PROCESS VALIDATION

Includes | WORKSHOP ACTIVITIES

- ☑ Understanding Process Parameters
- ☑ To what extent can process parameters be changed?
- ☑ Identifying which process parameters are critical
- ☑ How to set clear product specifications
- ☑ How is the sample size determined?
- ☑ How to document non-conformances during validation
- ☑ Common process validation mistakes

PROCESS VALIDATION

ABSTRACT, TWELVE (12) HOURS COURSE

The preparation and planning for manufacturing drug and biological products require developing and implementing an adequate control strategy. Understanding and implementing a process validation lifecycle for the manufacture of pharmaceutical products facilitates, not only the establishment of a robust control strategy, but also a risk management system to ensure the consistent quality of drug products.

Effective process validation is essential for ensuring pharmaceutical drugs quality as each drug produced should be fit for its intended use. Applying Quality by Design principles (QbD) and understanding and controlling the sources of process and product variation will facilitate maintaining processes in the commercial phase of the Validation Lifecycle in a state of control.

Participants will understand and apply the acquired knowledge during the collection and evaluation of data, from the process design stage through commercial production, establishing scientific evidence that a manufacturing process is capable of consistently delivering a quality product. Participants will also understand how the implementation of a quality system that incorporates risk management principles is the foundation for continual process and product improvement that supports business efficiency.

COURSE AGENDA
FIRST DAY:

- **Introduction to Process Validation (1 hour)**
  - Defining Process Validation
  - Significance of Process Validation
  - Process Validation: Common Misconceptions
  - FDA requirements and Guidance Document
  - International requirements and guidance

- **The Process Validation System (2 hours)**
  - Establishing the structure
  - Roles and responsibilities
  - Personnel qualifications and training
  - Process validation policies, procedures and plans
  - Facilities and equipment
  - Supplier and purchasing requirements
  - Do's and Don'ts: **Exercise session #1**

- **The Validation Lifecycle, PART I (3 hours)**
  - **Stage 1 – Process Design**
    - Building and Capturing Process Knowledge and Understanding
    - Establishing a Strategy for Process Control
  - **Stage 2 – Process Qualification**
    - Design of a Facility and Qualification of Utilities and Equipment
    - Process Performance Qualification (PPQ)
    - Concurrent Release of PPQ Batches

COURSE AGENDA
SECOND DAY:

- **The Validation Lifecycle, PART II (4 hours)**
  - **Stage 3 – Continued Process Verification**
    - Process Monitoring
    - Process Changes in Validation Documentation
    - Design Documentation
    - Policies
    - Validation Master Plan
    - Procedures
    - Protocols
    - Reports
  - **Exercise sessions #2 and 3:** Group discussions of the Process Validation Lifecycle - Stages 1, 2 & 3 and associated documentation

- **Common Process Validation Deficiencies and Precursors (2 hours)**
  - Design and development activities
  - Process Performance Qualification Studies
  - Trending, parameters and criteria of commercial processes
  - Handling non-conformances during the Process Validation Lifecycle
  - Assessing the status of existing processes based on commonly used quality indicators
  - Change control and monitoring activities
  - **Exercise session #4:** Group discussion: Areas of concern

WHO SHOULD ATTEND?

- QA/QC Directors, Managers and Supervisors
- Validation Scientists and Technical Operations
- Technical Development and Analytical Services
- Production and Contract Manufacturing

SPEAKER

Rebeca Rodríguez, ASQ CQE
Industry Advisor/President
Former FDA National Expert Investigator

Rebeca Rodríguez is an Industry Advisor and President of FDA Regulatory Compliance Advisors, Inc.™ She worked for **27 years** at the **Food and Drug Administration (FDA)** as Investigator.

For the last 13 years of her career Rebeca worked as a **National Expert Drug Investigator** reporting to FDA ORA Headquarters in Rockville, MD.

Ms. Rodríguez received her degree in Chemistry from the University of Puerto Rico, Río Piedras Campus. Ms. Rodríguez is certified by the ASQ (American Society for Quality) as a **Quality Engineer (CQE)** since 1991; as such, she has specialized knowledge in the principles and tools that have been used to support Quality by Design **(QbD)** and Statistical Process Control **(SPC)** in the regulated industry.

During her FDA career Ms. Rodríguez has accumulated expertise in areas such as **complex** biotechnology, drug and medical device **inspections,** both domestically and internationally. Her professional experience includes planning, conducting and directing highly technical, complex and **multi-faceted inspections** and in-depth investigations, including regulatory inspections and criminal investigations of **data integrity cases.**

Ms. Rodríguez was one of the **first four** ORA Investigators that were certified as members of the **PAT (Process Analytical Technologies)** Review and Inspection Team, and more recently was the S**enior ORA** representative to the **ETT** (Emerging Technologies Team).

Ms. Rodríguez was the leader of the team that conducted two of the first PAT pre-operational visits that resulted in the approval of the **first PAT Comparability Protocol** that proposed changes in the manufacture and control of both the active pharmaceutical ingredient (manufactured in Germany) and the drug product (manufactured in the US).

Ms. Rodríguez also **led** an **FDA/EMA** team on a foreign pre-approval inspection of a **QbD NDA** that identified and established a process control strategy using PAT, multivariate modeling, SPC and risk management tools. In addition, she led several FDA/EMA teams on **CM (Continuous Manufacturing)** pre-operational visits and pre-approval inspections. These team inspections used FDA's integrated approach that includes Reviewers and Compliance Officers on inspections. Ms. Rodríguez has also demonstrated her specialized knowledge and support of **FDA's QbD and PAT initiatives** by providing numerous presentations and frequent technical assistance to FDA personnel, Academia and Industry.

In July of 2004, Ms. Rodríguez was among the first to become certified as Level II Drug Investigator and as Level II Drug Investigator Certification Performance Auditor under the newly implemented Drug Certification program. She was also among **the first five Investigators** certified at **Level III (Pharmaceutical Inspectorate).** Ms. Rodríguez was an **Instructor in FDA training courses** such as Pharmaceutical Inspectorate, Process Validation, Basic Drug School, API (Active Pharmaceutical Ingredients) Manufacturing, International Inspections, Pre-Approval Inspections, Industrial Sterilization, and Computer-Aided Inspections. Since 2013, she was the **Lead Instructor** in one of the two main **Drug Investigator** Training Courses, DG 230. This 2-week course comprised Systematic Drug Inspection elements of drug manufacturing principles, Process Validation and inspectional/auditing techniques. Ms. Rodríguez was also responsible for providing on-the-job training to ORA Investigators and Analysts. CDER personnel also received on-the-job training from Ms. Rodríguez. In addition to training FDA staff, Ms. Rodríguez has regularly provided **drug GMP training** to Industry and regulatory bodies from foreign countries. Ms. Rodríguez has extensive experience providing advice and serving as liaison to international organizations such as WHO, regulated industries, other Federal agencies and executive managers within FDA.

Ms. Rodríguez work in the international arena included activities that supported FDA's leveraging efforts. For instance, Ms. Rodríguez was **ORA's field expert** working towards FDA's acceptance in **PIC/S (Pharmaceutical Inspection Convention Scheme).** Ms. Rodríguez also worked for three years with representatives of regulatory bodies from US, Canada and Latin American countries in drug GMP harmonization activities promoted by **PAHO/WHO.**

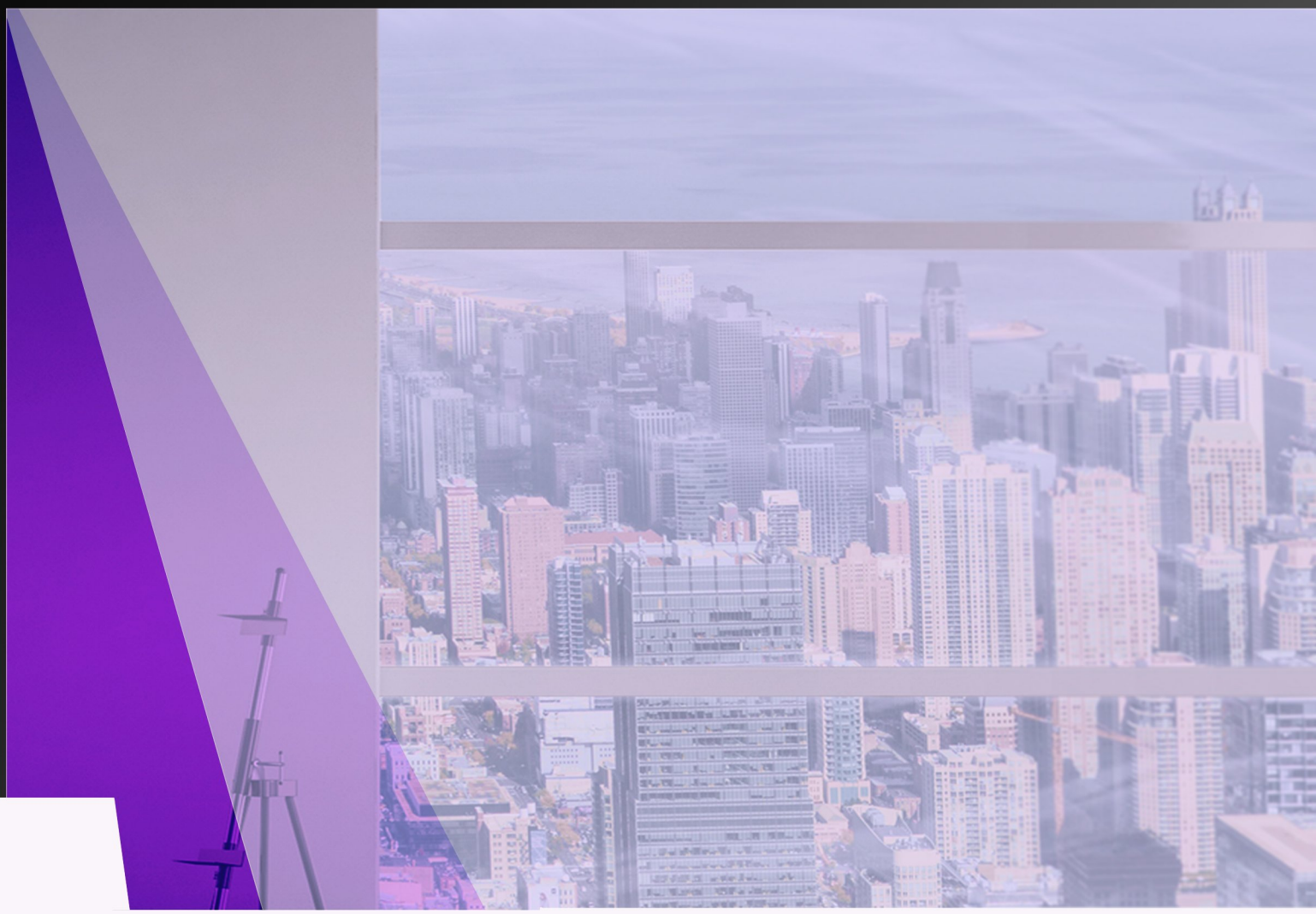
In June of 2004, Ms. Rodríguez was the only **ORA representative** in outreach meetings held in South Africa and India under **PEPFAR** (the President's Emergency Plan for AIDS Relief). This high-profile mission was assigned by the Department of Health and Human Services, and was led by the Assistant to the HHS Secretary. The US Embassies in both countries hosted the US HHS Team and participated in the meetings with local government authorities and drug manufacturers. Ms. Rodríguez' role in these meetings was to explain **FDA's inspectional process** to firm's interested in getting FDA's expedited approval for Anti-Retroviral drugs intended for the treatment of AIDS in the countries listed under PEPFAR.

During her FDA career Ms. Rodríguez regularly wrote and/or evaluated regulatory and policy documents, such as **Compliance Programs,** CDER's Q&A documents, and **Guidances to Industry** on OOS Investigations, PAT (Process Analytical Technologies), **Process Validation,** Contract Manufacturing, etc. In addition, she prepared and delivered briefings, technical and scientific papers, specialized and complex training, and official reports and decision memos. **Ms. Rodríguez** is the recipient of numerous prestigious awards for outstanding performance.

CONTACT US:

REQUEST FOR QUOTATION

ONLINE QUOTE REQUEST



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