



#### Directions:

From San Juan: Take the express way No. 22 to Arecibo. After the Vega Alta Toll take exit 32, keep right toward Vega Baja after four traffic lights you will see a bridge with a sign "Bienvenido a Vega Baja Ciudad del Naranja". After the next traffic light keep your right and turn right just before the next traffic light towards the Las Flores Avenue. Continue straight until you see PVSR which is the first industrial building at your right. The parking is behind the building.

From Arecibo: Take the express way No. 22 to San Juan. After the Manati Toll and take the Morovis Vega Baja Exit 42b and keep your right towards State Road No. 2. At Road No. 2 turn right. After five traffic lights do a U turn in the next traffic light keep your right and turn right just before the next traffic light towards the Las Flores Avenue. Continue straight until you see PVSR which is the first industrial building at your right. The parking is behind the building.

#### Materials:

You don't have to bring any materials to the courses everything will be provided to you.

#### Food & Beverages:

We will provide you with Coffee, refreshments and snacks but feel free to bring your own.

Sorry, no video or audio recorders!

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**COMPUTER  
SYSTEMS  
VALIDATION**



PVSR Corporation philosophy and management is based in the quality of our services and cost effective solutions. PVSR focus not only in validation solutions know but also on resources and training needs for the all areas of the Pharmaceutical, Biotechnology and Medical Devices industry.

# Computer Systems Validation

Tired of daily duties without challenges? Want a challenge that leads to further professional development? Want to learn about the professional tasks best paid in Puerto Rico? Want an opportunity in Validation? PVSR has your solution.



What you get is what you need:

- (1) Learn the latest and most useful information from active consultants in the Regulated Industry - you will learn the do's and don't to be successful, even interview and resume tips.
- (2) Small groups (18) - Courses are easier to follow, you will get the attention you need and your questions will be answered.
- (3) Advanced Active Learning Methods - You will view professional made PowerPoint presentations that include equipment, processes diagrams and images.
- (4) Experience group discussions and real industry validation applications and situations.
- (5) We will provide with a cGMP's booklet, Regulatory reference information & access to our reference documentation database.

The Computer System Validation (CSV) Course has a length of 8.5 hours on. An approximately 17 hours of direct contact.

Discussion Topics:

☀ 21 CFR Part 11 and Computer Systems Validation Overview:

- Development and Validation Activities
- Terminology, Acronyms and Definitions
- Maintaining a Validated State

☀ Process Control System Validation. Aspects covered:

- Validation Life Cycle Models
- Types of Process Control Systems
- Specification and Design
- Design Review
- Software Review
- Supplier Development & Acceptance Testing
- Instrument Inspection and Calibration

☀ Validation Planning activities

☀ Supplier Audit Validation Some topics to be covered are:

- When they are required?
- Types of Audits

☀ Risk Assessment Methodology

☀ Categories of Software and Hardware

☀ Design Review and Requirements for Traceability Matrix

☀ Guideline for Validation Reporting

☀ Guideline for Project Change Control, Configuration Management and Document management

- ☀ Sample Procedures for creation of
  - User Requirement Specification
  - Functional Specification
  - Hardware Design Specification
  - Software Design Specification

☀ Guidelines for Testing of an Automated System

☀ Guidelines for Periodic Review

☀ Guidelines for System Security

☀ Guideline for Record Retention Archiving and Retrieval

☀ Guideline for Backup and Recovery of Software and Data.

☀ Live Class examples and exercises

☀ General Methodology and Documentation Development Techniques

☀ Class Validation Testing and documentation exercises

☀ Interview and Resume Tips

## ONLY \$699

(Spaces are limited)

For latest Courses Schedule Dates visit our website at [www.pvsrwebsite.com](http://www.pvsrwebsite.com)  
Saturday Course (Two days) From 8:30AM TO 6:00PM

**Reservations:** You can reserve your space now (available 24 hours) in our Fully Automated Electronic Reservation and Payment System (all major Credit cards accepted) at our website [www.pvsrwebsite.com](http://www.pvsrwebsite.com)

FAX RESERVATION FORM ALSO PROVIDED AT WEBSITE (Fax reservations will be confirmed by phone)

## QUESTIONS?

E-mail:

[contactus@pvsrwebsite.com](mailto:contactus@pvsrwebsite.com)

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