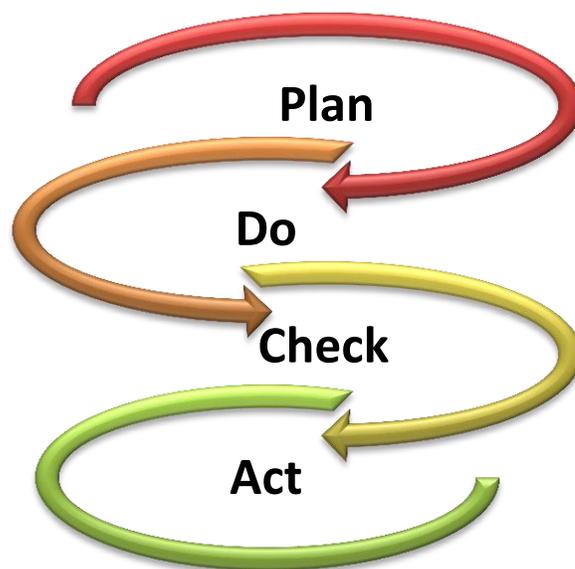




Case Study: Information Technology Assessment of a Contract Research Organization (CRO)



Information Technology Assessment of a CRO

Business Need

The CRO market has expanded at a rapid pace over the last decade, largely due to increased outsourcing from big pharma as part of their Research and Development strategic adjustment. In parallel, CROs have been realigning their systems to leverage the evolving technology and comply with the increasing quality and regulatory standards. Biovalorem worked with CRO whose rapid expansion triggered the need to assess their existing Information Technology (IT) structure in terms of software and hardware in order to create a road map on how best to move forward while sustaining existing operations in compliance.

Innovative Solution

Biovalorem selected a Plan-Do-Check-Act approach to assess the existing IT structure in order to provide the appropriate recommendations based on the CRO's level of operational maturity. The assessment was done in the following steps:

⊙ **PLAN**

A preliminary meeting was held with the client team to gather the required information on the existing structure and the expansion plans. A set of tools were established to evaluate the relevant processes, hardware, software, and people in terms of capabilities and capacity to perform.

⊙ **DO**

An on-site assessment was conducted with the focus on four major areas and all gaps were noted and reviewed with client.

⊙ **CHECK**

An analysis of the assessment findings and observations was prepared in order to precipitate conclusions and recommendations. The analysis focused on prioritizing IT Performance and IT Compliance recommendations. IT Performance assessment included strategic considerations, hardware & supporting software and software for operations while IT Compliance assessment verified the compliance of patient information security and confidentiality and processes regarding data management with HIPAA and ICH GCP guidelines.

⊙ **ACT**

Based on the assessment and analysis, key recommendations were provided to the Client; to formalize the strategy and how to link to the IT, to establish a cost structure for IT, to decide on the appropriate level of outsourcing versus in-house activity in IT, to move forward with certain hardware tactics and most importantly to formulate a plan in order to architect, design, test and implement solid processes that would benefit from a strong integration.

Benefits

Biovalorem's integrated assessment of compliance and IT ensured that the client's existing processes are in compliance to the current guidelines. The recommendations proposed assisted in prioritizing improvements to not only increase efficiencies and quality but also to diminish the risks of IT non-compliance findings.