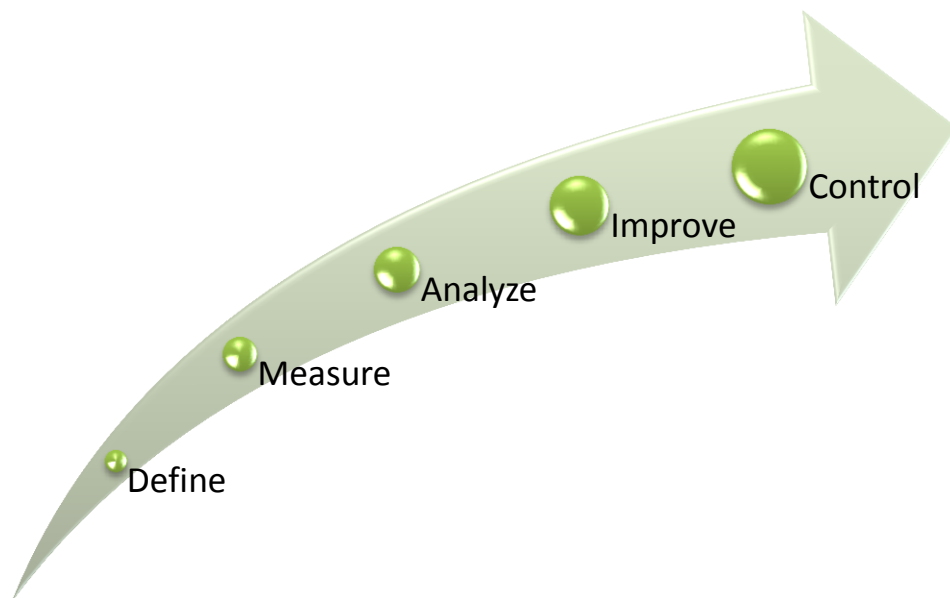




BIOVALOREM
value imagination.

**Case Study: Global Alignment of Policies,
Procedures and Instructions for
Mergers & Acquisitions**



Global Alignment of Policies, Procedures and Instructions

Business Need

Today's ever-changing life science market experiences numerous mergers and acquisitions. Hence, it is not unusual for organizations to realign their internal processes for efficient and effective integration. Biovalorem has performed such integration at the enterprise and departmental level for some of its clients. One case involved the realignment of Policies, Standard Operating Procedures (SOPs) and Work Instructions to meet the process requirements of the newly formed organization and manage the entire integration program.

Innovative Solution

Biovalorem leveraged a Lean Six Sigma approach to define, measure, analyze, improve, control (DMAIC) the integration process. The program involved the following the following phases:

⊙ **DEFINE**

Initially, the existing versions of the Policies (POLs), Standard Operating Procedures (SOPs) and Instructions (INS) of both integrating companies were obtained from the client and reviewed to gauge the current established level of detail in each respective organization's culture as well as any omissions of certain processes.

⊙ **MEASURE**

The process documents were further reviewed against process requirements for efficiency opportunities as well as the regulations to ensure that the appropriate level of compliance was in place. The gaps and issues were identified along with the required corrections to ensure a future seamless process.

⊙ **ANALYZE**

The identified gaps in compliance and process efficiency were analyzed to determine the required activities to improve the process using the policy, procedure and instruction infrastructure. In order to prioritize the program, the multiple activities were also weighted in terms of complexity, effort and criticality to the business.

⊙ **IMPROVE**

Standard content templates were established to prepare and/or adapt the required POLs, SOPs, INS, and the respective process workflows. A plan of the program was designed to monitor progress automatically as the deliverables went through the multiple reviews, approval, training and implementation as a controlled document for operations.

⊙ **CONTROL**

The new process structure is scrutinized by the client to ensure both organizational cultures are functioning according to their designed workflows. The processes are subject to the established quality check and internal audits as part of the program's performance monitoring activities.

Benefits

Biovalorem's client has emerged as a completely integrated organization with respect to its Policies, Standard Operating Procedures and Instructions. The infrastructure is compliant to the respective local, country and global regulations. Additionally, a well-developed program management process has been established for tracking future changes to the established documents along with a priority model of how these tools relate to the overall business.