VALIDATION CENTER

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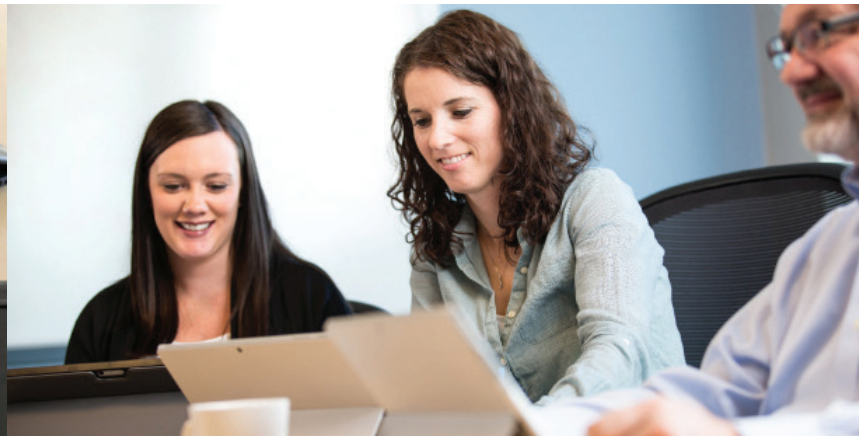
# INTRODUCTION TO COMPUTER SYSTEM VALIDATION



## Online Training

An introductory course designed to build a solid foundation in the key concepts required for IT solutions in an FDA regulated environment. This course establishes a knowledge base of the essential elements of computer system validation (CSV).

## Our Instructors

### Rodrigo Perez

Rodrigo brings +35 years of experience in validation, including computer system validation, process, equipment, and others across the regulated life sciences industry. He teaches risk-based processes to not only save time and effort, but to comply with both US and international regulations.

### John Gow

John has been actively working in the pharmaceutical industry for +30 years across the UK, Europe, and US. He specializes in Data Integrity and Computer System Validation and brings a wide range of experience to help students grow their validation skills and get inspection-ready.

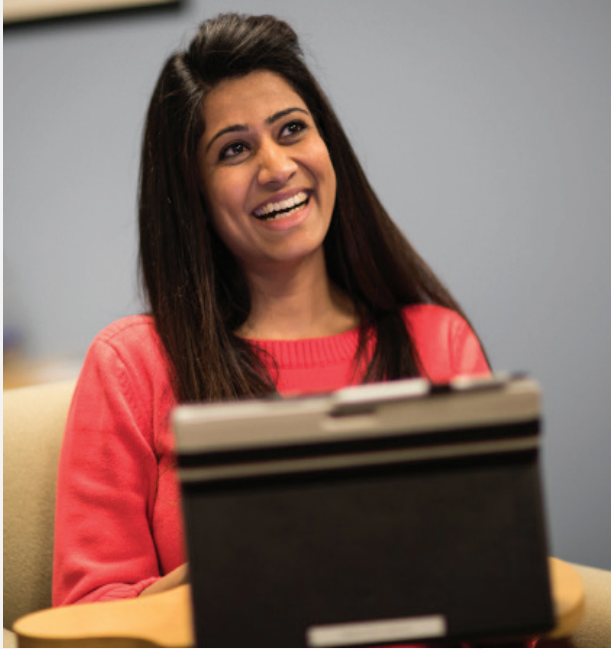
## Learning Objectives

- Understand the background for computer system validation (CSV) elements
- Be able to describe the CSV framework and deliverables, including the Validation Plan, Requirements, IQ, OQ, PQ, Trace Matrix, and Validation Report
- Understand where CSV deliverables fit into your Software Development Life Cycle
- Be able to discuss the principles of testing and the associated documentation that the FDA expects
- Demonstrate knowledge of 21 CFR Part 11 (electronic records and electronic signatures) applicability and requirements

## Course Description

What is computer system validation? Which systems do you need to validate? Where does validation fit into your SDLC or SALC? These are some of the questions answered in this live e-learning course.

This introductory class helps managers and team members establish a solid foundation for understanding the key concepts and skills needed to successfully deliver IT solutions in an FDA regulated environment. This course establishes your knowledge base by focusing on the essential elements of computer system validation — all without leaving the office.



## Who Should Attend the Introduction to CSV Course?

**IT, QA, Engineering & Business Managers and Professionals who need:**

- An introduction to the key FDA & international regulations and guidance documents, including 21 CFR Part 11
- An overview of the computer system validation framework and each of its key deliverables, including the Validation Plan, IQ, OQ, PQ, Trace Matrix, and Validation Report
- An understanding of the basics of inspection-ready validation testing and documentation

## Testimonials from Past Students

"The instructor did an excellent job of making the class feel involving and applicable by referencing specific application to individuals in the class. I really appreciated that."

"The course was well-paced and presented in a friendly and professional manner. I would highly recommend the course."

"Made sense of many of the things we do routinely, but also brought to light areas we need to strengthen in our daily practices."

# INTRODUCTION TO COMPUTER SYSTEM VALIDATION

## Registration

**Single Student: $700**

**3 Students: $1,400**
*(Buy 2, Get one FREE)*

### Registration Cost Includes:

Course materials, Certificate of Completion

## Online Training

### Attend from the comfort of your home or office.

Our experienced computer system validation consultants have designed a concise, yet thorough course to equip you with the information you need to validate purchased applications.

A mixture of instructor lectures, activities, and real-world examples will keep you engaged. And, there will be plenty of opportunities to get answers to your company-specific questions.

**Professional Development Credits:**
6 hours/PDUs

**Continuing Education Units:** 0.6

You will need internet access, a phone and a PDF reader.

Register online at ValidationCenter.com

or by calling our office: **+1 847.295.7160**