Version 2016

™

CSV certification program ™

All conferences, exercises and tests online.

- ✓ Master the CSV & Data Integrity Process.
- ✓ CDS real-life example: Learn the actual validation process of a laboratory Chromatography Data Software.
- ✓ Learn how to document Quality Events in CSV.

Become a CSV - SME
Prevent FDA - 483's

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★★★★

Endorsed By Industry Professionals

Learn how to THINK like the FDA®

- ✓ Develop specialized FDA-regulatory knowledge and skills.
- ✓ Be able to review, improve, approve, guide and teach regulatory technical work to others.

GCGI's CSV CERTIFICATION PROGRAM ™

The Computer System Validation (CSV) Certification Program encompasses three (3) Certification Training Modules for a total of sixty (60) hours or ten (10) training days.

The program addresses the application of Software Development Life Cycle (SDLC) to automated Manufacturing and Laboratory systems.

Each participant will be able to understand the rationale within the CSV process and overall, understand ***"How FDA Thinks"*** when auditing firm's CSV, Data Integrity in computerized systems and Part 11 documentation.

Three CSV Certification Training Modules are available to personnel with diverse educational backgrounds.

MODULE 1: FDA-regulatory module (6 hours).
MODULE 2: Development of validation documents (42 hours).
MODULE 3: Documenting **CSV QUALITY EVENTS** (12 hours).

The certification program is delivered by **Johnny Guerra**, a former **FDA Computer Specialist**, ensuring that participants learn all CSV requirements for the proper detection, correction and prevention of computer and software anomalies that could impact on product quality and validated processes and systems as well.

The program enables employees to implement, maintain and document a fully functional, FDA-oriented CSV program emphasizing in the development of CSV documentation requirements such as Design Qualifications (DQ), Installation Qualifications (IQ), Operational Qualifications (OQ) and Performance Qualifications (PQ) as well as system maintenance procedures.

By understanding the qualification and validation fundamentals included in a Master Validation Plan (MVP), personnel would be able to properly implement User Requirements, Functional Specifications/Testing during the life cycle approach of a laboratory or manufacturing application.

Identifying FDA's CSV/Part 11 regulatory areas is of up most importance during equipment/ instrument commissioning and deployment activities.

Conducting Quality Risk Management assessments under a computer and software maintenance program provide companies with effective tools for the implementation of a well-balanced **Corrective and Preventive Action (CAPA)** plan during the lifetime of the process.

Each CSV certification program module includes a workshop section emphasizing on exercises related to CSV situations and CSV Exams to ensure that the certification process has been effective.

CDS real-life example

- ✓ Learn the actual validation process of a laboratory ***"Chromatography Data Software (CDS)".***
- ✓ All validation documents included.
- ✓ Use them as reference or templates for CSV projects.

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MODULE 1: FDA-REGULATORY MODULE

This six hours CSV Certification Program Module has been designed to help participants develop FDA regulatory-auditing/compliance skills in automated systems that would satisfy Agency's requirements.

By discussing current FDA Computer/Software Validation Guidelines (including Part 11) and the FDA-triggered approach process to CSV in Pharmaceutical, Medical Devices and Biotechnology systems, the participant would be able to identify areas requiring validation/ re-qualification and capable of providing solutions and alternatives that otherwise might end as an FDA-483 objectionable observation and consequently, as an **FDA Warning Letter (WL)**.

The course includes workshop exercises and a certification test exam for the first module.

CHAPTER 1: Introduction to Computer System Validation (CSV), 1 hour.

- Relationship between CSV, Part 11 and cGMPs in the Pharmaceutical, Biotechnology and Medical Device Industry.
- FDA Systematic Approach to Manufacturing and Laboratory Inspections:
  - A CSV Preventive Perspective.
  - When CSV is triggered?
  - Documenting CSV Quality Events.
- **CSV Workshop Exercise #1.**

CHAPTER 2: Computer Systems Validation (CSV), 3 hours.

- DQ, IQ, OQ and PQ documents.
- Software Development Life Cycle.
- Data Accuracy, Data Integrity and Data Security.
- Infrastructure Qualifications.
- Equipment and Instruments.
- Functional and Structural Testing.
- Deficiencies of Software Applications.
- Part 11, Electronic Records; Electronic Signature Requirements.
- Evaluation of Computer System Validation Documents.
- Computer and Software Limitations.
- Managing Software Defects.
- Quality Events related to CSV: Manufacturing and Laboratory Operations.
- **CSV Workshop Exercise #2.**

CHAPTER 3: Computer System Maintenance Procedures, 1 hour.

- Change Control, Software Maintenance, Error Logs and Audit Trails.
- Backups, Restore and Archival.
- Disaster Recovery.
- Software Security and Data Integrity Policies.
- Corrective and Preventive Action Plan (CAPA).
- **CSV Workshop Exercise #3.**

MODULE 1: CSV Certification Test Exam

An open-resource exam where each participant will analyze a regulatory CSV situation. To pass the test, the participant will be required to document alternatives and solutions that would resolve a GMP regulatory situation involving either a Manufacturing or Laboratory System that otherwise could end as an FDA-483 objectionable observation and furthermore as an FDA Warning Letter.

DISCUSSION: CSV Certification Test Exam for MODULE 1, 1 hour.

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MODULE 2: DEVELOPMENT OF VALIDATION DOCUMENTS

This forty-two hours CSV Certification Program, Module 2 has been designed for inexperienced personnel requiring ***"Hands-On-Training"*** in CSV or experienced personnel that would like to learn Computer System Validation from an FDA auditing and regulatory perspective.

This module includes the discussion of a laboratory data acquisition system with corresponding documentation from a real-life validation study.

The course includes workshop exercises and a certification test exam for the second module.

CHAPTER 1: Design Qualification (DQ) Document, 12 hours

- The essence of validation.
- Why validation is required?
- DQ - the most important validation document;
  - User Requirements Specification (URS) Document.
  - FDA/Company Contract Agreements.
  - Vendor Evaluation, Auditing and Certification Process.
  - Infrastructure Qualifications.
  - Instrument and Equipment Qualifications.
  - Development and implementation of a good Validation Plan (VP).
  - Part 11 Requirements.
  - Functional Requirements Specification (FRS) and cross-reference to URS.
  - Traceability Matrix (TM) Document.
  - Computer System Design and documenting limitations & system constraints.
- **CSV Workshop Exercise #1: Development of the DQ Document.**

CHAPTER 2: Installation Qualification (IQ) Document, 6 hours

- Infrastructure Requirements and Qualifications.
- Factory Acceptance Tests (FAT) and Vendor's IQ & Performance Tests.
- Computer System Installation Qualification Process.
- IQ Forms, GMP requirements, Protocol and test execution format.
- Report execution: Conditions and conclusions.
- Documenting deviations.
- **CSV Workshop Exercise #2: Development of the IQ Document.**

CHAPTER 3: Operational Qualification (OQ) Document, 12 hours

- Relationship to URS/FRS document.
- Designing OQ Test Cases: Where to begin?
- How much testing would be necessary?
- Functional Testing modes: Normal and Stress Testing.
- How to design, develop and configure challenge Test Cases that would satisfy regulatory Agencies.
- When Structural Testing is necessary?
- The Ins and Outs of Data Integrity testing and Audit Trails.
- Why and When to test for Part 11 requirements?
- When to use Vendor's FAT and Auditing results?
- OQ Forms and GMP requirements.
- Protocol and test execution format.
- Report execution: Conditions and conclusions.
- Documenting deviations.
- **Workshop Exercise #3: Development of the OQ Document.**

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MODULE 2: DEVELOPMENT OF VALIDATION DOCUMENTS

CHAPTER 4: Performance Qualification (PQ) Document, Final Report and Maintenance Procedures, 11 hours

- The need of a Performance Qualification.
- Relationship to the URS document.
- Designing tests with company's products. How to properly select test batches.
- How to challenge the validation.
- PQ Forms and GMP requirements.
- Protocol and test execution format.
- Report execution: Conditions and conclusions.
- Documenting deviations.
- Evaluation of IQ, OQ and PQ results.
- **Final Report:** Evaluation of results, deviations and system's limitations.
- SOP recommendations based on validation results.
- **Maintenance Procedures:**
  - SOP development based on the outcome of DQ, IQ, OQ and PQ activities.
  - Firm's documentation and SOP strategy based on system limitations.
  - Firm's policies based on:
    - Data Accuracy, Data Integrity and Data Security.
    - Backups, Restore, Archival and Disaster Recovery.
    - Computer and Software Limitations.
    - Software Defects.
    - Vendor's response time, follow-ups and support.
    - Change Controls, including software versions and error logs.
    - Part 11 constraints and limitations.
    - Monitoring the effectiveness of CAPAs.
- **Workshop Exercise #4: Development of the PQ Document. Development of the Software Maintenance Procedure Document.**

MODULE 2: CSV Certification Test Exam

An open-resource exam where each participant will analyze a regulatory CSV situation. To pass the test, the participant will be required to document alternatives and solutions that would resolve a GMP regulatory situation involving either a Manufacturing or Laboratory System that otherwise could end as an FDA-483 objectionable observation and furthermore as an FDA Warning Letter.

DISCUSSION: CSV Certification Test Exam for MODULE 2, 1 hour.

MODULE 3: DOCUMENTING CSV QUALITY EVENTS

This twelve hours CSV Certification Program, Module 3, is geared toward CSV personnel required to document software anomalies, deviations, errors, and system limitations during commercial manufacturing and laboratory activities.

To be effective, the workshop training-course emphasizes on situations or events experienced by participants. Firm's Quality Events will be studied during the course and used as a training tool to promote change during the identification of areas for improvement.

Participants completing this course module are normally called by upper management to perform as ***"FDA ESCORTS"*** by providing and answering CSV-related issues involving firm's Quality Events, Complaints, Annual Product Reviews, Field Alert Reports, Manufacturing/Laboratory Failure Investigations and Corrective and Preventive Action (CAPA) plans.

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MODULE 3: DOCUMENTING CSV QUALITY EVENTS

CHAPTER 1: Handling Investigations, 2 hours.

- FDA's position within the investigation process.
- FDA-483 CSV trends and Warning Letters.
- Laboratory Events: Discussion of FDA Guidance for Industry, *"Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production".*
- Manufacturing Events: Discussion of cGMP requirements and ***"FDA's Thinking"*** related to Quality Events.
- **Workshop Exercise #1: CSV Assessments and Regulatory concerns for Laboratory and Manufacturing Operations.**

CHAPTER 2: Root-Cause-Analysis (RCA) and Problem-Solving Tools (PST), 4 hours.

- Systematic approach for determining possible causes of deviation(s).
- Root-Cause-Analysis (RCA) and Problem-Solving Tools (PST) applicable to Investigation Reports.
- Discussion of Root-Cause-Analysis (RCA).
- FDA Regulatory/Investigation's Life Cycle approach within Root-Cause-Analysis (RCA) and Problem-Solving Tools (PST).
- Problem-Solving Tools (PST) within FDA's Investigator frame-of-thought.
  - Brainstorming/Affinity Diagrams and Lean Sigma 5-Why's.
  - Kepner-Tregoe® (KT).
  - Input-Process-Output (IPO).
  - Cause-and-effect (Fishbone) Diagrams.
  - Pareto Charts and Failure Mode and Effect Analysis (FMEA).
- **Workshop Exercise #2: The application of Root-Cause-Analysis (RCA) and Problem-Solving Tools (PST) on firm's CSV Quality Events.**

CHAPTER 3: Writing Investigation Reports, 5 hours.

- Methodology of the Investigation.
- Writing the Investigation Report.
- FDA and cGMP Regulatory considerations.
- Technical-Writing (TW): Issues to consider when writing the Investigation Report, i.e., Active vs. Passive Sentences, rationale thinking, etc.
- Investigation's reporting-format template:
  - Headings defining important key elements to be addressed during the investigation process.
  - Heading's relationship to RCA, PST, Impact to Product Quality and Data Accuracy, Data Integrity and Data Security.
- **Workshop Exercise #3: The study of real cases from your company in order to apply technical and FDA-regulatory concepts during the development of the Investigation Report.**

MODULE 3: CSV Certification Test Exam

An open-resource exam where each participant will analyze a regulatory CSV situation. To pass the test, the participant will be required to document alternatives and solutions that would resolve a GMP regulatory situation involving either a Manufacturing or Laboratory System that otherwise could end as an FDA-483 objectionable observation and furthermore as an FDA Warning Letter.

DISCUSSION: CSV Certification Test Exam for MODULE 3, 1 hour.

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CSV CERTIFICATION: PROGRAM BENEFITS

- Define and comply with FDA regulatory requirements on CSV, Part 11 and Data Integrity in computerized systems applicable to Laboratory and Manufacturing Operations.
- Understand the fundamentals of a Master Validation Plan for CSV applications.
- Learn how to develop and execute DQ, IQ, OQ and PQ validation protocols.
- Implement User Requirements, Functional Specifications and Functional Testing during the life cycle of the laboratory and/or manufacturing application.
- Develop a change control program during deployment of CSV and Part 11 applications.
- Adapt internal procedures to develop adequate CSV documentation.
- Learn how to audit CSV documents.
- Maintain data reliability in automated applications.
- Learn the ins and outs of software vendor qualifications and vendor audits.
- Work with computer/software vendors/suppliers to minimize regulatory breach.
- Understand cGMP limitations of third-party validations and software validation packages.
- Learn audit trail review limitations during the evaluation of Data Integrity in computerized systems.
- Prepare a Quality Risk Management assessment strategy to validate software applications in order to pass an audit.
- Implement validation programs for automated equipment.
- Learn how to document Failure Investigations and Quality Events related to automated equipment and computerized laboratory instruments.
- Define and apply remedial action plans (CAPA) under a software maintenance program.

CERTIFICATE OF COMPLETION

After the satisfactory completion of exercises and exams, the participant will receive a certificate of completion indicating that he/she possesses the knowledge, skills and abilities required by the program and able to apply such knowledge in the execution of good Computer System Validation practices at a regulated facility.

The certificate titled "***GCGI's CSV Certification Program™***" is a recognition to the participant and to the industry stating that the individual has fulfilled GCGI's requirements for in-depth knowledge in CSV and capable of implementing, maintaining and documenting a fully functional, FDA-oriented CSV program at Pharmaceutical, Biotechnology, R&D, Medical Device and Clinical/Non-clinical facilities.

Recognition

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PREVENT FDA-483 OBJECTIONABLE OBSERVATIONS

The participant who has earned **GCGI's CSV Certification ™** will be able to detect, correct, prevent and predict **CSV QUALITY EVENTS** that otherwise could trigger regulatory compliance situations ending as FDA-483 objectionable observations and consequently **FDA Warning Letters**.

CDS

real-life example

- ✓ Learn the actual validation process of a laboratory ***"Chromatography Data Software (CDS)".***
- ✓ All validation documents included.
- ✓ Use them as reference or templates for CSV projects.

Participants log-in to WebEx from a conference room, office or mobile device from any location worldwide!

Participants are connected to GCGI and able to talk directly to the speaker and/or use the Chat Box for interactive discussion!

Cisco webex Event Center

e learning

GCGI's CSV CERTIFICATION PROGRAM™ is available through online webinars.

Training activities are presented live including individual and group discussions, workshop exercises and Q&A sessions.

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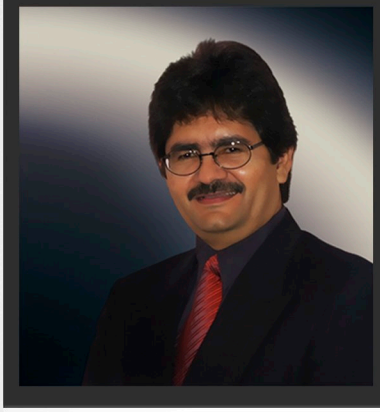
WHO CAN BENEFIT FROM THE CSV CERTIFICATION PROGRAM?

Any pharmaceutical, medical device, biotechnology, biologics, GLP and R/D professional who performs or oversees the following functions:

- Data Integrity Corporate Management
- QA/QC Directors, Managers and Supervisors
- QA/QC Validation Managers
- Internal Auditors and Regulatory Affairs
- GMP Compliance
- Laboratory Directors, Managers, Supervisors and Scientists
- Validation Scientists
- IT/IM System Managers and Analysts
- Project Leaders for IT.
- Technical Operations and Development
- Technical and Analytical Services
- Metrology Groups
- Engineering
- Production, Manufacturing and Manufacturing QA.
- Chemical, Pharmaceutical and Medical Device Engineers.

The CSV Certification Program is suited to:

- Deviation Investigation Writers
- CAPA Investigators
- Pharmaceutical Technical Writers
- Specialist/Technical Writer-Documentation
- Technical Writer - Investigations Specialist
- Process Excellence Specialist
- Data Integrity Specialist
- Lean Six Sigma Leaders
- Consultants
- Contract Personnel



CERTIFICATION INSTRUCTOR

Johnny Guerra, Industry Consultant

"Former FDA Instrument and Computer Specialist"
"Former FDA Supervisory Chemist"

Johnny Guerra is an Industry Consultant, Regulatory Compliance, and the President of Guerra Consulting Group, Inc. He worked for 20 years at the **Food and Drug Administration (FDA)**, San Juan District Office and held positions such as Acting Science Branch Director, Supervisory Chemist, the District Instrument and Computer Specialist and as a Senior Food and Drug Chemist.

He received his degree in Chemistry certified by the American Chemical Society (ACS) from the University of Puerto Rico, Río Piedras campus and later was certified in Electronics Engineering in Minicomputers and Microprocessor Technology by the Capitol Radio Engineering Institute (CREI), Washington, D.C.

Guerra has over 37 years of experience in areas such as electronic instrument design, microcomputers, laboratory automation, Local Area Networks (LANs), Quality Assurance, Quality Control and auditing laboratory/manufacturing computerized processes and manufacturing/laboratory operations at Pharmaceutical, Biotechnology, R/D and Medical Device firms.

He was also member of the FDA Foreign Inspection Cadre where he traveled overseas performing audits in manufacturing processes, quality assurance, manufacturing/laboratory computer validation and analytical methods validation as well.

Guerra has published several articles in **Pharmaceutical Technology**, has authored many technical papers, reports and course manuals including a chapter titled ***"FDA Approach to Laboratory Inspections"***; A Laboratory Quality Handbook of Best Practices, ASQ Quality Press, and others published in FDA's internal scientific journal ***"Laboratory Information Bulletin" (LIB).***

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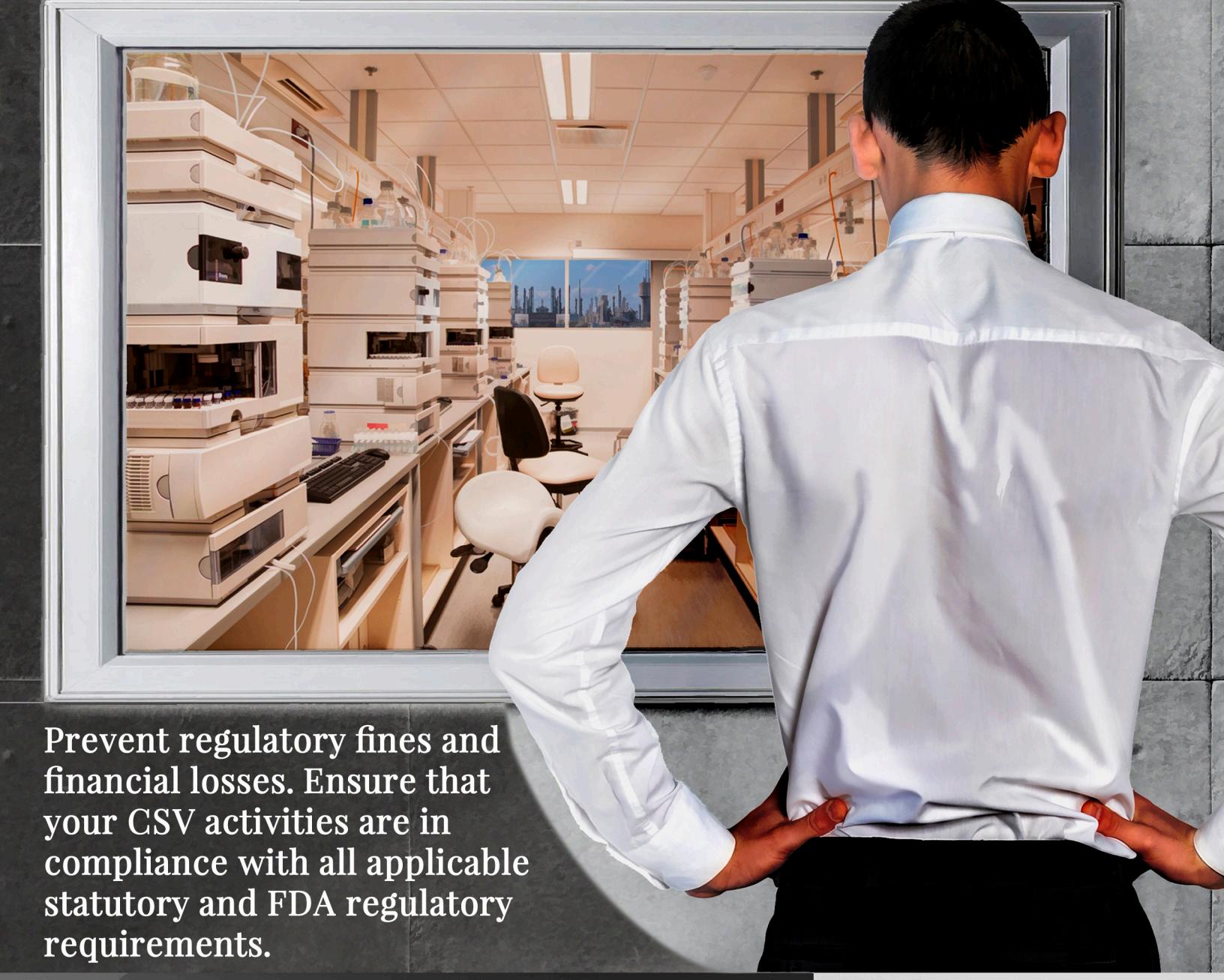

Prevent regulatory fines and financial losses. Ensure that your CSV activities are in compliance with all applicable statutory and FDA regulatory requirements.

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