

RISK ASSESSMENTS AND MITIGATION
PLANS:
BEST PRACTICES AND LESSONS LEARNED

PHARMACEUTICAL COMPLIANCE FORUM, MINI SUMMIT XVIII
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OBJECTIVES



KEY TAKEAWAYS



Always start with the “why” – do not assume everyone understands risk assessments or what to expect from them.



There is no one-size-fits-all approach. Each organization’s process should evolve with time and experience.



Resist the urge to do everything at once. Prioritization is key to meeting timelines and gaining traction.



Expect your risk assessment to identify gaps, process improvements, and areas to audit and monitor.



APPENDIX

QUESTIONS TO CONSIDER

- Why does risk matter? Why do we need risk assessments?
- How do you explain the importance of a risk assessments to business stakeholders?
- How do you differentiate the risk assessment process between US and Global affiliates?
- How do you simplify the risk assessment process to achieve business buy-in?
- How do you position risk management as a core business function?
- Which departments / personnel should weigh in on the risk assessment?
- Can you summarize your risk assessment process? What information do you consider?
- Post-assessment, how do you handle risk mitigation?
- How do you react if a risk becomes reality?
- How do you handle the ad-hoc risks that occur between assessments?
- How do you incorporate potential future risk areas into a risk assessment?