PQC
PARKER QUALITY & COMPLIANCE

CAPABILITY STATEMENT

Fixed-price complaint handling, MDR reportability and post-market surveillance services for medical device manufacturers

SUMMARY

Parker Quality & Compliance helps medical device manufacturers identify gaps in complaint handling, MDR reportability and post-market surveillance and prioritize recommended fixes ahead of an FDA inspection or notified-body audit. Every engagement is led by Nathan Parker, who has more than 10 years in medical device quality and regulatory affairs and has hosted multiple FDA inspections, all closed with zero findings.

WHO WE HELP

- **Small and mid-size device manufacturers** that need an independent check without a big-firm budget
- **Startups after a 510(k) or De Novo clearance** that need complaint and PMS processes ready for first commercial sales
- **Companies answering an FDA Form 483 or warning letter** that cites complaint handling, MDR, corrections and removals, or CAPA

Start here: Complaint File Mock Inspection — $2,500

Remote · fixed price · report within 10 business days of receiving your files · full fee credited toward any package booked within 60 days

- **Scope:** 15 closed complaint files and their reportability decisions from one product family, plus your complaint, MDR and corrections-and-removals procedures, sampled in a mock inspection.
- **Checked against:** ISO 13485:2016 §8.2.2 (Complaint handling) and §8.2.3 (Reporting to regulatory authorities), incorporated by reference at 21 CFR 820.7 and required by 21 CFR 820.10(a); complaint record content (21 CFR 820.35(a)); MDR procedures, files and timeliness (21 CFR 803.17, 803.18, 803.50, 803.53); Part 806 decisions; and the link to CAPA.
- **You get:** a mock 483-style list of observations, a file-by-file findings matrix, a prioritized fix list, and a 60-minute readout.

PACKAGES

PACKAGE	PRICE	TIME	WHAT YOU GET
1. Complaint Handling & MDR Reportability Audit	**$6,500**	2–3 wks	Audit of complaint, MDR and vigilance procedures and up to 25 records for one product family; graded report with recommended actions; 60-minute readout
2. Post-Market Surveillance System Setup	**$10,500**	4–6 wks	PMS procedure, PMS plan for one device family, trending method, EU MDR Article 85 post-market surveillance report (PMSR) and Article 86 PSUR templates, one draft report if data are supplied, 90-minute team training
3. Inspection Preparation & Mock Audit (FDA or notified body)	**$9,500**	2–3 wks	Document request, two-day mock inspection, interview practice, mock 483 or findings report, prioritized remediation plan
Ongoing or ad hoc support	**$185/hr or $1,480/day**	As agreed	Scoped in writing before work starts

Remote by default. On-site work available as needed; travel billed at cost. Prices are fixed for the stated scope at one site. A written proposal confirms scope, deliverables and exclusions before work begins. Remediation work, submissions to regulators and any guarantee of inspection outcome are excluded unless agreed in writing.

WHY PARKER QUALITY & COMPLIANCE

- **Fixed price, in writing.** You approve scope and price before work starts, and the invoice matches.
- **Practitioner, not a generalist.** Hands-on experience running complaint handling and MDR programs, including hosting multiple FDA inspections, all closed with zero findings.
- **Current with the QMSR.** Work is mapped to the requirements in effect since February 2, 2026, which incorporate ISO 13485 by reference.
- **Findings you can act on.** Each finding cites the requirement and the record behind it and says what to fix first.
- **Remote by default, on-site as needed.** Secure file sharing and video readouts; you work directly with the principal, with no big-firm overhead.

CREDENTIALS

- More than 10 years in medical device quality and regulatory affairs
- Hosted multiple FDA inspections, all closed with zero findings
- Working knowledge of ISO 13485:2016, FDA QMSR (21 CFR 820), 21 CFR 803 and 806, EU MDR vigilance and PMS, and Health Canada mandatory problem reporting

PROOF OF WORK

- Free weekly FDA device data and commentary: pqcregwatch.com
- Complaint handling and reportability templates: etsy.com/shop/ParkerQMSDocs

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