



COMPANY	Compliance Apex Inc.
BUSINESS OPERATING NAME	Compliance Associates
JOB TITLE	Senior Validation Consultant
REFERENCE #	#25-01 SVC
BUSINESS ADDRESS	5160 Explorer Drive. Unit 31 Mississauga, Ontario Canada L4W 4T7
WORK LOCATION	5160 Explorer Drive. Unit 31 Mississauga, Ontario Canada L4W 4T7 (Hybrid work model is available)
STATUS	One (1) Temporary Full-Time position for up to one (1) year
LANGUAGE OF WORK	English
WAGE	Between \$70, 000 - \$80, 000 per year
JOB POSTING DATE	January 6, 2025
JOB CLOSING DATE	February 7, 2025

About Us

We are a software and services company and our clients are primarily but not limited to the Pharmaceutical, Medical device, and Cannabis industry. We offer validation services as well as the sale and implementation of our in-house software Validator, a tool for automation in Compliance. With nearly 20 years in operation, we pride ourselves in always providing excellent, professional, and knowledgeable consultants for each of our clients. We offer a competitive compensation package with benefits .

Purpose

We are seeking a Senior Validation Consultant to become an integral part of our team! You will service domestic and international clients, as well as support in-house software.

Position duties and Responsibilities:

- Knowledge in qualification and validation activities for computer systems and IT infrastructure.
- Experience working with Laboratory Information Management Systems (LIMS), Lab Execution Systems (LES) and Manufacturing Execution Systems (MES).
- Experience in installation and validation of chromatographic instruments and related software systems, and general pharmaceutical quality control and R&D laboratory instrumentation/equipment such as Dissolution systems, DSCs, and Balances.
- Know how in software implementation, computer system validation, equipment qualification etc. in regulated cGMP/GxP environments.
- Experience working in GxP regulated Environments.
- Good understanding of GxP and regulatory Data Integrity requirements (ALCOA+), as well as understanding of Pharmaceutical Data risk assessment (as related to Quality Assurance, and Quality Control and Product release).

- Good understanding of GAMP, FDA, ICH and other relevant regulatory requirements in the MedTech and Pharma industries. Specifically, knowledge of 21 CFR parts 11, 210, 211, 600, 610, and 1271 along with associated best practices (e.g. ISPE GAMP) for CSV qualifications.
- Understanding of Change Control and Quality Documentation in the MedTech and Pharma Industries.
- Understanding of CSV and IT infrastructure qualification and validation activities and deliverables (e.g. VPPs, RAs, IQs, OQs, PQs, VSs, RTM, etc.)
- Able to write Validation Project Plans (VPP), IQ, OQ, PQ protocols, and Validation Summary Reports (VSRs).
- Experience in System Development Life Cycle (SDLC)
- Working knowledge of corporate Quality Management Systems, current Good Manufacturing Practices (compucGMP), and Good Clinical Practice (GCP)

Job Qualifications:

- Graduate degree in Computer Science, Engineering, Information Systems, or related technical field or 10+ years direct, relevant CSV experience in MedTech or Pharmaceutical Quality Control and/or R&D.
- Strong computer, scientific, and organizational skills
- Strong root-cause analysis skills
- Deadline and detail-oriented • Knowledge of 21 CFR Part 11 requirements and data integrity • Knowledge of risk-based Change Management and Quality Management systems.
- Strong communication skills.
- Must be able to travel within north America and abroad.
- Knowledge of 21 CFR Part 11 requirements and data integrity
- Knowledge of risk-based Change Management and Quality Management systems.

How to apply:

- Please submit your resume to careers@complianceassociates.ca

Only those selected to move forward in the recruitment process will be contacted. Please contact 1-877-488-2559 or email: careers@complianceassociates.ca for further information. Our mailing address is: 5160 Explorer Drive Unit 31 Mississauga Ontario L4W 4T7.

Compliance Associates is an equal opportunity employer and welcomes applications from all interested parties. If for any reason you require accommodation throughout the recruitment process, accommodation will be provided upon request in accordance with the Accessibility for Ontarians with Disabilities Act, 2005, to applicants with differing abilities.