

Qualification-Based Certification Requirements

Medical Device - Quality Management Systems (MD)

The qualification-based [Medical Device - Quality Management System \(MD\) auditor certification program](#) has been developed by Exemplar Global in liaison with industry representatives. The program provides international recognition for auditors who conduct management system audits using national or international management system standards, or other management system standards and normative and industry references that are recognized by Exemplar Global. [Please refer to the Exemplar Global Personnel Certification Guide for full details.](#)

Grade	Designed For	Training & education	Work Experience	Audit Experience	Personal Attributes
Associate Auditor	Those who have attended an auditor course and have work experience but have no audit experience.	Exemplar Global ISO 13485:2016 Quality Management Systems Auditor course And Associate degree or higher	Two years of full-time relevant work experience within the last 10 years	N/A	Auditor Work Style Assessment
Auditor	Auditors who audit as a member of an audit team and/or as a sole auditor	Exemplar Global ISO 13485:2016 Quality Management Systems Auditor course And Associate degree or higher	Four years of full-time relevant work experience within the last 10 years	Two complete management system audits and 10 audit days	Auditor Work Style Assessment
Principal Auditor	Auditors who audit as a sole auditor	Exemplar Global ISO 13485:2016 Quality Management Systems Auditor course And Associate degree or higher	Six years of full-time relevant work experience within the last 10 years	Four complete management system audits and 20 audit days	Auditor Work Style Assessment
Lead Auditor	Auditors who lead audits and audit teams	Exemplar Global ISO 13485:2016 Quality Management Systems Lead Auditor course And Associate degree or higher	Eight years of full-time relevant work experience within the last 10 years	Seven complete management system audits and 35 audit days, including three complete audits and 15 days as Lead Auditor leading a team of at least one other person.	Lead Auditor Work Style Assessment

This is a "controlled" document on day of printing only. Refer to the BMS online for current documents.

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Master Auditor	Experienced auditors with at least 12 years of lead auditor experience.	Exemplar Global ISO 13485:2016 Quality Management Systems Lead Auditor course And Associate degree or higher	Twelve years of full-time work experience within the last 12 years	Same as Lead Auditor plus 12 years or more of continuous certification as a Lead Auditor	Lead Auditor Work Style Assessment
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Where Education requirements cannot be met, applicants may submit an additional two years of work experience and complete the Exemplar Global MD examination to bridge the gap (will not apply to auditors who have already demonstrated training ISO 13485:2016 training).

Resources

Download Exemplar Global [Code of Conduct](#)

Download the Exemplar Global [Audit Log](#)

Download Exemplar Global [Personnel Certification guide](#)