

Criticality Assessment of Critical Utility Components to Optimize Maintenance Cycles



AT A GLANCE

INDUSTRY

Pharmaceuticals

AREA OF EXPERTISE

Technical Services

SERVICES PROVIDED

- Project Management
- Criticality Assessment
- Technical Documentation

DURATION

9 months

IMPACT

Brevitas developed a Criticality Assessment procedure, based on existing site SOPs, engineering guidelines, quality documents, and P&IDs to assess and categorize all components for 30 critical utility systems across our client's site.

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Our client required an approach to categorize critical utility system components, to allow for the adjustment of maintenance frequencies and verify the accuracy of information within SAP. Brevitas developed a standardized assessment method and successfully applied it to 30 critical utility systems across the site.

Business Challenge

Due to missing & inconsistent information in SAP, equipment & control components within critical utility systems were not consistently categorized in regard to product risk (SIS PQ) and impact to business continuity. Our client required a standardized method for categorization of these components, based on consistent and clearly defined criteria. The business drivers were to allow for the assessment and updating of maintenance frequencies to achieve cost savings and to help assess change control and validation requirements.

Our Scope

Brevitas was recruited to develop and execute a procedure to categorize critical utility system components (i.e. valves, gauges, filters, pumps, etc.) according to GMP-criticality and business-essentiality criteria, based on existing engineering guidelines, site SOPs, alarming statuses, & system P&IDs. This procedure would allow for the identification of higher/lower priority components from a maintenance perspective. The procedure was executed for Compressed Air, Purified Water, Water for Injection, Clean Steam, and Medical Gas systems across 6 production buildings.

Value Added

- Facilitated talks between Quality & Maintenance personnel regarding systems criticalities, compliance, & maintenance schedules
- Ensured correlation between system P&IDs and SAP data
- Verified accuracy of data being transferred into upgraded SAP system
- Reviewed existing technical & quality documents and suggested enhancements to procedures in place
- Built assessment method of existing site SOPs, quality documents, engineering guidelines, and system P&IDs

Results Achieved

- Developed a clear categorization procedure, agreed upon by both Technical Services and Quality
- Categorized all components as found on P&IDs for 30 critical systems across the site, based on consistent and clearly defined criteria for GMP-criticality and business-essentiality
- Presented data in a way that allowed for easy integration into SAP
- Facilitated identification of higher/lower priority systems, subsystems, and components to allow for adjustment of maintenance cycles, to achieve cost savings