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Title: QMS MDSAP Audit / Self-Assessment Qualifications and Training (<i>Optional</i>)		Project Manager: Hiromi Kumada, PMDA

Required Qualifications

- Must possess the knowledge and ability to effectively conduct different types of audits in a professional, ethical and objective manner using and interpreting applicable standards/requirements, with an awareness of potential regulatory ramifications.
- Must be able to effectively plan, develop, communicate and execute an audit within a defined scope, including resource scheduling, conducting necessary meetings in performance of the audit and using appropriate auditing techniques.
- Must be able to verify, document and communicate audit results, develop an audit report and evaluate the effectiveness of corrective action and follow-up
- .Must possess interpersonal skills to resolve conflict, conduct interviews and make presentations effectively.
- Must be able to participate in, lead and facilitate teams. Must understand how quality principles relate to business processes and be able to explain the importance of aligning the audit function to the organizations.
- Must be able to select and use a wide variety of quality and auditing tools and techniques in practical applications.
- Must possess a basic knowledge and understanding of quality management principles and the MDSAP quality management systems.

Additional Requirements if Lead Auditor

- Management or supervisory experience would be helpful.
- Specialized expertise related to one or more MDSAP technical operations such as medical devices, combined product, laboratory, and administration, etc.