

Facility Qualification

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Today's business environment in FDA-regulated industries forces facility planners, engineers, and designers to increase their efficiency and effectiveness in the planning and construction of new facilities. We are in an era characterized by exploding technology and expanding regulation. This coupled with escalating competition and increasing technical costs, forces planners to make responsible decisions that benefit their company's position in the marketplace. No longer can a current Good Manufacturing Practice (cGMP) facility be planned and implemented by a firm's internal staff group, no matter how knowledgeable and experienced they are. The complexity of modern plant technology requires that the planning process be a multi-disciplinary effort combining the expert knowledge of process architecture and engineering, materials handling, control systems, automation, compliance, validation, and construction with staff experienced in operations, maintenance, quality assurance, safety, environmental issues, and production. The requirements to be competitive in a global market, and to maintain control over increasing scope and facility costs, drive the need for early cost control. This is a critical element of the project.

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