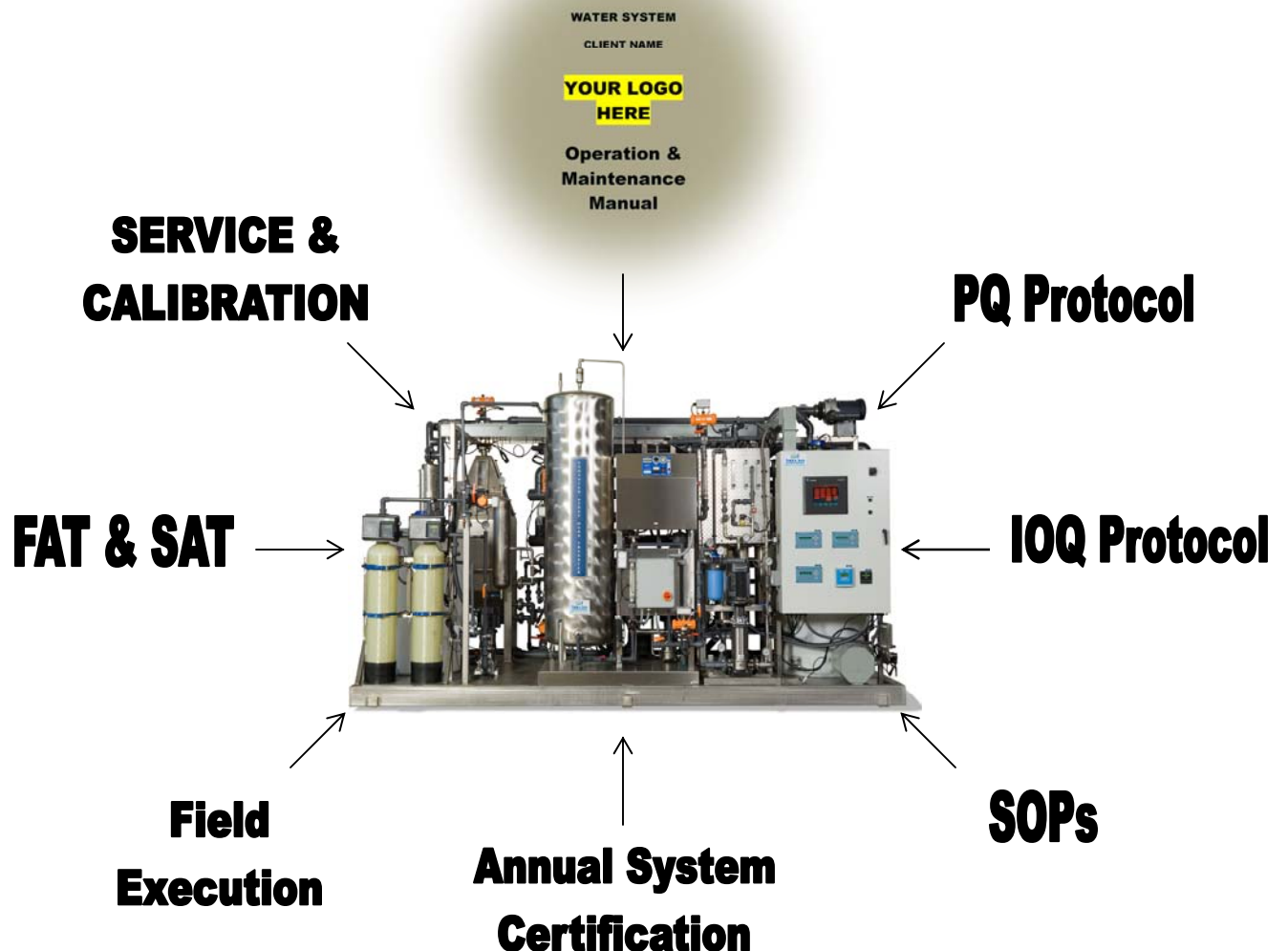**F**LEXIBILITY

LATITUDE

ENGINEERING

e**X**ECUTION

e**X**CELLENCE

*Process Water Systems designed with ultimate **FLEXXIBILITY** in mind.*

Comprehensive Validation Documentation & Field Execution by a group in the systems business.

WATER SYSTEM

CLIENT NAME

YOUR LOGO HERE

Operation & Maintenance Manual

SERVICE & CALIBRATION

PQ Protocol

FAT & SAT

IOQ Protocol

Field Execution
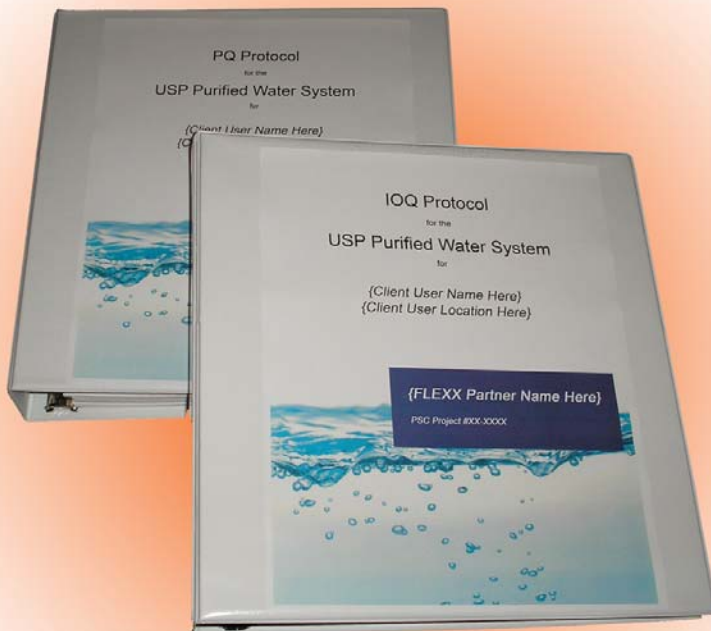
Annual System Certification

SOPs

FLEXX Network Validation Support & Services (FLEXX-V*SS*) have been developed to aid the Client in the validation process of Water Purification System, and incorporation into the Client's Validation Master Plan. FLEXX-V*SS* is flexible and offers numerous levels of expertise based on Client resources, requirements, demands and desires.

We assure that Client expectations of our Documentation & Services are consistent with industry standards:

- Validation Practices based on ISPE Baseline Series Guidelines, GAMP 5, FDA CFR.
- Validation Practices outlined in detail and defined in the FLEXX Network VSS document.

PSC VALIDATION SUPPORT ENCOMPASSES A VARIETY OF DISCIPLINES:

Compliance with Regulations thru Commissioning & Qualification:

⇒ Mechanical Engineering

⇒ Electrical Engineering & Programming

⇒ Documentation & Drawings

⇒ Field Execution

⇒ Certification Reports

DOCUMENTATION DESCRIPTION:

- Factory Acceptance Test (FAT) written & performed at manufacturing Facility.
- Site Acceptance Test (SAT) written & performed On-Site at Client's location.
- Installation & Operational Qualification (IOQ) Protocol.
  - ⇒ Execution of IOQ Protocol proves system was installed & operates as designed.
- Performance Qualification (PQ) Protocol.
  - ⇒ Execution of PQ Protocol proves system design provides water quality demanded by Client.
- Standard Operating Procedures (SOPs).
  - ⇒ Allows Client to Operate, Maintain & Monitor the system effectively to ensure water quality is consistent.
- Annual Certification & Qualification Reports.
  - ⇒ Execution of PQ Protocol proves system design provides water quality demanded by Client.
- Ability to provide a variety Design Documentation (such as URS, FDS, DDS, PDS).

EXECUTION DESCRIPTION:

PSC performs on-site visits to assist in Validation Activities on a global scale. PSC approaches each job with flexibility, adjusting to meet individual Client's schedule & demands. Problems encountered in the Validation process are quickly resolved; PSC has a versatile staff ready if engineering or programming changes are required to satisfy the Client's expectations at any stage of Validation/Qualification.