Digital Quality & Compliance

astrix

Digital Quality & Compliance Services - Overview

Astrix's Digital Quality and Compliance service offerings cover key strategic, technical, and operational areas of your organization to optimize efficiencies and reduce regulatory and compliance risk. In partnership with you, our group of industry experts provide a nimble approach to overcoming your quality challenges. We bring our insights, best practices, and solution delivery across product and process lifecycle to ensure your compliance needs are met.
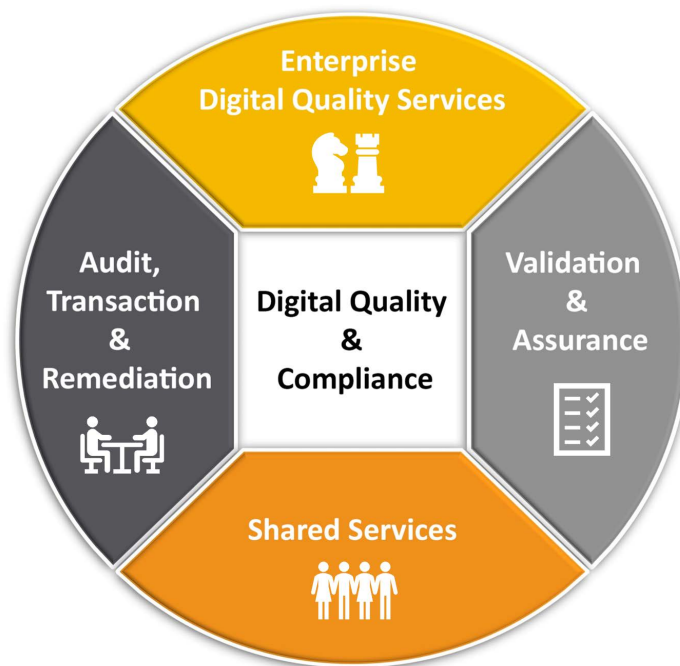
Audit, Transaction & Remediation

- Supplier / Vendor Quality Management
- Systems Periodic Reviews / Audits
- Audit Planning & Execution
- Regulatory Response & Remediation
- Transaction Services

Enterprise Digital Quality Services

- Strategy & Roadmap
- Framework & Operating Model
- Assessment & Technology Transformation
- QMS Implementation
- Analytics

Shared Services

- QMS Managed Services
- QMS Outsourcing
- Validation as a Service

Validation & Assurance

- Product / Application Validation
- Product Qualification
- Digital Validation

Organizations are pushing the boundaries of science and innovation in order to develop new products. Technology within the organization, including Quality, needs to transition from a digital transformation being a strategic initiative to a strategic imperative.

Quality organizations recognize the need to transform, however, their evolution has been encumbered by:
• a lack of willingness to embrace new capabilities
• disparate and fragmented traditional quality systems
• deficient data and governance methodologies and frameworks
• a lack of alignment across highly siloed organizational constructs

Organizations will need to evaluate their current quality systems strategy and take bold steps to align with digital quality for a future that will make them mature and robust. Our EDQS services help your Quality and compliance organization with an end-to-end digital quality strategy. We help you realize your digital quality strategy by implementing "fit for purpose" and practical quality management ecosystems. This assists you in meeting your objectives relative to customer satisfaction, providing continuous improvement, and influencing a positive "culture of quality". Our industry experts can help modernize your quality systems and unlock their value and potential by defining a strategy and through implementation support. We aim to deliver a digital, data driven, and fully seamless experience to our clients.

Strategy & Roadmap

• Quality Vision & Strategy

Benefit
• Identify key business levers that will enable compliance and drive innovation

QMS Implementation

• QMS Implementation

Benefit
• Maximize your business value through enablement of leading Digital Quality technologies

Assessment & Technology Transformation

• Quality Integration Strategy
• QMS Integration
• QMS Assessment & Transformation Strategy
• Quality Automation

Benefit
• Optimize business processes to improve operational efficiency, time to market and ROI

Framework & Operating Model

• Framework & Operating Model Design

Benefit
• Identify and optimize your ability to create and deliver value

Analytics

• Quality Analytics Strategy
• Quality Analytics Implementation

Benefit
• Identify and analyze key business performance indicators that will enable continuous improvement

Quality and Compliance Capabilities for Every Quality Situation

When you choose to work with us, you'll be working with an advisor that is well-prepared to provide a consistent level of service. Here's a look at how we help clients in each quality situation.

Area	Services	Description	Output
Strategy & Roadmap	Quality Vision & Strategy	Define the Quality Vision & Strategy to establish & drive compliance	• Quality Vision (policies, procedures, standards) structure • Quality Strategy Roadmap including high-level timelines, milestones, and effort estimates
Framework & Operating Model	Framework & Operating Model Design	Design & Support Implementation of Quality Framework & Operating Model	• Operating Model component definition • Quality function framework elements
Assessment & Technology Transformation	Quality Integration Strategy	Define the Integration & Harmonization Strategy for Quality Systems	• QMS evaluation • QMS Integration & Harmonization Roadmap including high-level timelines, milestones, and effort estimates
	QMS Integration	Quality Support for QMS Integration Efforts	• QMS gap assessment • QMS Integration Approach • QMS Integration Roadmap including high-level timelines, milestones, and effort estimates • QMS/Quality Data Migration
	QMS Assessment & Transformation Strategy	Define the QMS Assessment & Transformation framework to drive compliance	• QMS assessments/audits • QMS Transformation Approach • QMS Transformation Roadmap including high-level timelines, milestones, and effort estimates
	Quality Automation	Define and assess Quality Automation	• Quality automation evaluation • Quality automation Roadmap including high-level timelines, milestones, and effort estimates
QMS Implementation	QMS Implementation	Quality Support for QMS Implementation (including eQMS)	• QMS Implementation Approach including high-level timelines, milestones, and effort estimates • QMS high-level architecture and design support • Validation Execution and Documentation (IQ, OQ, PQ) • Authoring QMS Policies, Procedures, Work Instructions, KPI/Metric reports • QMS/Quality Data Migration • End User Training
Analytics	Quality Analytics Strategy	Define the Quality Analytics framework	• Quality KPIs/Metrics structure and definitions • Quality KPIs/Metrics establishment Roadmap • Data Modeling considerations for Quality • Analytics Governance model
	Quality Analytics Implementation	Quality Support for Quality KPIs and Metrics	• Quality KPIs/Metrics establishment • Authoring Quality KPIs/Metrics reports • Implement Analytics Data models/Governance

Audit, Transactions, & Remediation Services

As solutions and technologies evolve across the industry, it is critical to continually evaluate, identify, and implement improvements to the applications, systems, and platforms utilized in business operations. The establishment and execution of a robust and comprehensive audit program ensures that the applications, systems, and platforms utilized are performing as expected and in compliance with established guidelines, standards, and regulations. Other sources that may identify performance / non-compliance issues and improvements are Regulatory audits/inspections and merger and acquisition activities. If an application, system, or platform is not performing as expected, or a non - compliance with established guidelines, standards, and regulations is detected, remediation action is required. Remediation actions are crucial to ensuring that identified performance discrepancies and non-compliances are resolved and bring the applications, systems or platforms to the desired performance and compliance level.

Astrix quality experts have the understanding and in-depth regulatory experience with various industry solutions and platforms to define and execute an optimized audit strategy and assist with responses to Regulatory audits and remediation efforts. We provide value to our clients by:

- Incorporating proactive risk management into the process by leveraging appropriate technologies.
- Establish risk-based supplier/vendor quality programs.
- Plan and execute periodic audits/reviews, internal audits, pre- and post-implementation audits, supplier/vendor audits/qualifications
- Provide insights and responses to regulatory audit nonconformities and remediation situations

Quality Management

- Quality Manual
- Document Control
- Quality System Review
- Change Management
- CAPA
- Deviation Management
- Risk Management
- GDP
- Onboarding & Training

Product Lifecycle Management

- Release Management
- Configuration Management
- Coding Standards
- Verification & Validation
- Defect Management
- Product Support
- End-user Training

Supplier Quality Management

- Proactive Supplier Risk Management
- Supplier Assessment Framework
- Digitization of Audit Process

Transactions

- M&A Capability, Process, and Playbook
- Digital Health Assessments
- Integration/Remediation Plans & Execution
- Divestiture Assessments & Plans

Regulatory Response & Remediation

- Regulation & Standard Gap Assessments
- Systems Assessment
- Remediation Plans & Execution
- Response Writing

Quality and Compliance Capabilities for every Audit, Transaction and Remediation Situation

When you choose to work with us, you'll be working with an advisor that is well-prepared to provide a consistent level of service. Here's a look at how we help clients in each situation

Area	Services	Description	Output
Supplier/Vendor Quality Management	Supplier/Vendor Risk Program Review	Define approach for establishment of supplier/vendor risk program	• Supplier/Vendor risk program assessment • Supplier/Vendor risk program Roadmap including high-level timelines, milestones, and effort estimates
	Supplier/Vendor Quality Review/Audits	Define approach for Supplier/Vendor qualifications /audits Perform Supplier/Vendor	• Supplier/Vendor qualification process gap assessment • Supplier/Vendor qualification report • Supplier/Vendor audit report
Systems Periodic Reviews/Audits	Periodic Reviews/Audits	Perform Periodic review for Applications & Systems	• Periodic review/audit summary report
Audit Planning & Execution	Quality Audits	Define the approach and execute to assess the company's Quality organization, Product, Process, Applications, and Capability maturity	• QMS, GxP, CSV, and Data Integrity Assessments including high-level timelines, milestones, and effort estimates for Applications and Digital Assets • QMS/Controls (policies, procedures, standards) review framework • Comprehensive or Focused QMS Product/Process compliance audit
	QMS Assessment	Assess QMS maturity level for the organization	• QMS Gap Assessment • QMS/Product/Process compliance roadmap, including high-level timelines, milestones, and effort estimates
	PQMS Review	Define approach for PQMS assessment	• PQMS gap assessment for Applications and Digital Assets • Comprehensive or Focused PQMS compliance assessment • PQMS roadmap including high-level timelines, milestones, and effort estimates
Transaction Services	M&A Strategy & Risk Framework (IT Quality)	Define & Implement M&A risk framework (For IT Quality risks and controls)	• M&A Capability and Process setup • Organization Capability Assessment • M&A IT Quality Playbook
	IT Quality Due Diligence	Target Company Profiling, Planning, & Execution	• Compliance profile for target companies that accounts for known IT Quality related risks • GxP, CSV and Data Integrity Assessments for Applications and Digital Assets • Assessment framework for Infrastructure and Database, QMS/Controls, Digital Health applications, Supplier Qualification Management, & IT Quality Organization Capability • Controls (policies, procedures, standards) review framework

Transaction Services	IT Quality Remediation	Remediation Planning, timelines, effort estimates	- IT Quality Remediation Approach including high-level timelines, milestones, and effort estimates - Quality Agreements and Bridging Documents - GxP Assessment - CSV Remediation for Infrastructure, Applications and Digital Assets - Data Integrity Remediation - Authoring as Service (SDLC Artifacts)
	Integration	Define IT Integration Approach & Process for IT Quality including Planning, Execution Verification	- IT Application Inventory with Disposition of acquired company's applications - Infrastructure, Data and Application Migration - IQ (Infrastructure and Application) verification
	Divestiture	Identify impact of Divestiture on quality organization including Readiness Assessment and Approach for Migrate and Eliminate applications conveyed as part of Divestiture qualifications/audits	- New Company Readiness Assessment (including QMS, Infrastructure readiness, and To-be Organization readiness and planning) - Readiness Plan (including application divestiture, acquisition and support for GxP supplier management negotiation) while enabling accelerated TSA (transaction service agreement) exit - To-Be IT Quality GxP application and data mapping
Regulatory Response & Remediation	QMS Remediation Planning	Remediation Planning, timelines, effort estimates	- QMS Remediation Approach including high-level timelines, milestones, and effort estimates - QMS Remediation Roadmap
	Regulatory Response	Develop Responses to Regulatory Changes or Regulatory Deficiencies / Findings	- Regulatory Gap Assessment (Product, Process, System) - Regulatory Deficiency Review - Regulatory Responses including high-level timelines, milestones, and effort estimates

Validation & Assurance Services

As the advancement and utilization of computer solutions and technologies in regulated industry evolves, it is critical that GxP systems are validated and verified. This ensures that the systems are compliant with applicable regulatory standards, regulations, internal company policies and procedures, and industry best practices. The implementation of an effective Validation program allows for a standardized approach to your systems needs and provides confidence that the GxP systems are compliant, functioning as expected, and audit ready.

Astrix experts have extensive experience and knowledge of various computer solutions and technologies to help you implement, validate, verify, and improve your computer systems. We work with our client teams to:

- Provide validation system improvement insights for GxP systems
- Assist with validation of GxP systems
- Author Validation documents including plans, protocols, test scripts, reports, policies, and procedures

IT Quality (CSV) - Work Instructions & Deliverables

- System Impact Assessment
- Validation Risk Assessments
- Validation Plan
- Validation Report
- IQ, OQ, and PQ Scripts and Results
- Traceability Matrix

Validation

- Policies & Procedures
- Validation Approach
- Validation Plans, Protocols, & Reports
- Validation Execution

SDLC (Policies/Work Instructions & Requirements Review)

- SLDC Methodology (Agile / Waterfall)
- Sprint Backlog (Agile)
- User Requirements Specification
- Functional Requirements Specification
- Technical Requirements Specification
- Functional Risk Assessment
- Testing (Test Plan, Test Script, Test Report)

Data Integrity

- Data Integrity Assessments
- Data Controls Assessment
- Data Audits

Quality and Compliance Capabilities for every Validation & Assurance Situation

When you choose to work with us, you'll be working with an advisor that is well-prepared to provide a consistent approach and experience to the validation of systems across the Enterprise. Here's a look at how we help clients in each situation.

Area	Services	Description	Output
Product / Application Validation	SDLC Review / Assessment	Define the SDLC approach and process	• SDLC Gap Assessment • SDLC compliance Assessment • SDLC compliance roadmap including high-level timelines, milestones, and effort estimates
	CSV Review	Define the CSV methodology & approach	• CSV assessment for Infrastructure, Applications and Digital Assets
	Validation Support / Services	Perform validation for Applications & Digital Assets	• Author SDLC artifacts and deliverables to include policies/procedures/work instructions/validation plans/requirements/reports/test scripts • Executed Test scripts/validation reports
Product Qualification	Qualification Support / Services	Perform qualification for Products	• Author deliverables to include policies/procedures/work instructions/qualification plans/requirements/reports/test scripts • Executed Test scripts/reports
Digital Validation	Digital Transformation Strategy	Define the approach for adoption of Cloud/AI/SaMD	• Transformation Approach and Roadmap including high-level timelines, milestones, and effort estimates • Creation/Revision of procedures & policies
	Digital Validation	Perform validation activities	• Author deliverables to include policies/procedures/work instructions/validation plans/requirements/reports/test scripts • Executed Test scripts/reports
	Data Integrity Review	Define and establish Data Integrity process	• Data Integrity assessment • Author data integrity policies and procedures • Data Integrity remediation including plan and execution

The technological evolution of systems, tools, and platforms is transforming the way organizations approach managing and maintaining their systems. These organizations frequently encounter challenges in managing and maintaining their systems, primarily in finding the appropriate skilled resources, in parallel with the organization seeking to deliver high quality, reduced year-on-year cost, and navigate the evolving regulatory and compliance guidelines. Quality organizations are recognizing the value of partnering with experienced shared services specialists that can assist in establishing and providing the right services to overcome these challenges. This is helping organizations to become more efficient, highly productive, and to have a cost-effective team.

Astrix's team can work with you to identify the best cost-optimized service model to support your quality systems. This will enable your employees to remain focused on critical functions and developing new skill sets, while decreasing their time spent on less strategic tasks/activities. We bring value to our clients by:

- Providing the right skillsets and resources based on the platform/tools/system/region
- Deploying a core set of resources that can support multiple applications, thus reducing the overall cost of quality
- Establishing and adhering to industry standard SLAs for delivery expectations
- Optimizing delivery through the appropriate utilization of resources (onshore / near shore / offshore)

Management
- Governance
- Resource Optimization (On/Near/Off-shore)
- Quality Assurance/Systems
- Project Management

Services
- Audits (i.e., Quality, Supplier)
- QMS/CSV/SDLC Document Authoring and Reviewing
- Validation & Testing Support

Org Development
- Support company growth & transitions
- Onboarding & Training

Delivery Focus
- Cost of Quality
- Risk Management
- KPIs/Metrics
- Automation/Tools