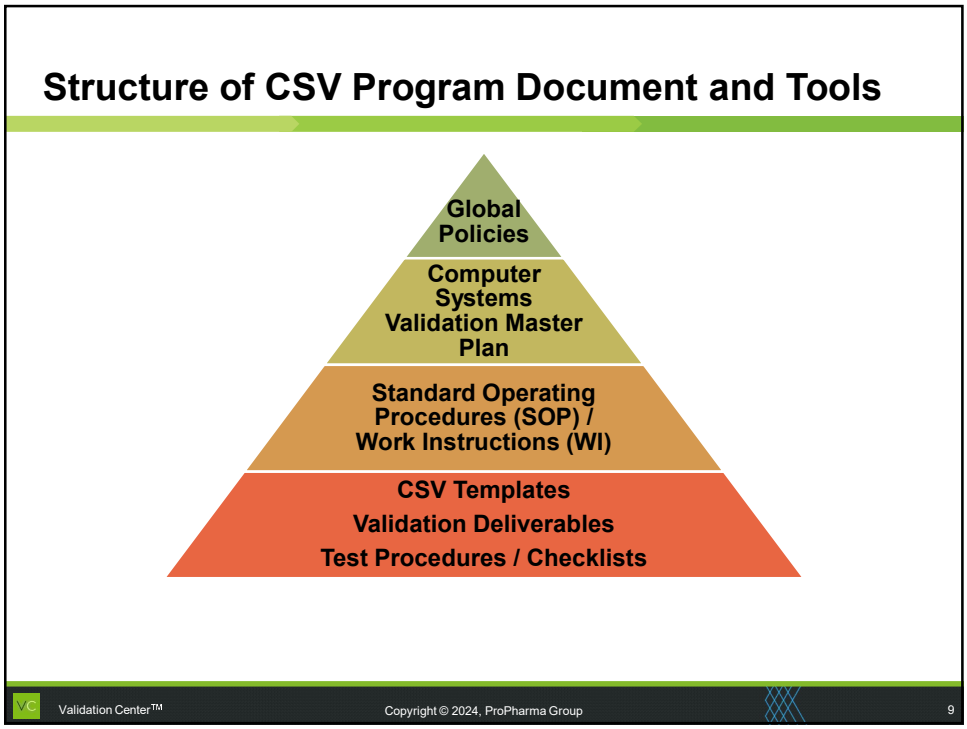

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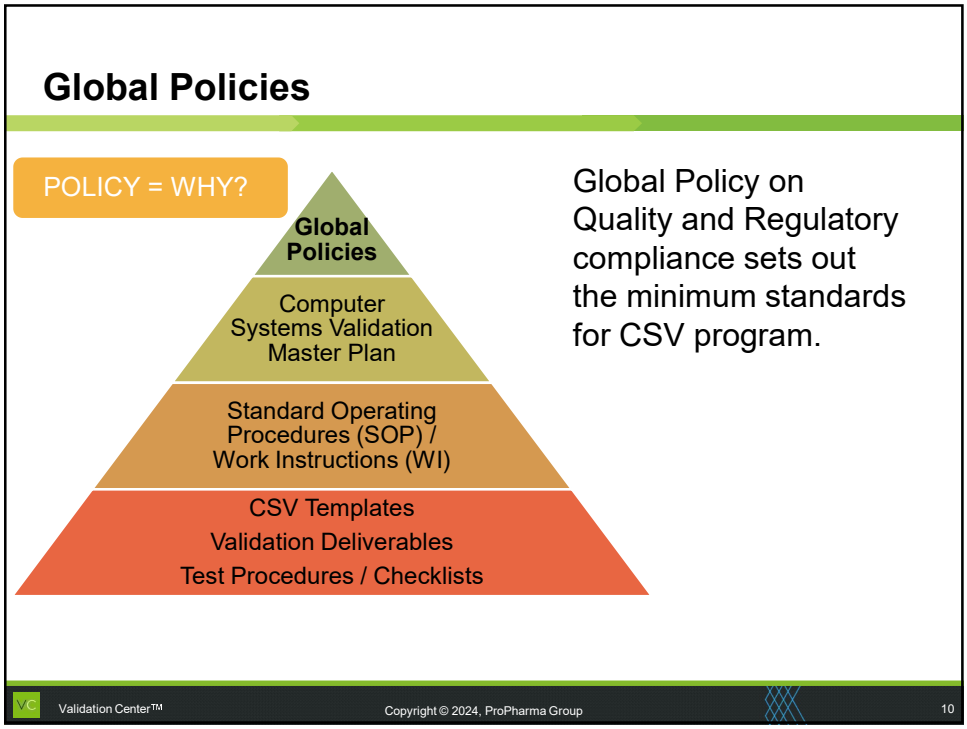

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Global Policies

Example Policies:

- Quality Policy
- Security Policy
- Data Protection Policy
- CAPA and Deviation Management Policy
- Conducting an Audit Policy
- Data Integrity and Reliability Policy

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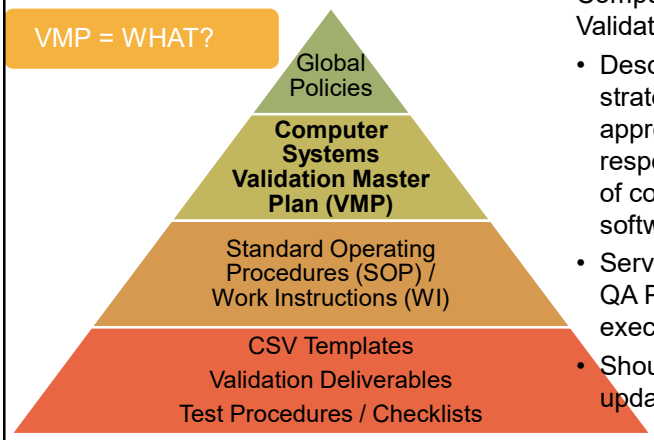
Computer Systems Validation Master Plan

VMP = WHAT?



Computer Systems Validation Master Plan

- Describes the overall strategy, high level approach, and responsibilities for validation of computer systems and software.
- Serves as a linkage between QA Policies and CSV execution documents
- Should be reviewed and updated regularly.

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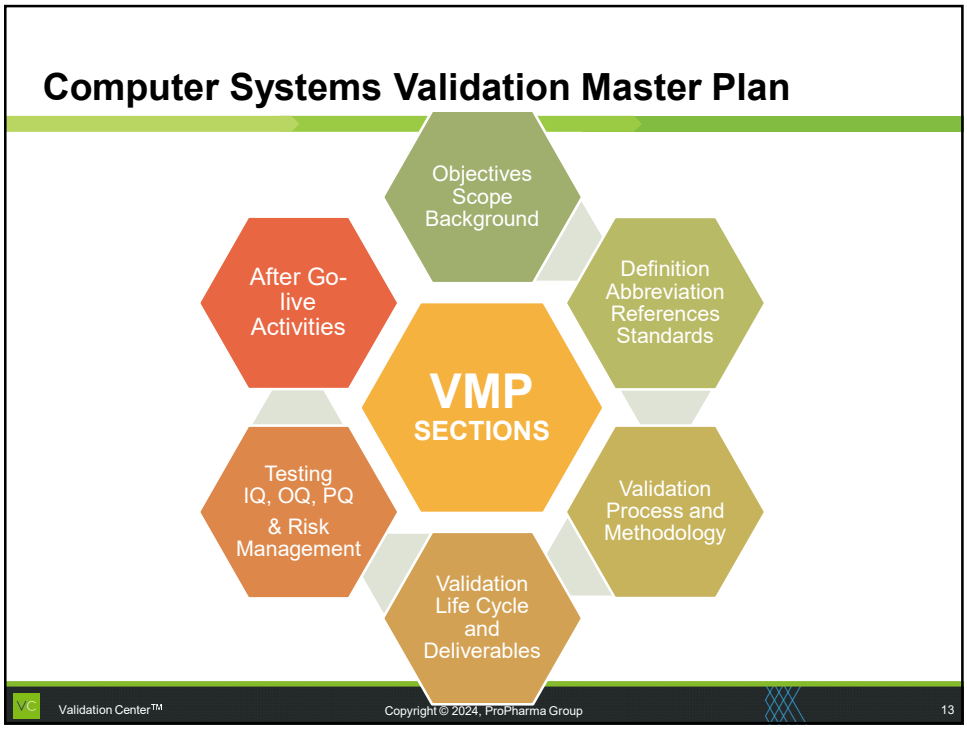

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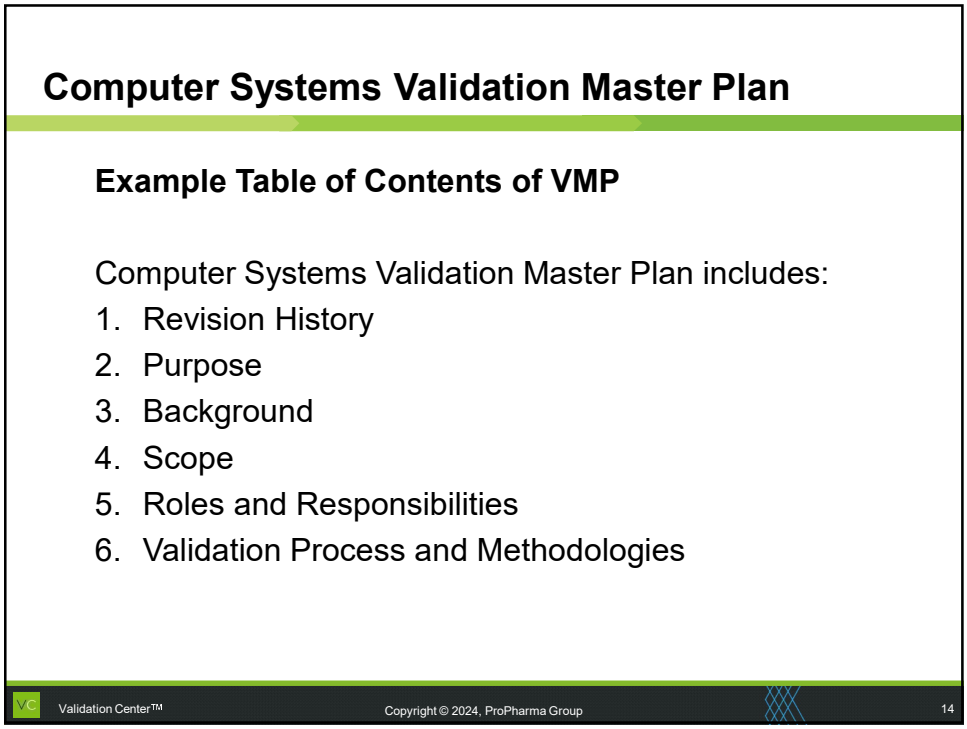

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Computer Systems Validation Master Plan

Computer Systems Validation Master Plan includes (cont'd):

7. Computer Systems Validation Lifecycle and Activities
7.1 Vendor Audit
7.2 Assessments
7.3 Requirement Specifications

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Computer Systems Validation Master Plan

Computer Systems Validation Master Plan includes (cont'd):

7. Computer Systems Validation Lifecycle and Activities (cont'd)
7.4 Validation Qualification Stages
Installation Qualification (IQ)
Operational Qualification (OQ)
Performance Qualification (PQ)
7.5 Risk-Based Testing
7.6 Qualification Environments
7.7 Incident Management

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Computer Systems Validation Master Plan

Computer Systems Validation Master Plan includes (cont'd):

7. Computer Systems Validation Lifecycle and Activities (cont'd)

7.8 ERES (21 CFR Part 11/ Annex 11) Compliance Assessment

7.9 Validation Summary Report and Certification

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Computer Systems Validation Master Plan

Computer Systems Validation Master Plan includes (cont'd):

8. After Go-Live Ongoing Support

8.1 Inventory of Computer Systems

8.2 Change Control

8.3 Periodic Review and Revalidation

8.4 System Retirement and Decommissioning

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Computer Systems Validation Master Plan

Computer Systems Validation Master Plan includes (cont'd):

9. Glossary of Terms
10. Abbreviations
11. References

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Computer Systems Validation Master Plan

Example:

CONTENTS

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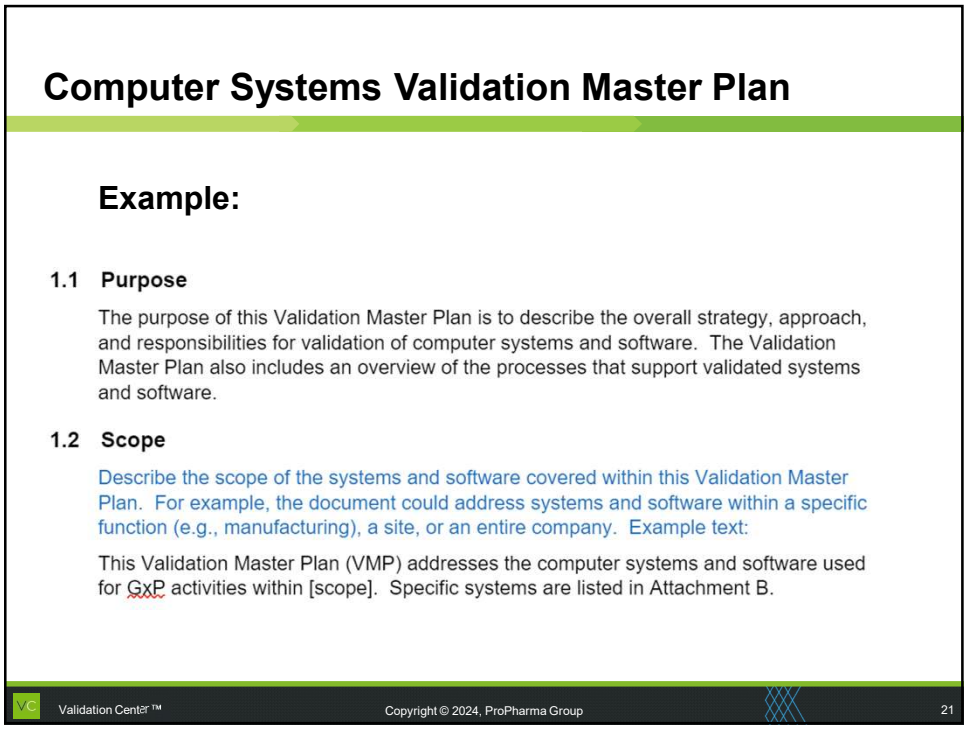

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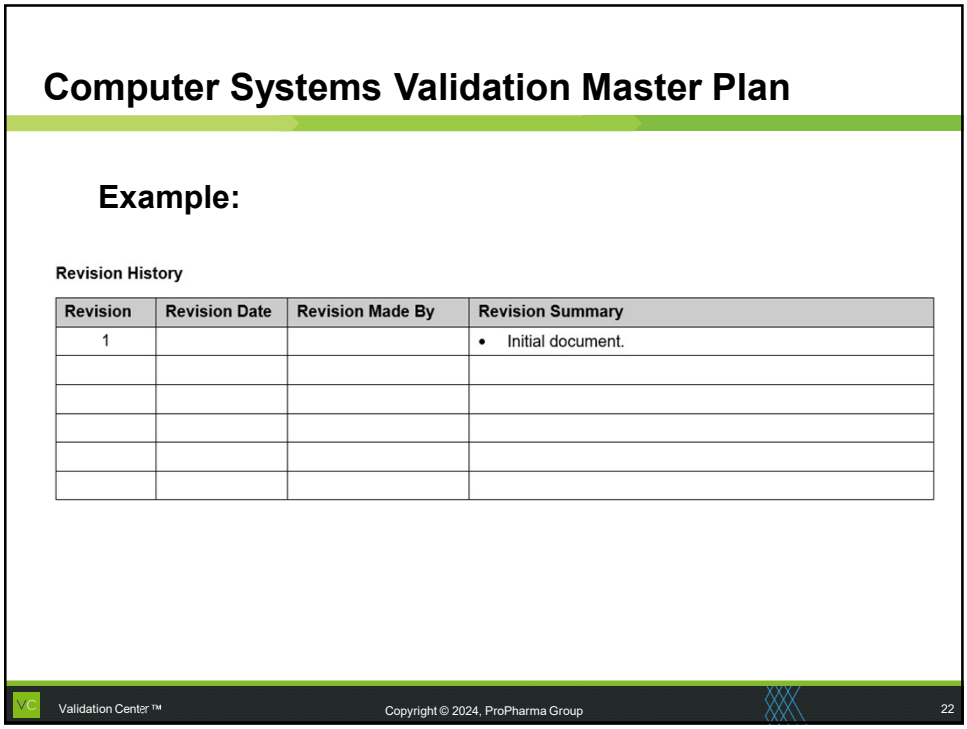

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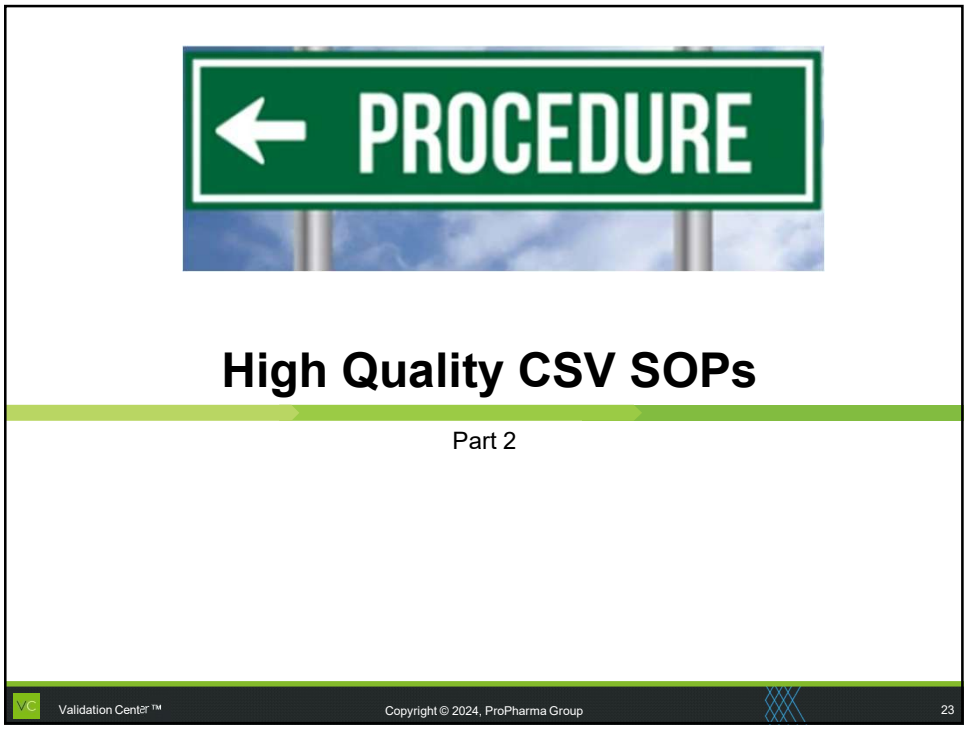

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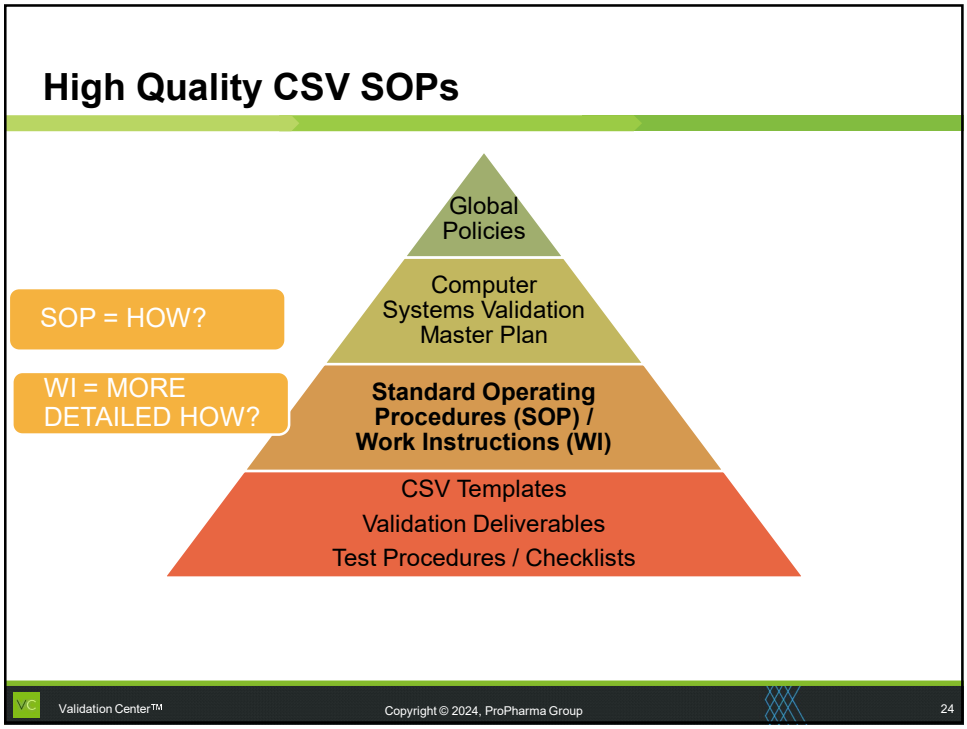

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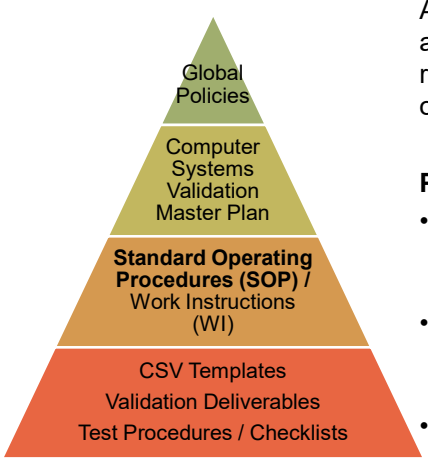
High Quality CSV SOPs



A Standard Operating Procedure (SOP) is a set of written instructions to document a routine or repetitive activity followed by an organization.

Purpose:

- To detail the regularly recurring work processes that are to be conducted or followed within an organization.
- To document the way activities are to be performed to facilitate consistent conformance.
- To minimize variation and promotes quality through consistent implementation of a process.

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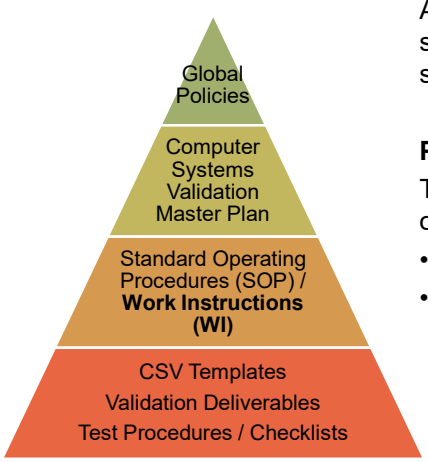
High Quality CSV SOPs



A Work Instruction (WI) describes function specific process in a detailed level and how something must be done.

Purpose:

To provide detailed and specific instructions on:

- How to perform a functional activity
- Use of computer systems and other operational tools in completing the tasks

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High Quality CSV SOPs

How to develop CSV SOP/WIs:

- Concise, step-by-step, easy to read format.
- The term “you” should not be used, but implied.
- The document should not be wordy and redundant.
- Keep it simple and short.
- Information should be conveyed clearly and explicitly to remove any doubt as to what is required.
- Where applicable, use flowchart to illustrate the process being described.
- There must be numbering system to identify and label the SOP.
- Revision number and effective date must be available.
- Page number and total number of pages are included.
- Use consistent format (e.g., date and time format)

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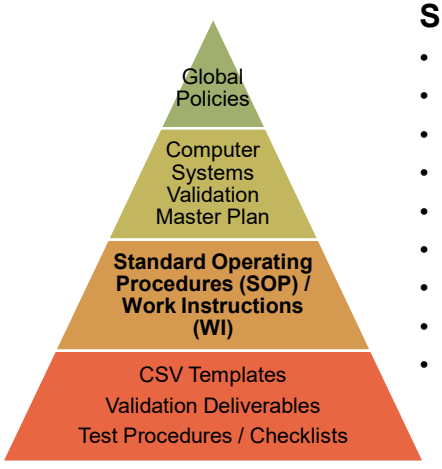
High Quality CSV SOPs



SOP sections should include:

- Purpose
- Scope
- Training Requirements/Applicability
- Reference Documents
- Definitions
- Procedure Steps
- Roles and Responsibilities
- Revision History
- Appendices (e.g., flowcharts, tables, forms)

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High Quality CSV SOPs

SOP Example:

STANDARD OPERATING PROCEDURE	SOP #:
Company:	Department:
Title: System Risk Assessment	Page 2 of 14
Effective Date:	Revision: 1

Contents

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High Quality CSV SOPs

SOP Example:

STANDARD OPERATING PROCEDURE	SOP #:
Company:	Department:
Title: System Risk Assessment	Page 3 of 14
Effective Date:	Revision: 1

1 Purpose

The purpose of this SOP is to provide a systematic approach to System Quality Risk Management and to describe the process to assess and analyze risk associated with Computer Systems and software used in GxP activities.

2 Scope

This SOP applies to Computer Systems and software used in GxP activities.

3 Definitions

Term	Definition
Complexity Level	A measure of the probability of hazard occurrence based on the complexity of the technology implementation.
Computer System	A set of software and hardware components which together provide functionalities to create, modify, maintain, archive, retrieve, or transmit in digital form

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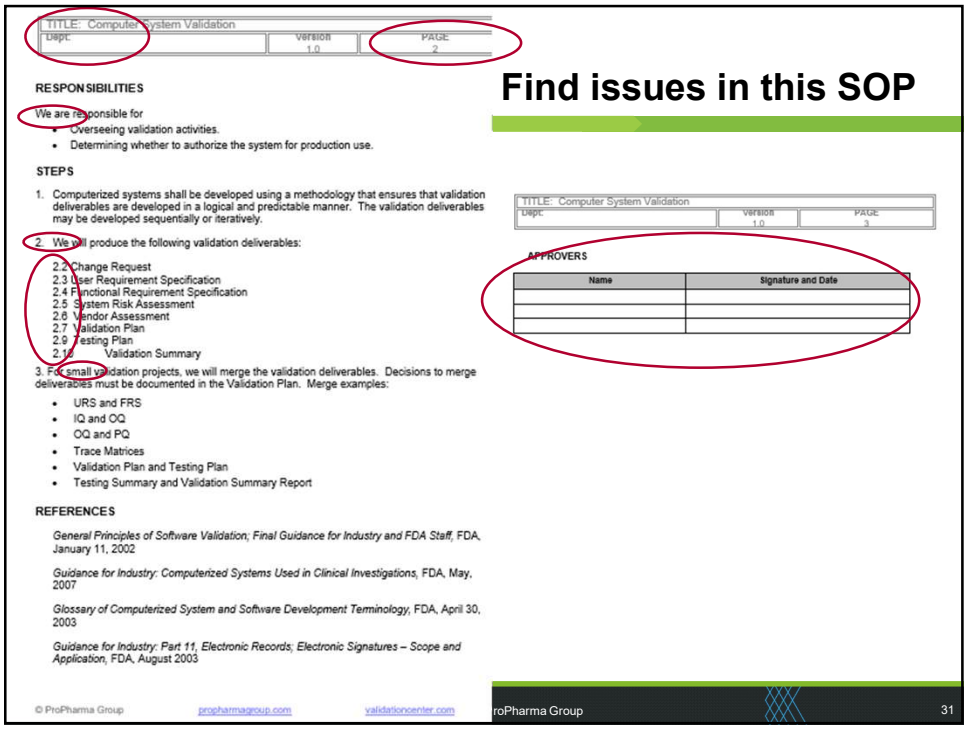

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Issues in this SOP

- There is no indication whether this document is an SOP, WI, or something else.
- No Effective Date
- No total number of pages
- No SOP number or ID
- ‘We’ should not be used
- Incorrect numbering
- Inconsistent formatting
- No clear explanation or description of a ‘small project’
- No meaning of signature included in the Approvers section.
- Purpose is not included.
- Descriptions are not included.

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High Quality CSV SOPs

WI Example:

How to listen to a Voicemail (VM)

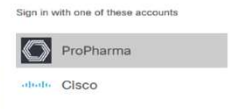
3 PROCEDURE

3.1 Receiving a VM

1. When a new VM is received, an automatic notification is sent to the designated ProPharma email address (e.g., client, coordinators, personal) from "Cisco Unity Connection Messaging System unityconnection@sur01wx011cuc01.wx011.webexcce.com".

3.2 Accessing Your Personal VM

1. Click on the following link or Copy and Paste into your web browser:
   https://sur01wx011cuc01.wx011.webexcce.com/ciscopca
2. Select the "ProPharma Group" option



3. Enter your Propharma Group Credentials (email address and windows password)

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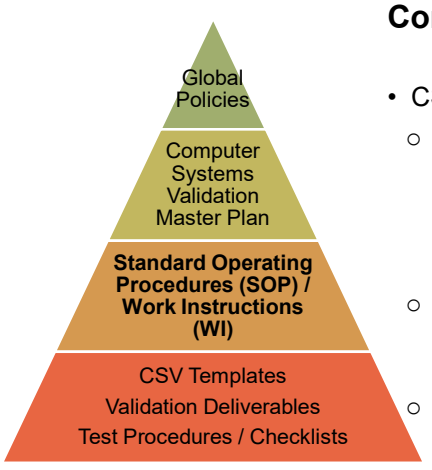
List of CSV SOPs



Core CSV SOPs:

- CSV Life Cycle and Execution
  - To establish the minimum requirements for the life cycle approach to Computer Systems validation including the development, review and approval of CSV documentation.
  - To provide the steps and requirements for IQ, OQ, PQ, and final approval/release of the qualification process.
  - To provide steps on how to perform validation per user requirements and applicable regulatory requirements.

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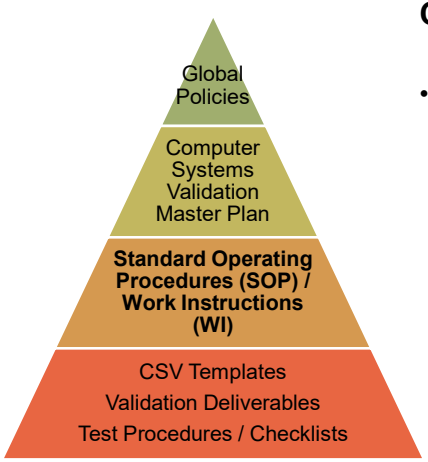
List of CSV SOPs



Core CSV SOPs (cont'd):

- Computer Systems Change Control Process
  - To define and outline steps and requirements in proposing, assessing, documenting, evaluating, and controlling changes related to Computer Systems that have potential impact to the patient safety and/or product quality.
  - To describe how change control is established and maintained for validated GxP impacting Computer Systems.

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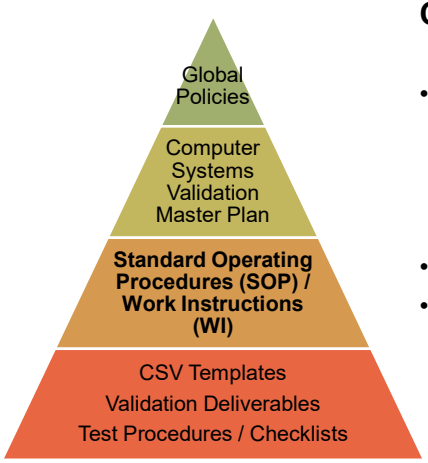
List of CSV SOPs



Core CSV SOPs (cont'd):

- Electronic Records (ER) and Electronic Signatures (ES)
  - To define ER and ES regulations and steps for testing against these regulations.
- Risk Management
- Incident Management

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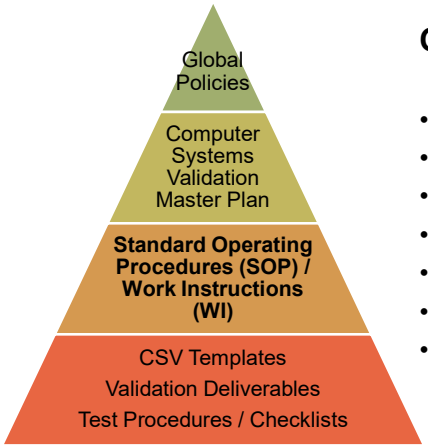
List of CSV SOPs



Other CSV SOPs:

- Vendor Audit
- Computer Systems Periodic Review
- Computer Systems Decommissioning
- Cloud Solutions Qualification
- Data Migration Qualification
- Spreadsheet Validation
- Inventory of Computer Systems

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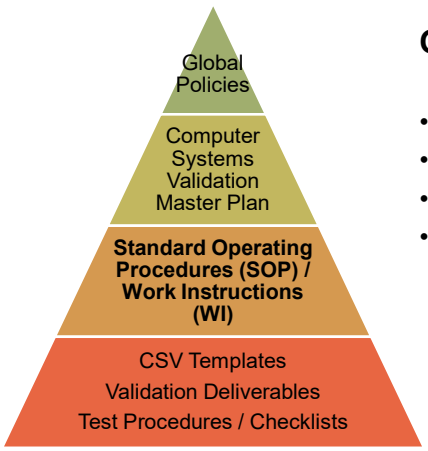
List of CSV SOPs



Other Supporting IT SOPs:

- Back up and Recovery
- Disaster Recovery
- Network Access and System Security
- User Management

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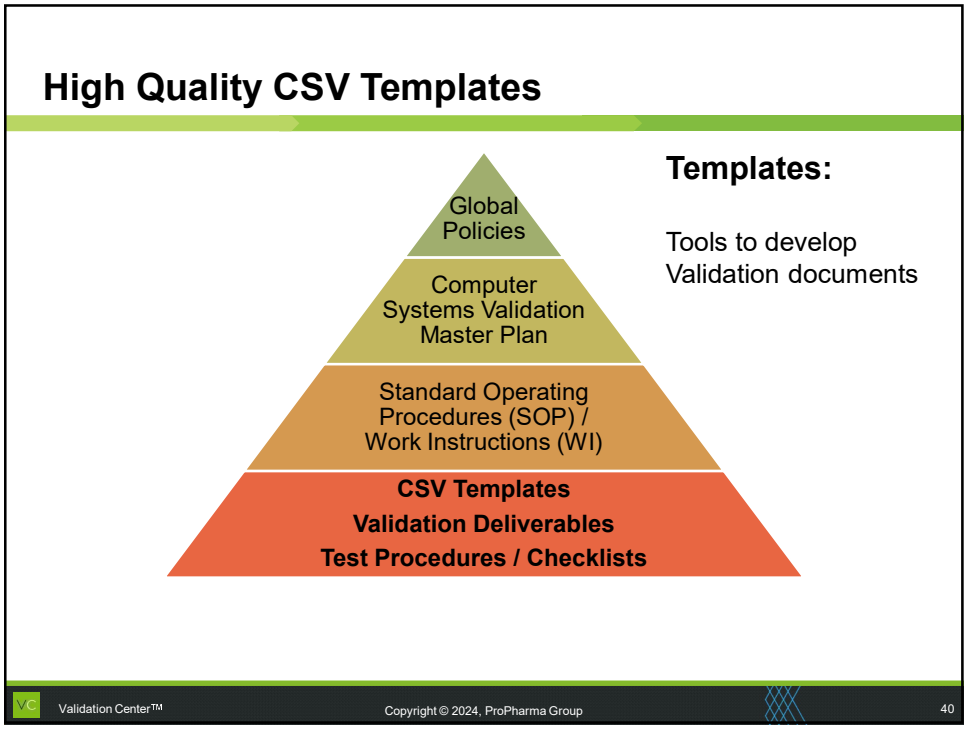

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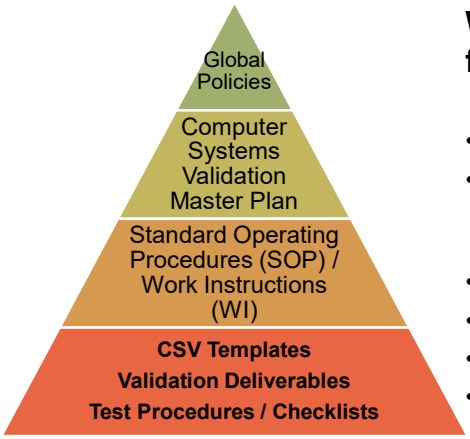
High Quality CSV Templates



What templates are required for CSV?

- Vendor Assessment (if applicable)
- User Requirements Specification (and other applicable specification documents)
- Validation Plan/Protocol
- ERES Compliance Assessment
- Traceability Matrix
- Validation Report

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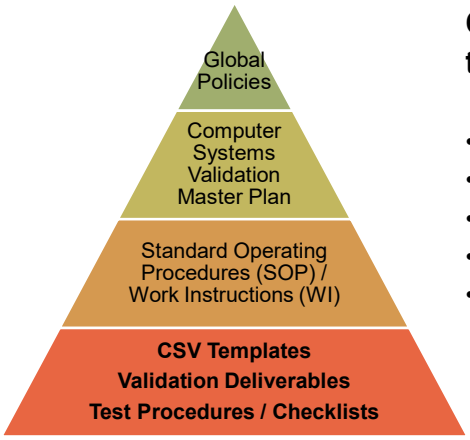
High Quality CSV Templates



Other supporting CSV templates:

- Test Plan
- Test Case
- Test Result
- Incident
- Incident Report

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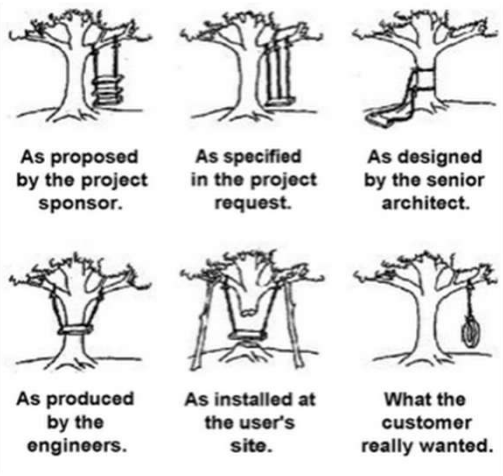
High Quality CSV Templates

User Requirements Specification

- Functional/Operational
- Data
- Interface
- Report
- Data migration
- Infrastructure
- Performance
- Regulatory compliance
- Procedural



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High Quality CSV Templates

Validation Plan/Protocol:

- Revision History
- Glossary and Definitions
- References
- Roles and Responsibilities
- Validation Scope
- System Description
- Technical Details and Implementation Methodology
- Risk Management and Assessments
- Validation Approach and Deliverables
- Testing Approach and Environments
- Deviation/incident Management
- Procedures and Training
- Change Control

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High Quality CSV Templates

ERES Compliance Assessment

- Mapping to tests and results, procedures, validation documents, policies for each 21 CFR Part 11 requirement.
- Mapping to tests and results, procedures, validation documents, policies for each Annex 11 and other applicable standards.
- Making sure that all Electronic Records and Electronic Signatures compliance requirements are fulfilled.

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High Quality CSV Templates

Validation Summary Report

- Revision History
- Glossary and Definitions
- References
- Summary of Validation activities
- Summary of Test Results
- Summary of Incidents and solutions
- List of validation documentation
- Conclusion

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High Quality CSV Templates

Consider the following when creating templates:

- Templates must be aligned with company standards and SOPs.
- Structure templates that can work for different methodologies: Waterfall, Agile and Hybrid
- Must include:
  - Template version number
  - Title of the document
  - Template ID
  - Revision history
  - Page number and total number of pages
  - Author, reviewer, and approvers identified

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High Quality CSV Templates

Consider the following when creating templates:

- Pre-write general applicable default content for consistency
- Use styles and good formatting
- Use instructional text (in capitals, highlights, italic, different color, etc.)

Example:

VALIDATION PROTOCOL
FOR
SYSTEM NAME

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High Quality CSV Templates

Example: URS

	Company/Site:	
	System Name:	System Version:
	Document Title: User Requirements Specification	Page **2** of **11**
	Document ID:	Document Revision: 1

Contents

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High Quality CSV Templates

Example: Validation Plan

1.1 Purpose

The purpose of this Validation Plan is to describe the project's validation deliverables, testing process, and schedule. The Validation Plan also defines who is responsible for creating, reviewing and approving each validation deliverable.

1.2 Scope

1.2.1 System Description

Describe the system that is covered within this Validation Plan. Include a brief description of the business processes within which the system is used.

1.2.2 Validation Scope

Describe the scope of the system requirements covered within this Validation Plan. Refer to the Functional Requirements Specification. Also include a description of any portion(s) of the system requirements that are outside the scope of this plan.

1.3 Definitions, Acronyms, and Abbreviations

Term	Definition

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High Quality CSV Templates

Example: Test Case

TEST CASES

Test Case 1:							
Step	**Description/Action**	**Expected Result**	**Actual Result**	**Pass, Fail?**	**Tester Initial/Date**	**Verifier Initial/Date**	**Comment**
1.1							
1.2							
1.3							

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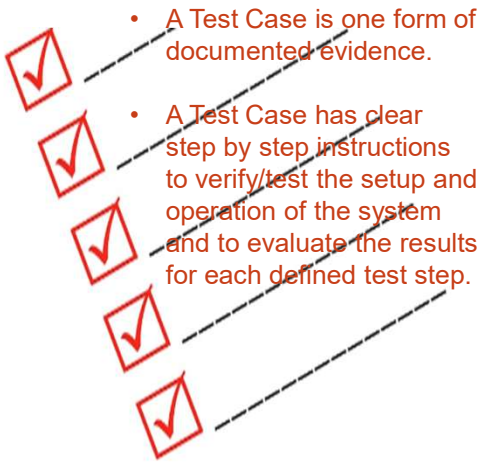
High Quality CSV Templates

Standard/Generic Test Case Templates:

- Create standard Test procedures that can be used repetitively for different projects or changes, such as:
  - Software IQ for Server
  - Redundancy Test
  - Hardware IQ for Server
  - Virtual Machine Creation
  - System Connectivity



- A Test Case is one form of documented evidence.
- A Test Case has clear step by step instructions to verify/test the setup and operation of the system and to evaluate the results for each defined test step.

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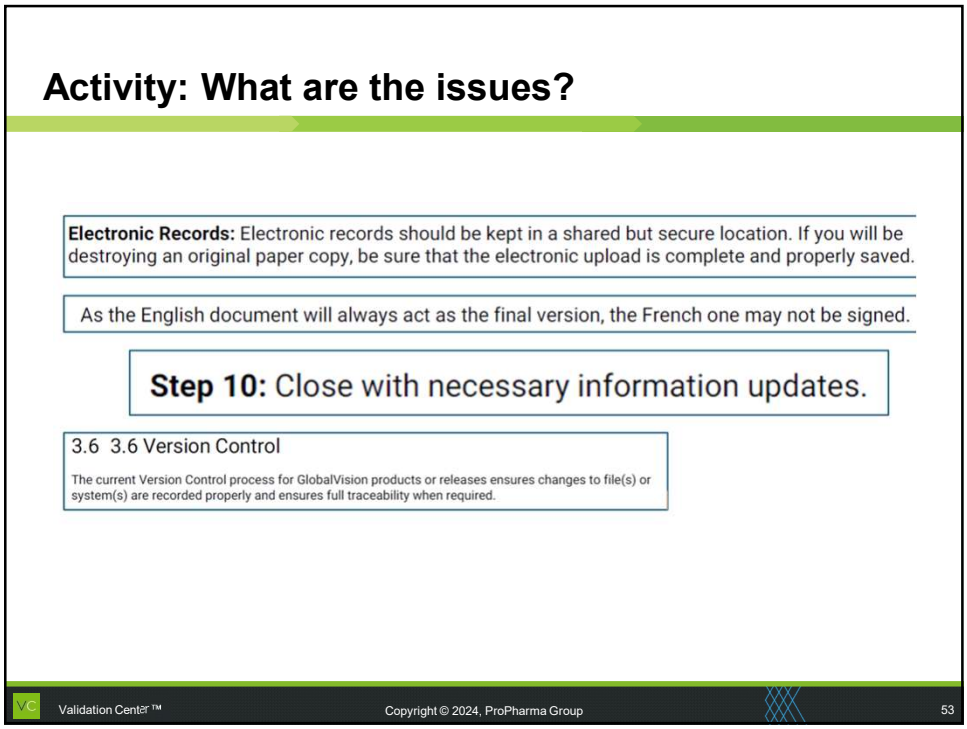

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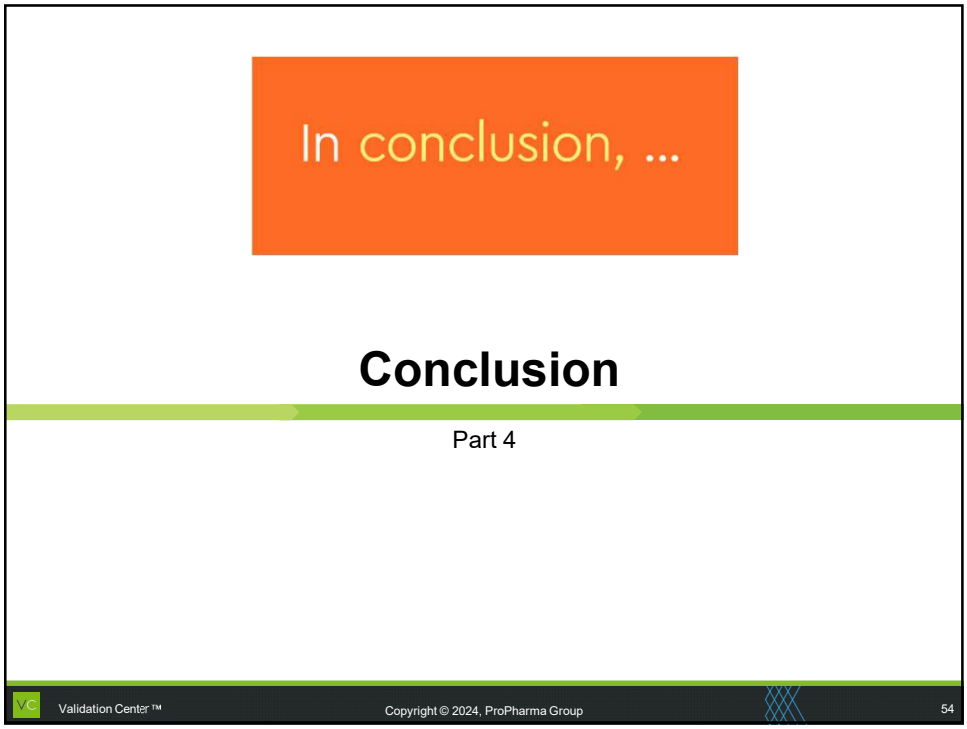

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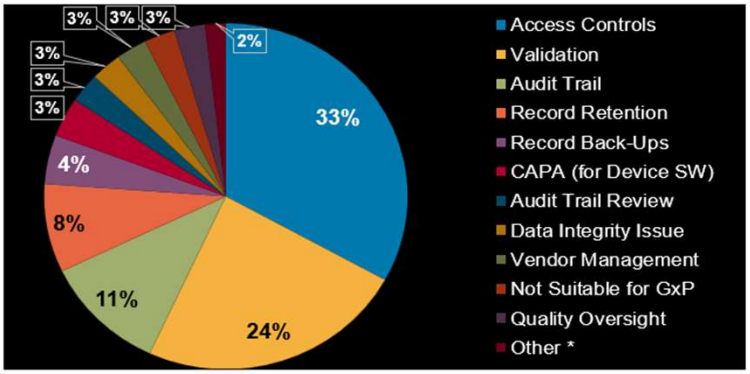
Conclusion

- A well-established Computer Systems Validation Program and IT Quality plays an important role being compliant with regulations.
- Validation is one of the highest observation area companies receive.

3 Year Summary by Observation Topic



"Other" observation topics include Risk Management, Software registration with the FDA

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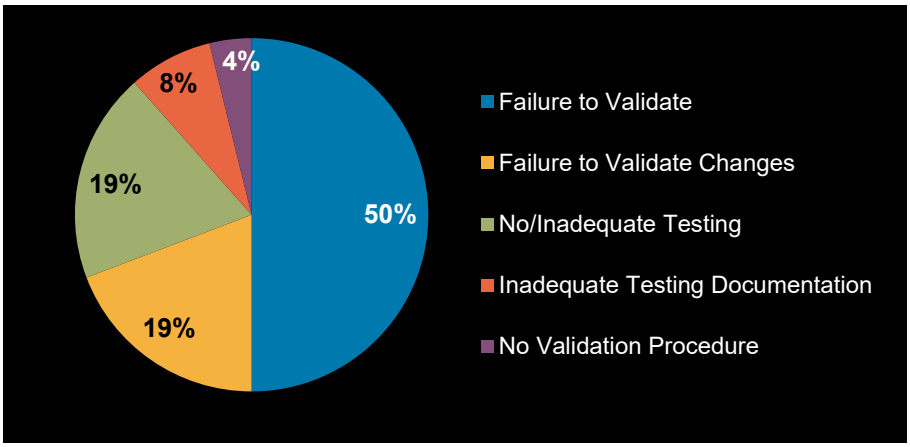
Conclusion

3 Year Summary by Observation Topic – Validation Only



Software & Computer Warning Letter Citations

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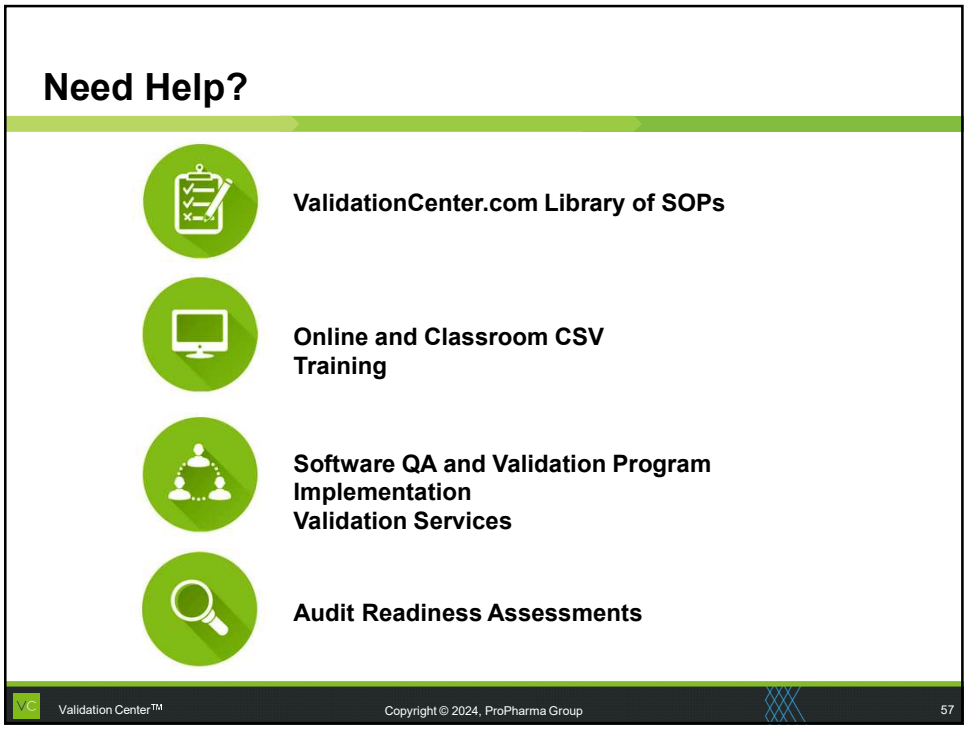

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