



QUALITY MANAGEMENT SYSTEM REQUIREMENTS & STANDARD OPERATING PROCEDURES

Do you need Standard Operating Procedures?

Our Quality Management System Includes:

- 46+ SOPs compliant with ISO 13485:2016, FDA Regulations (21 CFR 820, 803, & 806), Canadian Medical Device Licensing, and European CE Marking
- Associated forms, logs, and templates
- Updated procedures for Regulation (EU) 2017/745 (MDR) & EU 2017/746 (IVDR)

US Market Compliance Package:

- Includes SOPs for FDA Regulations (21 CFR 820, 803, 806, & 830)
- Price: \$7,000
- Implementation: Est. 100-120 hours with a minimum of 4-8 hours/week for maintenance. Billed Hourly.

Note:

- Additional pricing options available (see table below)
- "Turnkey" doesn't mean "work-free"
- Suitable for small start-ups with mostly outsourced processes

Quality Management System Package Includes:

- Draft quality manual
- Procedures, forms, logs, and templates
- 16 pre-recorded training webinars
- Training verification quizzes

Customization Required:

- Add your company name and logo
- Adapt documents to your operations

Training Certification Available:

- Submit completed quizzes in MS Word format
- Receive corrected exams and training certificate

QMS Options	Length	Consulting	Total
US Only	4 Months	No	\$7,000 (\$1,750/month)
Global	4 Months	No	\$8,500 (\$2,125/month)

All Pricing as of July 16, 2025



QUALITY MANAGEMENT SYSTEM REQUIREMENTS & STANDARD OPERATING PROCEDURES

Procedures	Individual Price	QMS US Only	QMS Global
POL-001 Quality Manual (Webinar Bundle)	\$599	Yes	Yes
WI-002 Remote Auditing (Webinar Bundle)	\$129	Yes	Yes
WI-003 Electronic Submission Gateway	\$199	Yes	Yes
WI-007 Cybersecurity (Webinar Bundle)	\$399	Yes	Yes
WI-008 Security Incident Response Policy (Webinar Bundle)	\$299	Yes	Yes
WI-009 Conducting FDA Inspections (Webinar Bundle)	\$299	Yes	Yes
SYS-001 Document Control (Webinar Bundle)	\$299	Yes	Yes
SYS-002 Control of Records (Webinar Bundle)	\$299	Yes	Yes
SYS-003 Management Review (free example with webinar)	\$0	Yes	Yes
SYS-004 Training Procedure (Webinar Bundle)	\$299	Yes	Yes
SYS-005 Facility, Plant and Equipment Maintenance (Webinar Bundle)	\$299	Yes	Yes
SYS-006 Change Control (Webinar Bundle)	\$299	Yes	Yes
SYS-007 Customer Related Processes	\$299	Yes	Yes
SYS-008 Design Controls	\$299	Yes	Yes

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Procedures	Individual Price	QMS US Only	QMS Global
SYS-009 Clinical Procedure (Webinar Bundle)	\$299	Yes	Yes
SYS-010 Risk Management	\$299	Yes	Yes
SYS-011 Supplier Quality Management (Webinar Bundle)	\$299	Yes	Yes
SYS-012 Production Process Controls	\$299	Yes	Yes
SYS-013 Servicing (Webinar Bundle)	\$299	Yes	Yes
SYS-014 Process Validation	\$299	Yes	Yes
SYS-015 Distribution Procedure (Webinar Bundle)	\$299	Yes	Yes
SYS-016 Calibration (Webinar Bundle)	\$299	Yes	Yes
SYS-017 Monitoring, Measuring & Analysis	\$299	Yes	Yes
SYS-018 Customer Feedback & Compliant Handling (Webinar Bundle)	\$299	Yes	Yes
SYS-019 Post-Market Surveillance	\$299	Yes	Yes
SYS-020 Recalls & Advisory Notices (Webinar Bundle)	\$299	Yes	Yes
SYS-021 Quality Audits (Webinar Bundle)	\$299	Yes	Yes
SYS-022 Statistical Techniques	\$299	Yes	Yes
SYS-023 Nonconforming Product (Webinar Bundle)	\$299	Yes	Yes
SYS-024 CAPA (Webinar Bundle)	\$299	Yes	Yes

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Procedures	Individual Price	QMS US Only	QMS Global
SYS-025 Technical Documentation	\$299	No	Yes
SYS-027 Purchasing	\$299	Yes	Yes
SYS-029 Medical Device Reporting (Webinar Bundle)	\$299	Yes	Yes
SYS-030 Labeling Procedure	\$299	Yes	Yes
SYS-031 EO Sterilization Validation	\$299	Yes	Yes
SYS-032 Identification & Traceability (Webinar Bundle)	\$299	Yes	Yes
SYS-033 Receiving Inspection (Webinar Bundle)	\$299	Yes	Yes
SYS-034 Monitoring of Controlled Environments	\$299	Yes	Yes
SYS-035 Incident Reporting	\$299	No	Yes
SYS-036 Vigilance Reporting	\$299	No	Yes
SYS-037 Implant Card Procedure	\$299	No	Yes
SYS-038 Controlled Environment Gowning	\$299	Yes	Yes
SYS-039 UDI Procedure	\$299	Yes	Yes
SYS-041 Clinical Evaluation Procedure (Webinar Bundle)	\$299	No	Yes
SYS-042 Canadian Licensing Procedure	\$299	No	Yes
SYS-043 Steam Sterilization Validation Procedure	\$299	Yes	Yes

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Procedures	Individual Price	QMS US Only	QMS Global
SYS-044 Software Development and Validation Procedure (Webinar Bundle)	\$399	Yes	Yes
SYS-045 Returned Materials Authorization Procedure	\$299	Yes	Yes
SYS-046 Packaging Validation Procedure	\$299	Yes	Yes
SYS-047 GAMMA Sterilization Validation Procedure	\$299	Yes	Yes
SYS-048 Usability Procedure (Webinar Bundle)	\$299	Yes	Yes
SYS-049 Communication with Competent Authorities, Notified Bodies, & Other Economic Operators	\$299	No	Yes
SYS-051 Software Tool Validation Procedure (Webinar Bundle)	\$299	Yes	Yes
SYS-052 Translation Procedure	\$299	No	Yes
SYS-053 Medical Device File Procedure (Webinar Bundle)	\$299	Yes	No
SYS-054 VHP Sterilization Validation (Webinar Bundle)	\$299	Yes	No

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