SERVICE PACKAGE 01

GMP Gap & Inspection Readiness Review

IDENTIFY GAPS / PRIORITIZE ACTIONS / STRENGTHEN READINESS

An independent, risk-based review of GMP implementation and inspection preparedness, focused on the evidence that supports routine control and defensible quality decisions.

SERVICE OBJECTIVE

Identify material GMP compliance and execution gaps, assess inspection-related risks, and establish a practical, prioritized corrective-action roadmap.

Who this service is for

- Manufacturers preparing for regulatory inspections
- Sites seeking an independent GMP baseline assessment
- Facilities facing recurring deviations, CAPA weaknesses or execution inconsistencies
- New or expanding operations approaching GMP readiness

Core review scope

Pharmaceutical Quality System

- Quality governance and accountability
- Deviation, CAPA and change control
- Quality risk management; document and record control
- Self-inspection, management review and quality metrics

GMP Operational Controls

- Training effectiveness and demonstrated competence
- Production, packaging and material traceability
- Cleaning, sanitation and contamination prevention
- Alignment of procedures with routine execution

Inspection Readiness

- Availability and traceability of critical evidence
- Open quality risks, commitments and investigation effectiveness
- Ability to explain and defend quality decisions
- Consistency between documented controls and site practices

HOW THE REVIEW WORKS

A defined assessment. Actionable outputs.

Review approach

01 Agree facility profile, applicable GMP framework and priority risks

02 Review selected SOPs, quality records, trends and supporting evidence

03 Conduct interviews and process walkthroughs (remote or on-site)

04 Classify findings by compliance significance and product/patient risk

05 Present priorities, actions and evidence needed for closure

Deliverables

- GMP Gap Assessment Report
- Risk-Prioritized Findings Register
- Inspection Readiness Summary
- Corrective Action Roadmap
- Management and Technical Debrief

Delivery and indicative timeline

Remote / On-site / Hybrid. Indicative 2–4 weeks, depending on facility complexity, agreed sampling and evidence availability.

Expected business value

- Visibility of the highest-impact GMP vulnerabilities
- Prioritized use of compliance resources
- Stronger traceability and defensibility of quality evidence
- Practical actions for sustained inspection readiness

Scope and important boundaries

This is an advisory diagnostic review, not a regulatory certification or guarantee of inspection outcome. CAPA execution, SOP rewriting, validation studies and regulatory representation require separate scope.

NEXT STEP | REQUEST A GMP READINESS DISCUSSION

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.

AVISAN | Pharmaceutical GMP, Quality Systems, Validation & Engineering Compliance
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