ComplianceMedQRA

REGULATORY & QUALITY AFFAIRS

Summary

Who we are: Compliance MedQRA is a regulatory and quality affairs consultancy headquartered in Dubai, working with medical device, SaMD, IVD, digital health, pharmaceutical and life sciences companies across Europe, the United Kingdom, the United States and the GCC. Our delivery team is doctorate-led, combining PhD-level expertise with senior QA/RA practitioners who have successfully guided products through the regulatory pathways they advise on.

What we do: Compliance MedQRA provides regulatory and quality expertise across the product lifecycle - from early regulatory strategy and product classification through development, submission, market access and post-market activities. Our capabilities include technical documentation and regulatory submissions, ISO 13485 and FDA QMSR quality systems, IEC 62304 software lifecycle support, ISO 14971 risk management, clinical evaluation, cybersecurity, data protection and post-market surveillance. We support clients through focused projects, ongoing QA/RA partnerships, and dedicated expert resources integrated into their teams.

Why it matters. We combine scientific expertise, regulatory knowledge and practical quality experience to help companies turn complex requirements into clear, workable solutions. Our focus is on building regulatory documentation and quality systems that are compliant, well-structured and sustainable - supporting not only the immediate submission or audit, but the organization's continued growth and future products.

15+ years
Specialized in regulatory and quality practice

4 markets
EU, UK, US and UAE/GCC covered end-to-end

PhD-led
Doctorate-led team

Platform
QraOne -e-QMS system built by regulatory experts

SECTORS AND PRODUCT TYPES WE SUPPORT

Medical Devices
Class I to III, active and non-active, EU and US pathways

Software as a Medical Device
Standalone clinical software, mobile and cloud

AI/ML-Enabled Devices
Model lifecycle, change control, predetermined change plans

In Vitro Diagnostics
IVDR classification, performance evaluation, LDT and CLIA

Digital Health & Wellness
Borderline products and wellness-safe positioning

Neurotechnology
Neuromonitoring, imaging analysis and decision support

Wearables & Remote Monitoring
Continuous monitoring and connected patient programmes

Diagnostic Imaging
Image analysis, PACS integration and clinical workflow

Pharma & Biotech
GxP quality systems and regulatory documentation

Laboratories
CLIA applicability, laboratory quality and reporting

Early-Stage MedTech
Pre-seed to first submission, built right the first time

Investors & Acquirers
Regulatory and quality due diligence on target companies

MARKETS WE COVER

European Union
MDR 2017/745, IVDR 2017/746, notified body liaison, EU Authorised Representative coordination

United Kingdom
UKCA marking, MHRA registration, UK Responsible Person coordination

United States
FDA 510(k), De Novo, PMA, QMSR, CLIA applicability, US Agent coordination

UAE, Saudi Arabia & GCC
EDE, DHA and DOH registration, SFDA registration, PDPL and ICT Health Data Law

Canada & Australia
MDSAP-based routes, Health Canada and TGA alignment

OUR MISSION

To simplify compliance so that quality-driven companies can scale faster and smarter - bridging the gap between groundbreaking innovation and stringent regulatory requirements, so that safe, effective products reach the patients waiting for them.

Founded and led by Dr. Basant Bajpai, PhD, bringing 12+ years of international Quality and Regulatory experience across medical devices, SaMD, IVDs, AI-enabled healthcare and digital health, supported by a multidisciplinary background in neuroscience, neuromonitoring and bioengineering.

02 · SERVICES

Services

Engage us across the full product lifecycle or for a single deliverable. Every workstream is led by a senior specialist and produces evidence in regulatory required format expected by authority reviewer.

STRATEGY

Regulatory Strategy & Market Access

Intended-use definition, classification and pathway selection, and jurisdiction sequencing across EU MDR/IVDR, FDA, UKCA, MDSAP and UAE/GCC. Gap assessments, regulatory roadmaps, and US reimbursement and market-access strategy.

SUBMISSIONS

Technical Documentation & Submissions

CE marking technical files, FDA 510(k), De Novo and PMA, UKCA files, MDSAP country dossiers, SFDA, and UAE MOHAP, DHA and DOH registration. Authored, reviewed and defended through reviewer questions and deficiency letters.

QUALITY SYSTEMS

Quality Management Systems

ISO 13485 and FDA QMSR implementation, remediation and audit readiness. Internal audits, supplier qualification, CAPA and change control, management review, and full notified-body or registrar audit support - opening meeting to closure.

SOFTWARE & SAMD

Software, SaMD and AI/ML

IEC 62304 software lifecycle, SOUP management, design controls and traceability, verification and validation, usability engineering, and AI/ML model change management including predetermined change control plans.

RISK & SECURITY

Risk, Cybersecurity & Data Protection

ISO 14971 risk management files, security risk assessment and SBOM readiness, and data protection across GDPR, HIPAA, UAE PDPL and the ICT Health Data Law. ISO 27001, SOC 2 and HITRUST readiness where information security is in scope.

CLINICAL & POSTMARKET

Clinical, Post Market & Vigilance

Clinical evaluation reports and literature strategy, clinical investigation design and study support, PMS and PMCF plans, vigilance and incident reporting, periodic safety update reports, and surveillance audit preparation.

LIFECYCLE COVERAGE

STAGE	WHAT THE REGULATOR EXPECTS	WHAT WE DELIVER
01 **Concept & Classification**	**Defensible intended use, classification and route to market** MDR Annex VIII · 21 CFR 860 · EDE/DHA	Regulatory strategy memo, classification rationale, multi-jurisdiction roadmap and budgeted timeline
02 **Quality System & Readiness**	**A conforming, operating and evidenced quality management system** ISO 13485:2016 · FDA QMSR · MDSAP	QMS build or remediation, procedure set, internal audit program, mock & external audit and non-conformity closure
03 **Design & Development**	**Design controls, risk management and software lifecycle evidence** ISO 13485 §7.3 · ISO 14971 · IEC 62304	Design history file structure, risk management file, software lifecycle plan, V&V protocols and traceability
04 **Submission & Certification**	**A complete, reviewer-ready technical file or submission** MDR Annex II/III · 510(k) · UKCA · SFDA	Technical documentation, FDA submission package, UAE registration dossier, and reviewer question response
05 **Post Market**	**Ongoing surveillance, vigilance and periodic reporting** MDR Art. 83–92 · 21 CFR 803/806	PMS and PMCF plans, vigilance procedures, PSUR authoring, surveillance audit support and annual QMS upkeep

03 · TECHNOLOGY

QraOne e-QMS

qraone.com

Regulatory and quality expertise, built into the platform. QraOne is Compliance MedQRA's AI-enabled electronic Quality Management System, developed to bring quality processes, controlled documentation and regulatory readiness into one connected environment.

Built by the same regulatory and quality professionals who support our client engagements, QraOne translates hands-on QA/RA experience into a practical system for **Medical Devices, IVD, SaMD/AI, Digital Health and Life Sciences organisations.**

- **Document Control—** Controlled documents, reviews & approvals
- **Quality Processes—** CAPA, change control, audits & PMS
- **Supplier qualification —** structured approval and ongoing monitoring
- **Developer tool integrations —** GitHub, GitLab and Jira mapped into design controls
- **Role-based training —** targeted assignment with automated tracking
- **Design controls —** traceability from requirement to validation
- **AI-powered regulatory insight —** gap identification and decision support

04 · WORKING WITH US

Flexible support, built around your needs

01
Understand
We start by understanding your product, target markets, current documentation and immediate priorities.

02
Define
We agree the scope, responsibilities, deliverables and timeline so there is a clear plan from the outset.

03
Collaborate
Our specialists work directly with your team, integrating with existing development, quality and regulatory activities

04
Delivery
Documentation, systems and regulatory outputs are developed, reviewed and delivered against agreed milestones.

05
Continue
Support can extend beyond the initial project into submissions, audits, post-market activities, QMS maintenance and ongoing regulatory needs.

Focused Project

Engage us for a defined scope such as a gap assessment, technical documentation, clinical evaluation, QMS implementation, audit readiness or submission support.

Best when: planning the route, clearly defined objectives and deliverables.

Full submission

End-to-end ownership of the technical file, quality system and submission - through notified body, FDA or health authority review to certification or clearance.

Best when: the pathway is set and the file needs to be built

Support function

We complement your existing QA/RA team with additional expertise where needed - helping address knowledge gaps, complex regulatory requirements, resource constraints or specific quality challenges.

Best when: your QA/RA team is in place but needs additional expertise or capacity.

LET'S DISCUSS HOW WE CAN SUPPORT YOU

Whether you're preparing for market entry, strengthening | | your QMS, planning a submission or need additional QA/RA | | expertise, we're ready to support your next step

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