



Engagement Summary: ISO 9001 Quality Management System

A leading software-as-a-service provider of document management solutions to the Life Sciences and other regulated industries engaged Northfield to assist with the implementation of a Quality Management System (QMS). The company's goal was to implement a QMS meeting industry standards in departments impacting product, product delivery and service to clients. In addition to meeting immediate company and client needs, our client wanted to set the stage for ISO 9001 certification.

Northfield Associates LLC deployed a focused team with in-depth expertise in QMS, ISO 9001, Life Sciences, project management, risk management and complex implementation planning to specifically address the client's initiative. Operating in both coaching/advisory capacities and in hands-on roles, Northfield worked collaboratively as an integral part of a much larger team comprising client and representatives from other technology partners. Our key roles included assessment of compliance with industry standards, validation and implementation of an e-signature system and coaching client subject matter specialists in the update/development of controlled documents as well as all support functions including training, training compliance, communications and change management for the following departments:

- Client Services (client implementation)
- Global Services (support service call center)
- Product Engineering (software development)
- Quality Assurance
- HR/Training

The Northfield team demonstrated the capability and flexibility to seamlessly transfer from coaching/training to hands-on execution as dictated by client needs. We brought an implementation focus using a time-boxed approach to enable the client to meet aggressive target dates and build QMS expertise among client teams while supporting the implementation. Work products and deliverables included:

- Overall QMS Roadmap
- QMS Implementation Model and Toolkit
- Detailed, department-specific Readiness Assessments and Implementation Plans
- Training Courses and Training Compliance Reports
- QMS Internal Audit Pilot
- Management Review Process
- Risk Management Assessment and Mitigation
- Deployment and management of 21 mixed teams (client, partner and consultant)

Together with the corporate and department client team members and technology partners, Northfield customized and executed the QMS Implementation Model and Toolkit enabling a new quality baseline directly aligned with ISO 9001 certification standards. Certification readiness was confirmed through the new internal audit and external Life Sciences client audits.

Northfield Associates LLC is a consulting firm specializing in the design, development and implementation of strategies and performance improvement programs, with special expertise in healthcare and health-related industries, serving clients from start-ups to Fortune 50 companies on engagements that range from tactical process improvements to strategic, enterprise-wide programs. Contact: (802) 496-7815 or info@northfieldassoc.com.