

Meet the Expert



Aaron Weinstein possesses almost two decades of leadership and management experience in commissioning, qualification and validation of pharmaceutical, biopharmaceutical, laboratory and vivarium facilities, utilities and equipment.

Aaron's experience includes the development and implementation of both short and long-term commissioning, qualification and validation programs for projects ranging upwards of \$250MM. Aaron has provided technical and compliance consulting, CQV project planning and execution strategies (development of validation master plans, manpower estimates, schedules), developed and implemented computer systems validation programs, cGMP audits and Part 11 assessments for a number of US and multi-national companies around the world.

Throughout his career, Aaron has directed activities for capital projects including the specification, installation, commissioning and qualification of equipment, critical utilities systems and processes related to cGMP manufacturing. His facilities experience includes manufacturing areas, processing areas, data centers, stability areas, cleanrooms, clinical packaging areas, laboratories, warehouses, utilities and critical utilities, offices and cafeterias for facilities that utilize biotechnology, API, OSD, advanced aseptic and medical device manufacturing processes.

Aaron's broad range of practice includes software assessment, validation training and quality review of documentation. He has significant experience in auditing validation programs and facilities for compliance with FDA, EU and corporate requirements and the writing and execution of CQV documents for equipment and control systems.

At IPS, Aaron holds a leadership role as the Senior Director of Validation. His responsibilities include client development and management, project management, and departmental leadership. He leverages his insight and technical knowledge of operations, validation and quality systems to help achieve clients' project goals and strategic business objectives.

Aaron is a member of ISPE and the NJ Chapter COP for Commissioning & Qualification. He is a frequent presenter at industry events and recently gave two presentations at the 2014 ISPE Annual Meeting, Las Vegas, NV:

- "Calculating Odds of Success: A Workshop on Project Management (Making a Remediation Project Work: Knowing How to Beat the Odds)"
- "Don't Gamble Your Project Away: Real World Lessons of Project Management Top Ten Lessons Learned: A Study in Project Management (A Strategy for Remediation Under Consent Decree: Management, Project Controls and Deliverables Related To These Challenging Projects)"

Aaron Weinstein Validation Expert

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Areas of Expertise

- CQV Planning and Management of Large Scale Projects
- CQV Activities Related to Biotechnology Facilities, Utilities and Equipment
- Computer System Validation for ERP Systems