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REDUCING PAIN BY BRIDGING GAPS BETWEEN IT & QA

HOW ALIGNING IT QA TO BUSINESS NEEDS HELPED GROW VALUE & BUILD A CULTURE OF QUALITY

In 2017, after experiencing 10-fold growth, a leading U.S. biotechnology manufacturer faced the challenge of bringing the ITQ (Information Technology Quality) team up to speed with the stringent compliance and risk mitigation profile required of such a dynamic organization. Initially, ownership of the IT QA processes was transferred to a Global Quality team; however, it was apparent that an outside assessment was required in order to efficiently meet the needs of the organization and bring the processes back under the IT umbrella.

That's where Azzur IT Advisory Services (ITAS) stepped in. Charged with building an efficient and effective future state framework for the internal ITQ team, ITAS Azzur Group facilitated an organization self-assessment to uncover potential threats and compliance gaps related to the organization's structure, capability, capacity, and processes.

To do so, ITAS worked with a multidisciplinary internal team over a period of five months to interview stakeholders, review documentation, and analyze metrics for the existing ITQA domain. With five full-time employees, the internal ITQ team spent a majority of its time on GxP audit defense, acting as supportive liaisons with other departments within the company. Furthermore, the staff expertise was significantly underutilized, best practice frameworks were lacking, and there was a blurred line between GxP and non-GxP activities.

In order to achieve their organizational change management goals and use the ITQ group to its full potential, the Azzur ITAS experts documented an IT-Quality Strategy Roadmap focusing on six key areas: infrastructure qualification/ compliance, audit, risk, document control, change control, and training.

THE CHALLENGE
Identify inspection-ready, yet efficient future state for ITQ organization in order to scale with rapid company growth.

THE SOLUTION
Quality & Compliance Audit; Insights, strategy, organizational change management, and delivery of structure and processes for Computer System Validation, Risk Assessment, IT Quality Management, Change Control, and Training.

THE TEAM
Azzur IT Advisory Services (ITAS)

THE IMPACT
Delivery of tactical approach to achieve ideal future state outlining principles of risk-driven, compliant, enterprise-wide IT; Initiation of phase II implementation.

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USING THIS STRATEGY, AZZUR COMPILED COMPREHENSIVE FUTURE STATE ROADMAP, INCLUDING BUT NOT LIMITED TO:

- Implement an ITQ charter to grow the awareness and understanding of the function of the group.

- Leveraging GAMP 5 methodology, architected documentation hierarchy including policies, procedures, work instructions, templates, along with a complementary training program to ensure standardized processes, leading to clarity, efficiency gains and compliance.

- Create one scalable, consistent infrastructure qualification where rigor is commensurate with documented risk.

- Identify lean processes to improve the overall workflow, including agreed-upon RACI.

After pinpointing the optimal strategy for success, Azzur ITAS categorized next steps into a comprehensible road-map, identifying checklists for governance, people, processes, and tools necessary to achieve the future state, broken down in six-month phases.

The client, after gauging the recommendations and recognizing the value in Azzur's Discovery to Delivery™ model, again engaged Azzur ITAS to work side-by-side with their Quality and IT teams to deliver recommended solutions while building a culture of quality, efficiency, and risk-based best practices.