FSVP FDA Audit Preparation Services Action Items

Initial Consultation and Assessment

- **FSVP Readiness Review:**
  - **Conduct Assessment:** Schedule an initial consultation to review your current FSVP compliance status.
  - **Identify Gaps:** Analyze your existing processes to identify any gaps or areas needing improvement.
- **Regulatory Requirements Analysis:**
  - **Review FDA Requirements:** Thoroughly review the FDA's FSVP regulations to ensure your processes align with all necessary standards.
  - **Update Procedures:** Make necessary updates to your procedures and documentation based on the analysis.
- **Supplier Evaluation:**
  - **Assess Supplier Compliance:** Evaluate your foreign suppliers' adherence to FDA regulations and identify any compliance issues.
  - **Gather Documentation:** Collect relevant documentation from suppliers to verify their compliance.

FSVP Plan Development

- **FSVP Plan Creation:**
  - **Develop Plan:** Create a customized FSVP plan that meets FDA requirements and addresses your specific product and supplier needs.
  - **Outline Procedures:** Include procedures for supplier verification, risk assessment, and documentation.
- **Risk Assessment:**
  - **Conduct Assessment:** Perform a comprehensive risk assessment of your foreign suppliers and their products.
  - **Document Risks:** Identify potential risks and document them along with mitigation strategies.
- **Documentation Preparation:**
  - **Compile Documents:** Prepare all necessary documentation to support your FSVP plan, including risk assessments and supplier verification records.
  - **Organize Records:** Ensure all documents are organized and easily accessible for the audit.

Supplier Verification and Audits

- **Supplier Verification:**
  - **Verify Compliance:** Assist in verifying that foreign suppliers comply with FDA regulations through audits and documentation reviews.
  - **Update Records:** Keep records of verification activities and any issues identified.
- **Audit Planning:**
  - **Develop Audit Plan:** Create a detailed plan for evaluating foreign suppliers, including audit schedules and scope.
  - **Coordinate Audits:** Arrange for internal or external audits of suppliers as needed.
- **Audit Execution:**
  - **Conduct Audits:** Perform internal audits of foreign suppliers or support external audits to ensure compliance.
  - **Document Findings:** Record audit results and any issues found during the audit process.

Compliance Documentation

- **Record Keeping:**
  - **Maintain Records:** Ensure accurate and up-to-date documentation of all FSVP-related activities, including supplier verification and audits.
  - **Review Records:** Regularly review records for completeness and compliance.
- **FSVP Documentation Review:**
  - **Review Documentation:** Assess and organize all documentation required for the audit, including risk assessments and supplier verification records.
  - **Prepare Documentation:** Ensure all documents are ready and properly formatted for the audit.
- **Documentation Preparation:**
  - **Prepare Reports:** Compile all necessary documentation and reports to support your FSVP plan during the audit.

Training and Capacity Building

- **FSVP Training:**
  - **Develop Training:** Create training programs for your team on FSVP requirements, including documentation and record-keeping.
  - **Conduct Sessions:** Schedule and deliver training sessions to ensure staff understanding of FSVP requirements.

- **Audit Preparation Workshops:**
    - **Conduct Workshops:** Organize workshops focusing on preparing for FDA audits, covering common pitfalls and best practices.
    - **Provide Resources:** Offer resources and materials to support effective audit preparation.

Corrective Action Plan (CAP) Development

- **CAP Preparation:**
    - **Develop CAPs:** Create corrective action plans for any identified gaps or non-compliance issues.
    - **Document Actions:** Ensure all corrective actions are documented and aligned with regulatory requirements.
- **Implementation Support:**
    - **Assist with Implementation:** Help implement corrective actions and verify their effectiveness.
    - **Monitor Progress:** Track the progress of corrective actions and make adjustments as necessary.

Mock Audits

- **Internal Mock Audits:**
    - **Conduct Simulations:** Perform mock audits to simulate the FDA audit experience and identify areas for improvement.
    - **Review Performance:** Evaluate performance during mock audits and provide feedback.
- **Feedback and Improvement:**
    - **Provide Recommendations:** Offer detailed feedback and recommendations to address any issues found during mock audits.
    - **Implement Improvements:** Make necessary changes based on feedback to enhance audit readiness.

Regulatory Guidance and Support

- **Ongoing Guidance:**
    - **Provide Support:** Offer continuous support to ensure compliance with FSVP requirements.
    - **Update Procedures:** Update your procedures and practices based on the latest regulations and guidance.
- **Regulatory Updates:**

- **Monitor Changes:** Keep you informed about changes in FDA regulations and guidance related to FSVP.
- **Adjust Practices:** Modify your compliance practices to align with new regulatory requirements.

Audit Day Support

- **On-Site & Remote Support:**
  - **Provide Assistance:** Offer on-site or remote support during the FDA audit to facilitate smooth communication.
  - **Address Issues:** Address any issues that arise during the audit promptly.
- **Document Presentation:**
  - **Organize Documents:** Assist in organizing and presenting documentation to FDA auditors.
  - **Prepare Responses:** Help prepare responses to auditor inquiries and findings.

Post-Audit Follow-Up

- **Audit Report Review:**
  - **Analyze Report:** Review and analyze the audit report to identify any issues or areas for improvement.
  - **Discuss Findings:** Discuss audit findings and implications with your team.
- **Response Preparation:**
  - **Prepare Responses:** Help prepare responses to any observations or findings from the audit.
  - **Develop Improvement Plans:** Create plans for addressing audit findings and implementing improvements.
- **Continuous Improvement:**
  - **Implement Plans:** Develop and implement plans for continuous improvement based on audit results.
  - **Monitor Effectiveness:** Track the effectiveness of implemented improvements and make adjustments as needed.