SERVICE PACKAGE 02

Validation & Qualification Health Check

REVIEW LIFECYCLE / TEST EVIDENCE / PRIORITIZE REMEDIATION

A focused assessment of validation and qualification governance, lifecycle evidence, and continued control across selected GMP systems and processes.

SERVICE OBJECTIVE

Determine whether qualification and validation evidence adequately supports approved decisions and the continued validated state; identify gaps requiring remediation or reassessment.

Who this service is for

- Sites with legacy or fragmented validation packages
- Manufacturers preparing for inspections or system modifications
- Facilities with recurring qualification failures or open deviations
- Quality and engineering teams strengthening lifecycle governance

Core review scope

Validation Governance

- Validation Master Plan, strategy and responsibilities
- Risk-based scope and criticality
- Requirements, acceptance criteria and approval traceability
- Change control, periodic review and lifecycle decisions

Equipment & System Qualification

- DQ, IQ, OQ and PQ evidence for selected systems
- Protocol execution, deviations and report conclusions
- Requalification triggers and continued suitability
- Critical HVAC, cleanroom and water systems as agreed

Process & Cleaning Validation

- Process validation approach and continued verification
- Critical parameters, attributes and acceptance criteria
- Cleaning validation, sampling and analytical support
- Revalidation rationale and deviation impact

HOW THE REVIEW WORKS

A defined assessment. Actionable outputs.

Review approach

01 Establish system inventory and define representative, risk-based sample

02 Review selected protocols, reports, deviations and approval records

03 Trace requirements through acceptance criteria, results and conclusions

04 Assess change, periodic review and requalification controls

05 Present prioritized evidence gaps and remediation recommendations

Deliverables

- Validation & Qualification Health Check Report
- System-Level Risk and Gap Register
- Lifecycle Traceability Assessment
- Remediation / Requalification Priority Matrix
- Technical Review and Decision Workshop

Delivery and indicative timeline

Remote / On-site / Hybrid. Indicative 2–4 weeks for an agreed sample of systems and validation packages.

Expected business value

- Earlier identification of weak validation evidence
- Better lifecycle and change-impact control
- Clearer requalification decisions
- More defensible validation conclusions

Scope and important boundaries

Diagnostic review only. Protocol authorship, DQ/IQ/OQ/PQ execution, cleaning/process validation studies, sampling, testing and full dossier remediation are separately scoped. CSV is included only when explicitly agreed.

NEXT STEP | REQUEST A VALIDATION 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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