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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- Generate a draft guidance, using the definitions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

