



#### 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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## VALIDATION BASICS WORKSHOP



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.

# Validation Basic Workshop

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 Basic Workshop has a length of approximately 25 hours of direct contact and a total of 4 to 6 hours of home work.

Discussion Topics:

☀️ Current Good Manufacturing Practice (cGMP's) cGMP's definitions, history and impact in the Validation area focus in:

- Organization & Personnel
- Facilities
- Equipment
- Documentation

☀️ Good Documentation Practice Basic principles and guidelines for conducting a good documentation execution for compliance with regulatory requirements.

☀️ Validation Concepts Present an introduction of the components of the term "Validation" follow up with the definitions of these major concepts. Gave a taste of the history of validations based in the targets and seasoned with the regulatory requirements. Aspects covered:

- Validation Documentation
- Design Qualification (DQ)
- Commissioning
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Facilities, Equipments and Utilities
- Change Control and Re-Validation

☀️ Standard Operating Procedures Present the essential part of SOP's function and requirements related with validation activities.

☀️ Technical Writing for Validation Some topics to be covered are:

- What is a Validation Protocol?
- Regulatory requirements of the Validation Protocol

Protocol

- Validation Documents
- Protocol Contents
- Protocol Development
- IQ Documentation
- Engineering/ DQ Documentation
- Construction Documentation
- OQ Documentation
- PQ Documentation

☀️ Validation Master Plan Present definitions, contents, types and functions of Validation Master Plan

☀️ Equipment Qualification Delineate organized the most important aspects of:

- DQ
- IQ
- OQ
- PQ
- Re-Qualification

☀️ Process Validation Present the following topics:

- Product Attributes
- Process Parameters
- Process Control Parameters
- Technology Transfer
- Sampling
- Acceptance Criteria

☀️ Introduction to Statistical & Process Qualification

Computer and Control Systems Validations Some topics to be covered are:

- FDA's Definition & Regulatory Requirement
- Verification Techniques
- Validation vs. Verification
- CSV System Life Cycle
- CSV Risk Assessment
- General Methodology and Documentation

Development Techniques

☀️ Class Validation Testing and documentation exercises **ONE FULL DAY**

☀️ Interview and Resume Tips

## ONLY \$999

(Spaces are limited)

For latest Workshop Schedule Dates visit our website at [www.pvsrwebsite.com](http://www.pvsrwebsite.com)

Saturday Course (Two days) From 8:30 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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