Developing and Sustaining Quality Management Systems

in Compliance with Pharma Industry Standards

RAPS

AGENDA

11:00 am	**Opening Remarks**
11:05 am	**QMS Regulatory Requirements and Industry Standards** • Review the QMS regulatory requirements and pharma industry standards as it pertains to clinical research versus manufacturing. • Examine the aspects of a robust QMS and a Quality Assurance (QA) program • Deep dive into the experience and results of implementing a QMS and developing a quality culture in different types of pharma service environments • Q&A
12:15 – 12:25 pm	**BREAK**
12:25 pm	**How Quality Control Can Minimize Errors and Other Quality Issues** • Quality Control (QC) and why it is critical to the success, accuracy and compliance of a study, process or product • Explore how QC can be achieved in various pharma environments • Best practices and industry standards to document QC • The role of QC in system validation • Q&A
1:25 – 1:35 pm	**BREAK**
1:35 pm	**Root Cause Analysis (RCA)** • Planning, implementation, expectations and outcomes • Overview of RCA tools and resources • Considerations for regulatory responses or strategies • Establishing who should be involved in the process and how the RCA plan should be documented • Q&A
2:35 – 2:45 pm	**BREAK**
2:45 pm	**Corrective and Preventative Action (CAPA) Plans** • Define corrective and preventative action plans and understand their purpose • Tools to develop, manage and follow-up on CAPA plans • Understand the regulatory and quality implications of a poorly written or managed CAPA plan • Q&A
4:00 pm	**Wrap Up**

** Agenda is subject to change.*

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