

 Responsible Office/Division	Document No.: MDSAP QMS F0008.3.002	Page 1 of 2
	Version Date: 2013-12-02	Effective Date: 2013-07-15
Title: MDSAP QMS Assessor Qualifications and Training (<i>Optional</i>)	Project Manager: Liliane Brown, USFDA	

Required Qualifications

- Must possess the knowledge and ability to effectively conduct an assessment 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 assessment 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 assessment report and evaluate the effectiveness of corrective actions 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 assessment 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 Assessor

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

Proposed “Required” Training

- ASQ Auditing Training or other type of organization providing Auditing Courses such as ISO 9001 Auditing Practices; RABQSA – Management System Auditing; ISO 19011:2011 – Guidelines for Auditing Management Systems.
- Other - to add as needed

Recommended Courses or Certifications for Staff Members at FDA

- Quality Audits for Improved Performance, offered by the American Society for Quality, Dennis Arter, Author
- ASQ Certified Quality Auditor (CQA)

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Courses through HHS provided for FDA Auditors

- Translating Requirements into Process Goals
- Communication Skills and Project Management
- Managing Process and Improvements
- Measurement, Assessment and Metrics
- Problem Solving and Process Management Tools

Courses for other MDSAP Participants

To add as needed