



PremierC

Premier Compliance Services, Inc.
GMP Experts for the Healthcare Industry

Risk Assessment of GMP Compliance Status A Service Provided by PremierC

Service Description:

PremierC experts will perform an on-site audit of the client's six GMP systems as defined by the FDA. These are:

1. Quality Systems
2. Production System
3. Facility and Equipment
4. Laboratory Controls
5. Materials Systems
6. Labeling and Packaging Systems

Based on the audit we will make an assessment of GMP compliance status deficiencies. Using the guidelines defined in ICH Q9 these deficiencies will be categorized based on the risk level associated with them. Based on the risk assessment and categorization of the deficiencies identified and using guidelines outlined in ASTM E2500 standard, we will identify remediation requirements. Each proposed remediation will have an associated prioritization, extent and level of activity commensurate with the level of risk identified, and a categorization as to its importance to the regulators. This will result in the client's ability to:

1. Prioritize mitigating actions and focus their resources to address implement these actions.
2. Define the extent and level of mitigation required which would be commensurate with risk level.
3. Identify what would be the appropriate level of activity acceptable to the regulators.

Benefits of this Approach:

This approach will allow the client to recognize the GMP deficiencies associated with the operation they are conducting. It will also define appropriate Corrective Actions and/or Preventive Actions necessary to bring the operation into compliance with the regulatory requirements. This proposed approach will also define the proper level and extent of remediation required as well as the level of verification and validation needed and is commensurate with the level of risk. The following are defined benefits which would accrue:

1. Reduced cost of compliance since only appropriate activities associated with the level of risk are required
2. Focused use of resources to address the high and medium level of risk associated with the operation.
3. Reduced amount of paperwork through;
 - a. Reducing the level of documentation needed to verify the operation is suitable for the intended use.

- b. Definition of acceptable vendor and supplier documentation which maybe used in lieu of generating them in-house.

Scope of Service:

The following is the scope of work associated with this service:

1. Review operations and facility documentation a-priori
2. Conduct a one to three days audit of the operation and its systems.
3. Analyze the results of the reviews and the audit.
4. Prepare a report summarizing the findings of the review and audit.
5. Define the Risk Based GMP Compliance issues identified and define the risk level of each deficiency identified.
6. Prioritize Risk mitigation actions
7. Develop recommendations to mitigate the identified risk issues and provide a schedule for implementing such recommendations.

Deliverable:

The deliverable will be a Risk Assessment Report, which will identify the risk based compliance requirements for the operation and provide recommendation on how to mitigate these risks with a proposed implementation schedule. At the end of the effort PremierC's Expert will visit with the client to present the report and discuss its findings.

Cost:

Cost of the effort will vary based on the size and complexity of the operation being assessed. However the following guidelines can be used to estimate the cost:

1. Documentation review – PremierC will provide a list of documents to be reviewed during the audit to the client so that they may have them ready on the first day of the audit. Cost \$500 - \$1,000
2. Operation audit – PremierC will visit the operation and conduct a thorough audit which may last between one and three days. Cost \$1,000 - \$3,000.
3. Data review and analysis, again depending on the size and complexity of the operation this may requires one to two days. Cost \$1,000 - \$2,000.
4. Report preparation would require two to three days. Cost \$2,000 - \$3,000

Total cost would be \$4,500 - \$9,000. This cost does not include reasonable expenses associated with the execution of the project as well as travel to the client facility if necessary.