



# ***FLEXX*<sup>™</sup> NETWORK**

## **VALIDATION SUPPORT & SERVICES**



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## **FLEXX™ NETWORK VALIDATION SUPPORT & SERVICES (FLEXX™-VSS)**

### **OVERVIEW**

Validation is a process of *Commissioning and Qualifying* a water system for the pharmaceutical industry and involves the integration of all design, installation, functional, and operational specifications associated with the system.

FLEXX™ Network Validation Support & Services (FLEXX™-VSS) have been developed to aid the Client in validation efforts of a Water Purification System. FLEXX™-VSS have been developed to support the Client throughout various phases of the validation process of the Water Purification System and facilitate the integration of the Water Purification System validation into the Client's Validation Master Plan. FLEXX™-VSS is flexible and offers numerous levels of expertise based on Client resources, requirements, demands and desires.

SOPs are provided with all PSC Water Purification Systems which are to be validated.

### **DESIGN DOCUMENTS**

The following documents are required prior to the manufacturing of Water Purification Systems to be validated by PSC:

- User Requirement Specification (URS)
- Functional Requirement Specification (FRS)
- Detailed Design Specification (DDS)
- Project Design Summary (PDS)

**URS    →    FRS    →    DDS    →    PDS**

#### **I. User Requirement Specification (URS)**

A URS is required and is typically developed by the Client to define the scope of the project. The URS shall specify the source of the Detailed Design Specification.

If a URS does not exist, PSC will provide one at an additional cost.

##### **PSC Prerequisites:**

- A. PSC User Requirement Worksheet completed by the Client.



## II. Functional Requirements Specification (FRS)

A FRS is required and is typically provided by the Client.

If a FRS does not exist and will not be provided by others, PSC will provide one at an additional cost.

### PSC Prerequisites:

- A. User Requirements Specification.

## III. Detailed Design Specification (DDS)

A DDS is supplied by Client's Specifying Engineer or Equipment Manufacturer.

PSC provides DDS on all Water Purification Systems for which it is the primary equipment manufacturer and system integrator.

## IV. Project Design Summary (PDS)

This document is prepared for all systems in which PSC is the primary manufacturer and is writing the Site Acceptance Test, Installation Operational Qualification and/or Performance Qualification Protocol(s).

The PDS summarizes project design and functional requirements "As Ordered" including site-specific conditions (i.e.: final water quality specifications, feedwater specifications, make-up water requirements) and equipment specific requirements (e.g.: description and summary of equipment provided) to be considered during the validation of the system. Additionally, the PDS helps define validation responsibilities and introduces the Client's Distribution Loop into consideration for a Client specific, comprehensive, validation plan.

- Changes in design after approval of PDS will be captured by Engineering Change Orders until approval of IOQ Protocol.

A **Commissioning Plan** is provided by PSC in conjunction with PDS to document completion of all start-up activities and Setpoint prior to field validation.

### PSC Prerequisites:

- A. User Requirement Specification.
- B. Detailed Design Specification or equivalent.
- C. Proposal to Client (**prices redacted**).
- D. Client Purchase Order to Vendor if other than PSC (**prices redacted**).



## **STANDARD OPERATING PROCEDURES (SOPs)**

Standard Operating Procedures (SOPs) provide the Client with procedures & verification, as necessary, that the validated Water Purification System is Operated, Monitored, Maintained, Cleaned/Sanitized & Calibrated per manufacturer/purchaser design specifications in a state of control as required by the FDA and/or other regulatory agencies.

SOPs will be provided by PSC and verified during Performance Qualification and a minimum of once annually thereafter. Approval, control and revisions to the SOPs are the responsibility of the Client.

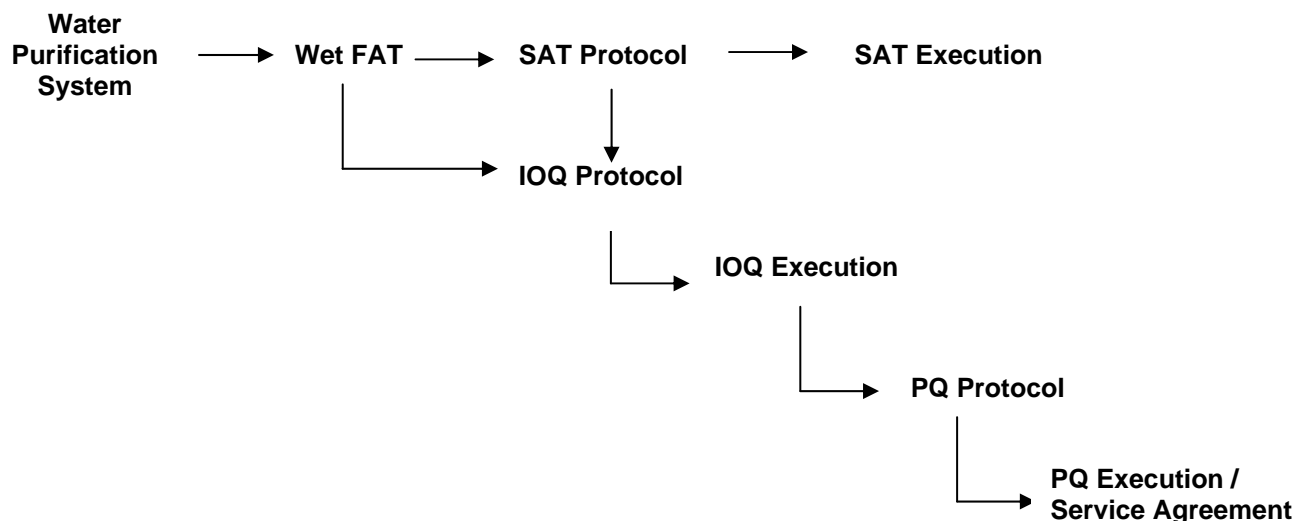
The following SOPs are provided by PSC for any validated Water Purification System:

- Operating Procedures
- Monitoring Procedures
- Maintenance Procedures
- Cleaning/Sanitization Procedures
- Calibration Procedures

## **STANDARD VALIDATION DOCUMENTS**

The following Protocols are required for any Water Purification System to be validated by PSC.

- Factory Acceptance Test
- *Site Acceptance Test (optional)*
- Installation Operational Qualification Protocol
- Performance Qualification Protocol





## **I. Factory Acceptance Test (FAT): Protocol and Execution**

A Wet FAT is offered and may or may not be witnessed by the Client at the Client's sole discretion. FAT for equipment manufactured by PSC will be performed in Tampa, Florida.

A FAT is verification of all System Drawings, Tagged Components, Control System Hardware/Software, Simulation of all Inputs/Outputs/Alarms, Operator Interface, and Sequence of Operations. The Pretreatment, Reverse Osmosis, Continuous Electro-Deionization (CEDI) and/or Distribution Skids are interconnected, water circulated, and functionally tested.

- Media is not loaded into the Pretreatment components.
- Storage Tank and some accessory components are not typically included in FAT.
- Exchange Carbon Filter units and/or Service Deionization units are not included.

### PSC Prerequisites:

- A. Must include Distribution Polish Skid and System Controls manufactured by PSC.
  - a. May include RO Skid manufactured by others.
- B. Project Design Summary and associated Prerequisites.

## **II. Site Acceptance Test (SAT): Protocol**

A SAT is offered only for equipment provided by and/or systems integrated by PSC.

A SAT is offered by PSC for Clients desiring an additional level of testing prior to initiation of an Installation Operational Qualification. The SAT protocol will be developed to verify that the equipment, having satisfactorily passed a Factory Acceptance Test, was shipped, configured and installed properly, and was not damaged in transit, delivery, or installation.

### PSC Prerequisites:

- A. Factory Acceptance Test and associated Prerequisites.

## **III. Site Acceptance Test (SAT): Execution**

SAT Execution is offered by PSC on SAT Protocols written by PSC or others.

SAT execution will verify: all System Drawings, Tagged Components, Control System Hardware/Software, all Inputs/Outputs/Alarms, Operator Interface, and Sequence of Operations. All calibration certifications will be reviewed for accuracy. All verifications to be performed on the system during the SAT will be performed on a fully installed, integrated, and operating system.



PSC Prerequisites:

- A. SAT Protocol approved by the Client.
- B. Protocol may be provided by PSC or others.
- C. Installation and Start-Up complete.
- D. Vendor Turn Over Package as described in PDS complete.

**IV. Installation and Operational Qualification (IOQ): Protocol**

IOQ Protocol is offered for equipment provided by PSC.

The Installation and Operational Qualification (IOQ) Protocol is to provide the Client with documented verification that equipment, controls, and software of the Water Purification System have been installed and operate per manufacturer/purchaser design specifications and that the Distribution Loop Points-of-Use have been properly identified and tagged.

The IOQ Protocol is a document that is custom written for a specific system, Client, and site. The document defines system requirements such as equipment specifications, water quality specifications, and specifications unique to the system and/or Client and provides the basis for verifying these specifications have been met.

See attachment I for typical PSC IOQ Protocol Table of Contents.

PSC Prerequisites:

- A. Project Design Summary and associated prerequisites.
- B. Factory Acceptance Test approved by the Client.

**V. Installation and Operational Qualification (IOQ): Execution**

Execution of IOQ Protocol is offered by PSC.

IOQ Execution is the "on-site" performance by the qualification team of all requirements established in the IOQ Protocol. PSC will provide a summary report of findings to the Client upon completion of all IOQ activities.

Protocol may be provided by PSC or others

PSC Prerequisites:

- A. IOQ Protocol approved by the Client.
- B. Protocol may be provided by PSC or others.
- C. Installation and Start-Up complete.
- D. Vendor Turn Over Package as described in PDS complete.



## **VI. Performance Qualification (PQ): Protocol**

A PQ Protocol is offered only on equipment provided by and/or system integrated by PSC.

The PQ Protocol integrates the Water Purification Equipment, the Distribution Loop, and the Points-of-Use into a comprehensive qualification package. Methods, responsibilities, procedures, and documentation to be utilized for the PQ are defined. PQ Phase I, Phase II and Phase III testing to be performed, points-of-use to be tested, and the methods of testing to be used are established. Acceptance Criteria for the parameters to be tested are identified and become the baseline for all-subsequent testing. Procedures for handling any deviations and avenues for resolution of these deviations are created.

See Attachment II for the Table of Contents of a standard PSC PQ Protocol.

### PSC Prerequisites:

- A. Factory Acceptance Test performed and approved by the Client.
- B. IOQ Protocol and Execution performed by PSC.

## **VII. Performance Qualification (PQ): Training and Support**

PQ Training and Execution Support are offered only on a PQ Protocol written by PSC.

PSC typically will provide minimum of 3 days on site to train Client in execution of PQ and train local service partner in execution of Service Agreement. PSC will also review PQ Phase I, PQ Phase II and PQ Phase III data (collected by the Client and/or service dealer) and provide PQ Phase I Summary Report and PQ Phase II Summary Report.

PQ Phase III Report will be limited in scope to verifying that Preventative Maintenance and Calibration schedules are sufficient to keep the system "in control" in view of seasonal variations. PQ Phase III report will be generated in conjunction with Annual Certification performed by service partner pursuant to Standard Operating Procedures.

### PSC Prerequisites:

- A. Approved PQ Protocol.





## ATTACHMENT I: IOQ PROTOCOL TABLE OF CONTENTS (*Sample*)

### IOQ Protocol Approvals

#### Section 1: Introduction

- 1.1 Purpose
- 1.2 Scope
- 1.3 Project Description
- 1.4 Project Team
- 1.5 Responsibilities
- 1.6 References
- 1.7 Execution Requirements
- 1.8 Codes and Abbreviations
- 1.9 Acceptance Criteria
- 1.10 Deviations
- 1.11 Basis of Design
- 1.12 Water Purification System Overview

#### Section 2: Documentation

- 2.1 System Specifications
- 2.2 System Drawings
- 2.3 System Certificates
- 2.4 System Calibration Certificates
- 2.5 Standard Operating Procedures
- 2.6 Major Component Manuals
- 2.7 Component Specifications

#### Section 3: Installation Qualification

- 3.1 System Documentation/Drawing Verification
- 3.2 SOP Verification
- 3.3 Utilities Verification
- 3.4 Components Verification
- 3.5 Piping/Fitting Materials Verification
- 3.6 Pressure Testing Verification
- 3.7 Control System Software Verification
- 3.8 PLC Input and Output Verification

#### Section 4: Operational Qualification

- 4.1 Loss of Power Verification
- 4.2 Sequence of Operations Verification
- 4.3 Operator Interface Verifications
- 4.4 Alarm Verifications
- 4.5 Recirculation & Supply Mode Verification
- 4.6 Maximum Daily Draw Verification

#### Section 5: Appendices

- Appendix A: Signature Log
- Appendix B: Test Instrumentation Calibration List
- Appendix C: Deviations
- Appendix D: Documentation
- Appendix E: IOQ Attachments



## **ATTACHMENT II: PQ PROTOCOL TABLE OF CONTENTS (Sample)**

### PQ Protocol Approvals

#### Section 1: Introduction

- 1.1 Purpose
- 1.2 Scope
- 1.3 Project Description
- 1.4 Project Team
- 1.5 Responsibilities
- 1.6 References
- 1.7 Execution Requirements
- 1.8 Codes and Abbreviations
- 1.9 Acceptance Criteria
- 1.10 Deviations
- 1.11 Basis of Design
- 1.12 Water Purification System Overview

#### Section 2: Documentation

- 2.1 Performance Qualification Overview
- 2.2 Documentation
- 2.3 Critical Testing
- 2.4 FIO Testing

#### Section 3: Appendices

- Appendix A: Signature Log
- Appendix B: Test Instrumentation Calibration List
- Appendix C: Deviations
- Appendix D: Documentation
- Appendix E: PQ Chart
- Appendix F: PQ Calendar

#### Section 4: Attachments

- Attachment A: PQTD Critical Testing Worksheets
- Attachment B: PQTD FIO Testing Worksheets