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A quality and regulatory it strategy for multi division life science companies

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Many Life Science organizations consist of multiple business units, and while they are generally supported consistently by quality governance, they most often find themselves faced with difficulty integrating IT quality workflows, data, and systems across business units in an efficient way which provides them the necessary business decision support and quality management. developing an IT Quality and Regulatory (Q&R) strategy that supports and is supported by business strategy is critical for generating business value and maintaining compliance.

The objective of this strategy is to develop a Q&R driven IT strategy which sets the direction for Q&R related tools and investments. The strategy will define the business adoption measures necessary for the creation of a global Q&R IT strategy in support achieving the following goals:

- Robust and Sustainable compliance
- Harmonized and Streamlined quality processes
- Single Quality System
- Reduced time-to-market via "right first time" submissions
- Improved relationship with Regulatory Authorities (FDA, EU, WHO, etc.)
- Globally harmonized tools for globally defined processes

This will be accomplished by taking a hierarchical approach to strategy definition. Breaking the effort into strategic imperatives will allow senior leadership to identify and align key stakeholders with the effort. Next, IT Initiatives in support of each Imperative shall be defined. The current IT inventory, existing in-flight projects, and future solutions will all be taken into consideration. The resulting road map will allow the organization to align, people, policies, procedures, and governance to a unified IT Q&R strategy for accomplishing these goals.

Biography

Roger E Gould is the Regional Director for Compliance Technology Group-South (CTG-South), an Engineering Services Firm with a 15 year history of proven success. Roger earned his BS in Applied Science Technology from Thomas Edison State University in 1985. He is an active Six sigma master black belt with a proven track record as an agent of organizational change. Throughout his career, Roger has demonstrated an expert knowledge of quality processes and programs including Corrective and Preventive Action (CAPA), Failure Mode and Effects Analysis (FMEA), and Root Cause Analysis (RCA). Roger possesses an expert level of understanding of GxP and Validation requirements for computer systems in regulated (GMP, GLP, GCP) environments.

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