Xcellas

Regulatory Compliance, Governance & Project Management Solutions

We are a professional consulting firm providing a full range of services from consulting assessment and requirements through project management solution strategies, implementation and optimization.

Xcellas provides lean alignment between business, engineering, quality, IT, tech services and manufacturing while maintaining overall governance and regulatory compliance.

Xcellas is a minority owned business and we pride ourselves to be small enough to provide the upmost attention to our clients as well as to scale up to any demands of our clients without sacrificing the quality and experience of our team members to lead successful implementations.

Governance, Regulatory & Compliance Services

- Quality Management
- 483/Consent Decree Remediation
- Periodic Equipment/System & Facilities Reviews
- Validation Master Plans
- Gap/Risk Analysis and Assessment
- Equipment, Facilities/Utilities Decommissioning
- Test Methods Validation, Cleaning Validation, Computer System Validation, Process Validation
- Qualification of Lab Equipment/ Instrument/System

Advisory Services

- Business Case, and ROI
- Program/Project Strategy Roadmaps
- PMO Maturity Assessment
- Organizational Change Management
- Process Mapping & Optimization
- Lean Six Sigma
- Facilities & Utilities Commissioning and Qualification

Engineering Services

- Lean Program Execution
- Commissioning New Manufacturing, Business and Laboratory Facilities
- Program & Project Management
- Construction Management
- Engineering & GxP Capital Project
- Developing and Testing New Product Lines
- Technology Transfers
- Quality Engineering

IT Solutions

- Application Portfolio Rationalization
- Enterprise Information Management
- Enterprise Portfolio Management
- Information Governance
- Application Development and Integration

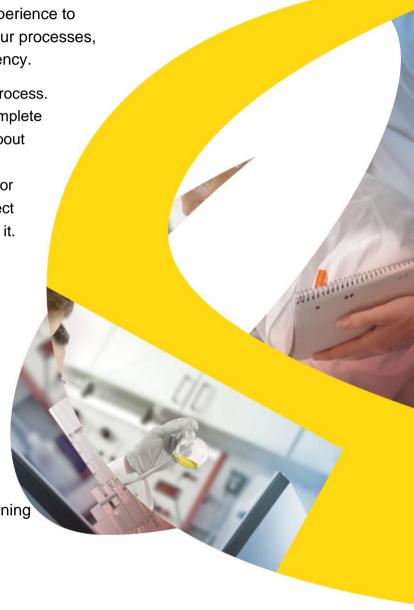# Governance, Regulatory & Compliance Services

Xcellas

When you're working in a tightly-regulated industry, compliance should come first. You must ensure that the necessary processes are in place to stay compliant, while maintaining operational output. Our team of experts has the necessary experience to make sure compliance is integrated throughout your processes, eliminating costly risks and maximizing your efficiency.

We offer services for every step of the compliance process. We're able to provide quality management and a complete gap analysis to help you make strategic decisions about compliance. If you've had, or are experiencing a compliance issue, we provide remediation services for 483s, and consent decrees. When a regulatory project overwhelms you, we can step in to help you salvage it.

Governance, Regulatory & Compliance Services

- Quality Management
- 483s and Consent Decree Remediation
- Periodic System and Facilities Reviews
- Validation Master Plans
- Gap Analysis
- Technology Transfers
- Equipment and Facilities/Utilities Decommissioning
- Test Methods Validation
- Cleaning Validation
- Computer System Validation
- Process Validation

GOVERNANCE, REGULATORY & COMPLIANCE SERVICES • ADVISORY SERVICES • ENGINEERING SERVICES • IT SOLUTIONS

Advisory Services

Xcellas

Sometimes you just need a fresh perspective. At Xcellas, we're happy to lend you our expertise with a wide variety of advisory services. We'll work with you to give you a new way of looking at your business, making you more productive, helping you perform better, and enabling you to grow.

Xcellas can provide help at any stage of the process – right when you need it. If you're just starting off, we can help you with strategy and business case planning. If you're looking to grow, we can help you with process mapping and change management. If you're just looking to find better ways to do business, we can help with ROI assessment and implementing Six Sigma. If your project needs extra help and attention, Xcellas is the company to call.

Advisory Services

- Business Case
- ROI
- Program/Project Strategy Roadmaps
- PMO Maturity Assessment
- Organizational Change Management
- Process Mapping and Optimization
- Lean Six Sigma
- Quality Engineering
- Facilities and Utilities Commissioning and Qualification

Engineering Services

Xcellas

We're proud to provide our clients with a unique set of engineering services designed to improve your entire engineering process – from initiation and planning to execution, control and closeout. Our team of certified Project Management Professionals (PMP) has the necessary experience to keep engineering costs down without sacrificing quality. Xcellas' engineers are expert at commissioning, qualification and verification/validation (CQV). Our team of experts has the ability to generate and execute quality documents for a wide variety of facilities and processes.

Engineering projects can quickly grow out of control. At Xcellas, we're able to prevent that mishap from happening. We work side by side with your company, leveraging our decades of experience and proven processes, and weaving them into your own. This approach results in new and improved lean engineering processes, which are tailored specifically to your organization's strengths and business needs. Xcellas' professionals are able and ready to swiftly step in to pull through and salvage a project that may need extra care during any phase of the project.

Engineering Services

- Lean Program Execution
- Commissioning New Manufacturing, Business and Laboratory Facilities
- Equipment/System Qualification
- Equipment/System Verification/ Validation
- Program and Project Management
- Construction Management
- Engineering and GxP Capital Projects
- Developing and Testing New Product Lines

IT Solutions

Xcellas

In today's business environment, technology is more than just a tool. It's not enough to have IT systems in place that simply allow you to get your work done. You need complete IT solutions that are chosen strategically to enhance your critical processes and provide a competitive advantage. Most of all, you need to make sure that your critical systems are given the attention and care they deserve.

At Xcellas, we understand exactly how important IT solutions are. Our team of experts will work with you to ensure that you have the right processes, strategies and technologies in place. We're able to help you transfer between systems, manage your technology, and develop your own systems and protocols.

IT Solutions

- Application Portfolio Rationalization
- Enterprise Information Management
- Enterprise Portfolio Management
- Information Governance
- Technology Transfers
- Application Development and Integration
- IT System Validation