Quality System Approaches Using Existing Data and Systems

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Risk Management in a GCP Environment

Consists of:

• Identifying and assessing compliance risk
• Advising teams to mitigate compliance risk
• Auditing to confirm compliance
Identifying Compliance Risk

Identify risk factors for:

- Therapeutic area program or a specific protocol
- Contract Research Organizations (CROs) who are providing services across programs
- Internal processes within the Sponsor’s organization
Identifying Compliance Risk

Examples of some risk factors that have been identified for protocols:

- Protocol design
- Total number of subjects
- Total number of sites
- Total number of countries
- Experience in running trials in countries and regulatory framework
- Service Providers (CROs)
- Unique risks
Assessing Compliance Risk

Create Risk Assessment Tools for:

- Clinical Study Protocols
- Service Providers
  - Laboratories
  - Contract Research Organizations for monitoring and data management
  - Safety Case Management
- Internal Processes
  - Randomization
  - Safety case management
  - Regional product labeling
Assessing Compliance Risk

- For each risk factor, define the level of risk:
  - What constitutes high risk?
  - What constitutes medium risk?
  - What constitutes low risk?
- Generate a draft guidance, using the definitions
- Assign numerical values for each level of risk
- Assign numerical values for overall risk assessment of the protocol, service provider and internal process
Assessing Compliance Risk

Collect data from:

- Study teams
- Internal teams overseeing service providers
- Past audit reports
- Metrics
- Regulatory inspections
Mitigating Risk

What can be done to lessen the severity of the risk?

• Plan risk mitigation
• Evaluate effectiveness of plan
Auditing to Confirm Compliance

• Develop annual audit strategy based on the results of the Risk Assessment Tools

• Add audits to the schedule as new emerging risks are identified
Successes & Challenges

Successes:

• Increased communication on risk
• Improved mitigation of risks
• Proactive involvement in compliance plans

Challenges:

• Changes are constantly occurring at sites, service providers and sponsor
Questions