SERVICE PACKAGE 03

Engineering & Utilities Compliance Review

ASSESS DESIGN / VERIFY CONTROL / TARGET CRITICAL RISKS

A modular engineering-quality assessment linking technical design, qualification, operation, monitoring and GMP compliance for selected critical pharmaceutical utilities.

SERVICE OBJECTIVE

Assess whether selected engineering systems are designed, operated, maintained and controlled appropriately for their intended GMP functions, and identify critical technical compliance gaps.

Who this service is for

- Manufacturers operating critical water, HVAC or cleanroom systems
- New facilities approaching commissioning or qualification
- Sites planning utility upgrades or equipment changes
- Operations facing repeated utility excursions or unstable performance

Core review scope

Pharmaceutical Water

- PW / WFI generation, storage and distribution
- PFD/P&ID review, sampling and monitoring strategy
- Sanitization, microbiological trends and operating limits
- Standby, shutdown, restart and maintenance arrangements

HVAC & Cleanrooms

- Zoning, classification and pressure cascade
- Airflow, filtration, temperature and humidity control
- Qualification, monitoring and contamination-control implications
- Engineering changes and system performance evidence

Engineering Quality & Other Utilities

- Selected clean steam, compressed gases and critical equipment
- URS, design review and commissioning-to-qualification interface
- Calibration, preventive maintenance, alarms and deviations
- Configuration control, change impact and continued suitability

HOW THE REVIEW WORKS

A defined assessment. Actionable outputs.

Review approach

01 Define selected system boundaries and intended GMP functions

02 Review drawings, specifications, operating and qualification records

03 Assess design and operational risks and critical control points

04 Verify selected evidence through interviews and walkthroughs

05 Issue a system-specific, risk-ranked engineering improvement plan

Deliverables

- Engineering & Utilities Compliance Assessment Report
- System-Specific Technical Gap Register
- Critical Control and Monitoring Gap Matrix
- Engineering Remediation Priority Roadmap
- Technical Recommendations and Management Debrief

Delivery and indicative timeline

Remote / On-site / Hybrid. Indicative 2–5 weeks, depending on the number, condition and complexity of selected systems.

Expected business value

- Earlier detection of utility-related GMP vulnerabilities
- Stronger alignment between design and routine operation
- Better prioritization of technical upgrades
- Clearer evidence for continued system use and inspection readiness

Scope and important boundaries

Review is modular and advisory. Detailed redesign, equipment procurement, construction, installation supervision, qualification execution and sampling campaigns require separate scope.

NEXT STEP | REQUEST A UTILITIES REVIEW

Share your facility type, selected system or GMP concern, location and preferred review model. AVISAN will confirm scope, required inputs, timeline and a tailored commercial quotation before any engagement.

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