

IT Quality Management Competence Center



QM as a Service

OUR COMPANY

Wizlynx group is a global IT company headquartered in Switzerland, currently employing about 140 highly skilled IT associates globally and serving more than 100 customers.

VISION

Our vision is to be a best-in-class global IT company, enabling customers to focus on their core business by providing innovative, high quality, value-added professional services.

HERE'S WHAT YOU CAN EXPECT

Wizlynx has built a solid foundation of project management know-how through people – people known for their ability to apply the right soft skills, at the right time. We make it our business to understand the unique infrastructure, needs and challenges of our customers. And we believe this level of understanding can only be achieved with the most capable and experienced of resources. But don't take our word for it. Through our interactive Competence Center, you can reach out to our associates any time, and draw upon their knowledge of processes, procedures, guidelines and tools. You'll be able to see – firsthand – the immeasurable value our team can bring to your organization.

- Minimal overhead to generate the best possible value or return
- SOX, GxP & ITIL trained workforce ready to serve in regulated industry sectors
- Extensive experience in pharmaceutical, IT, telecom, banking, nutrition and insurance industries, and in managing multimillion-dollar global technology and business projects
- Expertise in project management methodologies, frameworks and models (e.g. PMBOK, PRINCE2, COBIT, RUP, CMMI, Agile, Waterfall) enabling us to quickly adapt to your existing internal methods and processes
- Global experience, 100+ customers in Asia, Europe, Latin America and the United States of America
- Extensive knowledge of IT requirements to meet emerging growth market demands

WHAT WE CAN DO FOR YOU

Ensure Compliance With Your Quality Management System (QMS)

- Monitor and enforce adherence to your internal QMS consistently across the organization
- Continuously improve existing processes to raise compliance and efficiency
- Simplify complicated practices to maximize resource availability



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Change the Quality Culture

- Act as the agent for change
- Embed quality as a natural feature in every activity

Implement New Methods and Processes

- Design and build processes that work for the IT organization
- Use best practices and structures
- Enable compliance through process

THE WIZLYNX IT QUALITY MANAGEMENT COMPETENCE CENTER

In the last few years we have seen a steady downward pressure on costs, coupled with increasing quality systems complexity in the form of enhancements and developments around regulatory compliance and IT systems, services and organizations.

Even where cost reduction can be achieved with strategic outsourcing, regulatory accountability remains your responsibility. We will even demonstrate how a structured quality approach will add to the profitability of your business.

Highly skilled resources are vital to ensuring your organization can support continuous growth with cost-effective and highly available compliant systems and services.

Investments in the Quality Management sector can ensure you provide a professional interface between business and suppliers and ensure your quality requirements are met, both internally and externally, with third parties.

By taking advantage of our easy to deploy QM as a service model with no set-up cost, you can avoid the overhead of a recruiting process and managing headcount.

Wizlynx has worked extensively in the Quality Management sector with blue chip companies, and we understand best practices critical to establishing a new QMS and streamlining existing processes. The IT Quality Management Competence Center – our on-demand competence center of resources along with a catalog of tailored services for every quality need – will provide you with enhanced audit-readiness with a reduced risk of audit findings. It will enable you to deliver qualified services and validated systems successfully, even with the most challenging project, budget, resources and timeline constraints.

The logo for Wizlynx Group features the company name in a bold, lowercase sans-serif font. The word 'wizlynx' is in black, and 'group' is in a lighter grey. The letters are surrounded by a decorative pattern of small red and black dots, some of which are arranged in a grid-like pattern, suggesting a digital or data-driven theme.

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IT QUALITY MANAGEMENT COMPETENCE CENTER HIGHLIGHTS

VALIDATION AND QUALIFICATION STRATEGY DEFINITION

- Full computer system validation lifecycle execution
- Quality Management System establishment or enhancement
- Tailored resource development program and knowledge sharing

VALIDATION AND QUALIFICATION STRATEGY DEFINITION

- Quality and validation plan preparation
- Infrastructure qualification
- Documentation preparation and review

FULL COMPUTER SYSTEM VALIDATION EXECUTION

- Vendor audit
- Requirements engineering
- Gap analysis and risk assessment
- Design qualification
- Data migration analysis and support
- Definition and preparation of qualification protocols
- Evaluation of requirements for data integrity, security and confidentiality
- Operational handover management
- Support on service level agreement definition and review

QUALITY MANAGEMENT SYSTEM ESTABLISHMENT

- Definition of back-up and restore strategy
- Disaster recovery and business continuity plan establishment and periodic testing
- Mock inspection and audit readiness
- Change control strategy
- Configuration management

CORRECTIVE AND PREVENTIVE ACTION (CAPA) MANAGEMENT

- Periodic assessment
- Archiving strategy
- Retention period and system retirement

TAILORED RESOURCE DEVELOPMENT PROGRAM

- Training material preparation
- Training roll-out program
- Development of web-based training program
- Coaching of internal resources to ensure knowledge sharing

BENEFITS

- Easy and immediate access to our pool of associates at any time through our interactive Competence Center
- A team of professionals with experience in regulatory agency inspection and regulatory requirements (GMP, GLP, GCP, GDP, 21 CFR Part 11)
- Best practice approaches to streamlining existing processes through application of industry standards (GAMP, ITIL, CobIT, CSV, Six Sigma, ISO) to reduce lead time and increase key resource availability
- Enhancements of your internal Quality Management System in line with recent trends in regulation
- A partnership to achieve cost reduction and increase regulatory compliance for on-boarding activities
- Early identification of quality issues, risks and solutions to improve overall confidence of system and services compliance
- Improved system and service compliance to internal and external regulations, reduction of exposure to audit findings, and system or service management disruption
- Improved cross-functional collaboration through creation of synergic interactions
- Reduction of qualification time and increased system and services availability
- Implementing Continuous Improvement Processes (Fault and error reduction/Stabilization/Effective cost management)
- IT systems, vendor, project and process auditing (Security, reliability and availability/Assure supplier suitability pre- and post-contract/Quality, performance and cost/Efficiency and effectiveness)

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READILY ACCESSIBLE ACROSS THE GLOBE AND
PROVIDES HIGH-QUALITY, FAST RESULTS
AT A COMPETITIVE COST.

QM AS A SERVICE – THE SMART,
COST EFFECTIVE, ON-DEMAND OUTSOURCING
MODEL FOR YOUR QM!

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