

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 utmost 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.

DUNS: 059532258

CAGE: 7GES5

NAICS CODES:

- 541511: Custom Computer Programming Services.
- 541519: Other Computer Related Services
- 541611: Administrative Management and General Management Consulting Services.
- 541613: Marketing Consulting Services
- 541614: Process, Physical Distribution and Logistics Consulting Services.
- 541618: Other Management Consulting Services.
- 541690: Other Scientific and Technical Consulting Services.
- 541990: All Other Professional, Scientific, and Technical Services.

CONTACT INFORMATION

275 Dilworth Lane,
Langhorne, PA 19047
Tel: 215.287-9488
WWW.XCELLAS.COM
Maria T. Alvarez - CEO
maria.alvarez@xcellas.com

CAPABILITIES

EXPERTS IN:

- **Governance, Regulatory & Compliance Services**

Services for every step of the compliance process. Quality management and a complete gap analysis to help you make strategic decisions about compliance. Services for 483s, and consent decrees. When a regulatory project overwhelms you, we can step in to help you salvage it.

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

- **Advisory Services**

Wide variety of advisory services making you more productive, helping you perform better, and enabling you to grow at any stage of the process. Help with ROI assessment and implementing Six Sigma.

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

- **Engineering Services**

Provide our clients a unique set of engineering services designed to improve your entire engineering process Xcellas' engineers are expert at commissioning, qualification and verification/validation (CQV). Quality documents for a wide variety of facilities and processes.

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





PAST PERFORMANCE

- MERCK
- NOVARTIS
- EMSCO SCIENTIFIC ENTERPRISES, Inc
- GENERAL ELECTRIC
- TEVA
- ALPHARMA
- ALLERGAN
- ACTAVIS

• IT Solutions

Experts will ensure that you have the right processes, strategies and technologies in place. Help transfer between systems, manage technology, and develop your own systems and protocols.

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

• Procurement Services

- 3rd Party Vendor Assessments
- Supply Chain
- Periodic System and Facilities Reviews
- Contract Lifecycle Management
- Technology Transfers
- Process and Test Methods Validation
- Assessment/Gap Analysis

• Revenue Management

- Government (GP)
- Medicaid
- Contracts Management
- Sunshine Act Compliance
- Best Price

PRODUCTS

- Unique State of The Arti Healthcare Innovation and Pharma Solution Tool
- Claims Reimbursement Real-Time Eligibility Tool for Patients and Payors
- Credentialing Tool
- Pricing Analytics Tool

DIFFERENTIATORS

- Our niche is in the Life Sciences Industry including: Pharmaceutical, Biotechnology, Universities, Hospitals, Medical Device and Diagnostic, Consumer Products and Veterinary.
- Experienced professional use interviews, documentation reviews and observations to conduct comprehensive service audits for our business partners
- Establishes a set of directions with adequate element to tell the project team precisely what must be done, when it must be done and what resources to use for a successful project.
- Once we have partners buy-in, we execute and manage the implementation process from start to finish working hand-in-hand with our business partners
- Monitors Key Performance Indicators as established in the project plan, using engineering and Lean Six Sigma tools to adjust strategies as needed.