

COMPLIANCE & VALIDATION



IPS PROFILE

- Full range of consulting, engineering, design review and commissioning services
- Focused on high performance, technically complex facilities
- Strong Customer Base with Repeat Business
- Senior Experience with C&Q Risk-Based Approach
- Owned / Managed by industry-trained professionals
- Projects in 33+ states; Project Range \$1,000-\$17,000,000
- Founded in 1989; 18 year Proven Track Record
- 300+ Employees including:
 - Commissioning & Qualification Specialists - 85

COMPLIANCE/VALIDATION SERVICES

- Qualification and Validation
- Commissioning and Start-up
- Impact Assessments and Master Planning
- Construction & Design Interface/Review
- Equipment Selection
- Project Management
- Quality System Implementation
- Calibration System Consulting
- Audits
 - Quality System
 - FDA-Style
 - cGMP
- Remediation of FDA Form 483s / Warnings
- Validation and cGMP Training
- Process and Cleaning Validation
- Automation and Computer Systems Validation
- Full Service Commissioning
- Document Development / Management
 - Specification / SOP Preparation
 - Site / Project Document Control
 - Custom Protocols
 - Factory / Site Acceptance Tests

IPS VALUE

ACCELERATE

the Start-up Effort

REDUCE

Change Orders and Construction Costs

PRODUCE

Superior Documentation

ENSURE Design

Compliant Facility

IMPROVE

On-Line Time

IMPROVE

Energy Efficiency

INCREASE

Maintainability and Reliability

Our engineers have numerous years of experience in the design, operation, commissioning and validation of various types of high performance facilities.



Chuck Stock, CxA

Chuck has over 25 years of validation and operations experience for high performance, technically complex facilities.



Eric Zydel

Eric has over 15 years of validation experience with bulk drug manufacturing, aseptic processing, solid dosage manufacturing and packaging utility systems and equipment.



Vince Cebular

Vince has over 16 years of validation experience for high performance, technically complex facilities.



Jay Cantwell

Jay has over 30 years of validation experience in the pharmaceutical biotechnology and medical device industries, including manufacturing, product introduction, and facility startup.



Aaron Weinstein

Aaron has over 9 years of validation experience in the areas of Biopharmaceutical and API manufacturing, including facility, utility and process equipment validation.



Steve Wisniewski

Steve has over 30 years of experience in the design, construction, commissioning, and validation for compliant projects. Steve is a subject matter expert in the latest commissioning and qualification techniques supported by ISPE and the FDA.