



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: ~100-120 hours
- Maintenance: 4-8 hours/week minimum

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 Turnkey Quality Management System	4 Months	No	\$7,000 (\$1,750/mo)
Global Turnkey Quality Management System	4 Months	No	\$8,500 (\$2,125/mo)

Hourly Consulting – Available Upon Request

President: Rob Packard - \$350/hr

Senior Regulatory Consultants: Matthew - \$275/hr



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Procedures Available for Purchase Individually OR in QMS Bundle	Individual Prices	QMS - US Only	QMS - Global
POL-001 Quality Manual (Webinar Bundle)	\$599	X	X
WI-002 Remote Auditing Work Instruction (Webinar Bundle)	\$129	X	X
WI-003 Electronic Submission Gateway Work Instruction	\$199	X	X
WI-007 Cybersecurity Work Instruction (Webinar Bundle)	\$399	X	X
WI-008 Security Incident Response Policy (Webinar Bundle)	\$299	X	X
WI-009 Conducting FDA Inspections (Webinar Bundle)	\$299	X	X
SYS-001 Document Control (Webinar Bundle)	\$299	X	X
SYS-002 Control of Records (Webinar Bundle)	\$299	X	X
SYS-003 Management Review (free example with webinar)	Free	X	X
SYS-004 Training Procedure (Webinar Bundle)	\$299	X	X
SYS-005 Facility, Plant and Equipment Maintenance (Webinar Bundle)	\$299	X	X
SYS-006 Change Control (Webinar Bundle)	\$299	X	X
SYS-007 Customer Related Processes	\$299	X	X
SYS-008 Design Controls	\$299	X	X
SYS-009 Clinical Procedure (Webinar Bundle)	\$299	X	X
SYS-010 Risk Management	\$299	X	X
SYS-011 Supplier Quality Management (Webinar Bundle)	\$299	X	X
SYS-012 Production Process Controls	\$299	X	X
SYS-013 Servicing (Webinar Bundle)	\$299	X	X
SYS-014 Process Validation	\$299	X	X
SYS-015 Distribution Procedure (Webinar Bundle)	\$299	X	X
SYS-016 Calibration (Webinar Bundle)	\$299	X	X
SYS-017 Monitoring, Measuring & Analysis	\$299	X	X
SYS-018 Customer Feedback & Compliant Handling (Webinar Bundle)	\$299	X	X
SYS-019 Post-Market Surveillance	\$299	X	X
SYS-020 Recalls & Advisory Notices (Webinar Bundle)	\$299	X	X
SYS-021 Quality Audits (Webinar Bundle)	\$299	X	X
SYS-022 Statistical Techniques	\$299	X	X
SYS-023 Nonconforming Product (Webinar Bundle)	\$299	X	X
SYS-024 CAPA (Webinar Bundle)	\$299	X	X
SYS-025 Technical Documentation	\$299		X
SYS-027 Purchasing	\$299	X	X
SYS-029 Medical Device Reporting (Webinar Bundle)	\$299	X	X
SYS-030 Labeling Procedure	\$299	X	X
SYS-031 EO Sterilization Validation	\$299	X	X
SYS-032 Identification & Traceability (Webinar Bundle)	\$299	X	X
SYS-033 Receiving Inspection (Webinar Bundle)	\$299	X	X
SYS-034 Monitoring of Controlled Environments	\$299	X	X
SYS-035 Incident Reporting	\$299		X
SYS-036 Vigilance Reporting	\$299		X
SYS-037 Implant Card Procedure	\$299		X
SYS-038 Controlled Environment Gowning	\$299	X	X
SYS-039 UDI Procedure	\$299	X	X
SYS-041 Clinical Evaluation Procedure (Webinar Bundle)	\$299		X
SYS-042 Canadian Licensing Procedure	\$299		X
SYS-043 Steam Sterilization Validation Procedure	\$299	X	X
SYS-044 Software Development and Validation Procedure (Webinar Bundle)	\$399	X	X
SYS-045 Returned Materials Authorization Procedure	\$299	X	X
SYS-046 Packaging Validation Procedure	\$299	X	X
SYS-047 GAMMA Sterilization Validation Procedure	\$299	X	X
SYS-048 Usability Procedure (Webinar Bundle)	\$299	X	X
SYS-049 Communication with competent authorities, notified bodies and other economic operators	\$299		X
SYS-051 Software Tool Validation Procedure (Webinar Bundle)	\$299	X	X
SYS-052 Translation Procedure	\$299		X
SYS-053 Medical Device File Procedure (Webinar Bundle)	\$299	X	
SYS-054 VHP Sterilization Validation (Webinar Bundle)	\$299	X	
		\$7,000	\$8,500

Pricing as of October 18, 2024

