Biotechnology Firm Meets ISO 9001 Requirements Using Intelex Quality Management Software

> "The Intelex QMS and their top-notch customer support have helped us build superefficient and extremely effective Quality System processes to help our organization move forward at a faster pace. Intelex has taken our questions and concerns to heart andhelped customize systems that work for us.

Jason Usilton
Quality Supervisor
SDI

Challenge

- Wanted to be IS0 9001 compliant to facilitate the possibility of certification in the future.
- Needed to implement a Quality Management system, involving approximately 150 users, to stabilize the company's business processes.
- Needed to replace paper-based processes and eliminate inefficiencies when creating and distributing relevant documentation.
- Required a system that would ensure criteria is met regarding acceptable documentation by the FDA (CFR part 11).
- Wanted a system that could support the reorganization of the company and its evolving needs.

Solution

- Implemented Intelex's Quality Management system.
- Special focus on Document Control (loaded over 3,000 documents to date).
- Extensive ongoing support including responsive and knowledgeable client services representatives, free onlinerefresher training courses and convenient online resource library.
- Tailored on-site training provided full access users with the necessary skills to meet the needs of the organization's implementation objectives and effectively train lower level users.
- Currently rolling out nonconformance management, audits management and communication tracking to support the ongoing restructuring initiatives of the organization.

Results

- Achieved compliance with ISO 9001 regulations.
- The Quality Management system has successfully stabilized the company's business processes Ability to centrally maintain and retrieve documentation according to restructured company policy.
- Document Control system effectively enabling compliance with FDA regulations (CFR part 11) regarding electronic records and signatures.
- Confident in the implementation of nonconformance management, audits management and communication tracking to meet the developing needs of the company

Learn about how Intelex solutions can help your organization

🖥 **REQUEST A DEMO**
1 877 932 3747 | intelex.com