Life Sciences Consultant

consulting@dayspringtechnology.cc
www.dayspringtechnology.cc

Who Are You?

You're a consultant with a blend of technical and business expertise in the life sciences. You understand how your skills support regulated business processes and the science your skills support. You write well and often. You always look for improvement. You have exceptional people skills. Your background in IT business or functional analysis, Quality Assurance, Regulatory, Computer System Validation (CSV), or GAMP5 is an asset.

You'll need to work autonomously in a remote office and adapt quickly and professionally to our customers' expectations. Various arrangements exist regarding travel; all consultants can expect to travel balanced with applicable COVID-19 protocols. Dayspring prefers COVID-19 vaccinated candidates.

Who Are We?

Dayspring Technology, Inc. is committed to providing valuable, expert consulting services to the Life Sciences industry. We provide process expertise, technology implementation, computer systems validation, and business enablement consulting to our customers. Our advantage is our depth and breadth of knowledge in the life sciences, and our ability to see and improve the processes behind the technology.

Our people are experts at reducing the cost and struggle normally associated with doing business in regulated industries. Our breadth of experience and inability to sit still when we spot inefficiencies translate to time and overhead savings for our customers. We are diligent project managers, efficient business analysts, detail-oriented validation experts, creative problem solvers, clever metrologists, and what-if visionaries. Above all, we deliver results.

We are a small organization with a very flexible work environment. We offer retirement benefits after a vetting period.

What Do We Need?

We're looking for a minimum of 2 years experience working with technology solutions and regulated business processes in a life sciences environment such as clinical trials, manufacturing, medical devices, pharmaceuticals, or biotechnology.

Skills we're seeking:

- Strong project management and self-awareness skills are essential.
- Experience with risk-based systems validation to meet FDA regulations, including developing user requirements, system specifications, test plans, test scripts, and SOPs is essential.
- A background in FDA or EU life sciences regulations, including Data Integrity, 21 CFR Part 11 and cGxP systems. Experience with clinical trials or HIPAA is essential.
- Experience with software quality improvement and life-cycle deliverables (SDLC) is useful.
- Experience working under or implementing controls for ISO 9001, 14001, 27001 standards is useful.
- Knowledge of any of the following is useful: manufacturing automation software, ERP, laboratory informatics, eQMS or document management software.
- Regulatory filing experience or manufacturing automation experience very interesting.