

# 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	<u>Total</u>
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





# Quality Management System Requirements & Standard Operating Procedures

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POL-007 Quality Manual (Webinar Bundle)	Procedures Available for Purchase Individually OR in QMS Bundle	Individual	QMS - US Only	QMS - Global
Wi-002 Remote Auditing Work Instruction (Webinar Bundle)	POL-001 Quality Manual (Webinar Bundle)		Y	Y
Wi-003 Electronic Submission Gateway Work Instruction   \$199	,			
Wi-007 Cybersecurity Work Instruction (Webinar Bundle)				
Wi-008 Security Incident Response Policy (Webinar Bundle) \$299	•			
Wi-009 Conducting FDA Inspections (Webinar Bundle)	,			
SYS-001 Document Control (Webinar Bundle)         \$299         X           SYS-002 Control of Records (Webinar Bundle)         \$299         X           SYS-003 Management Review (free example with webinar)         Free         X           SYS-003 Family, Plant and Equipment Maintenance (Webinar Bundle)         \$299         X           SYS-005 Facility, Plant and Equipment Maintenance (Webinar Bundle)         \$299         X           SYS-005 Change Control (Webinar Bundle)         \$299         X           SYS-007 Customer Related Processes         \$299         X           SYS-008 Design Controls         \$299         X           SYS-018 Risk Management         \$299         X           SYS-012 Production Process Controls         \$299         X           SYS-013 Evoluting Webinar Bundle)         \$299         X           SYS-014 Process Validation         \$299         X           SYS-015 Distribution Procedure (Webinar Bundle)         \$299         X           SYS-016 Callbration (Webinar Bundle)         \$299         X           SYS-017 Monitoring, Measuring & Analysis         \$299         X           SYS-018 Custorino (Webinar Bundle)         \$299         X           SYS-020 Recalls & Advisory Notices (Webinar Bundle)         \$299         X           SYS-0212				
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