DINCON

Dinc Consulting

REGULATORY.
QUALITY.
MARKET ACCESS.

Making medical devices safe, effective and market-ready.

Consulting and hands-on support - from regulatory strategy to audit-ready evidence.

EU MDR / IVDR | SWISS MDR | FDA | AI & SOFTWARE

Regulatory Affairs · Quality Management · Supplier Quality · GMP

DINCON AT A GLANCE

Complex requirements. Clear execution.

DINCON combines regulatory strategy, technical depth and hands-on implementation - for active and non-active medical devices, software and IVDs.

Clear Regulatory Strategy

Intended purpose, classification, market pathway and required evidence are aligned early.

Practical Systems

QMS, technical documentation and interfaces that work in day-to-day operations.

Audit Readiness

Review-ready evidence for Notified Bodies, FDA, MDSAP, customers and suppliers.

TYPICAL STARTING POINTS

New product development · Notified Body submission · Legacy devices · QMS remediation · CAPA backlog · AI integration · Audit preparation

OUR APPROACH

1 **Assessment**

Status, risks, gaps and priorities.

2 **Roadmap**

Market pathway, work packages and responsibilities.

3 **Implementation**

Documents, processes, reviews and coaching.

4 **Evidence**

Submission readiness, audit and effectiveness.

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REGULATORY AFFAIRS & MARKET ACCESS

Make the right regulatory decisions early.

Aligning product strategy, development, evidence planning and market launch.

STRATEGY & MARKET ACCESS

- Product status, intended purpose, claims and classification
- Regulatory roadmaps for the EU, Switzerland and the USA
- Conformity assessment strategy and Notified Body interface
- Lifecycle and change impact assessments

MDR, LEGACY DEVICES & SWITZERLAND

- MDR/IVDR gap assessments and implementation of manufacturer obligations
- MDR Article 10: manufacturer obligations and QMS integration
- MDR Article 15: PRRC role, responsibilities and evidence
- Legacy devices and transitional provisions, including Article 120, EU 2023/607 and MDCG guidance
- Swiss MDR / MedDO, CH-REP and registration requirements

REGULATORY VIEW

01 What is the product - and what is being claimed?

02 Which classification and market pathway apply?

03 Which evidence is required, and when?

04 Which risks and changes affect the strategy?

05 How can the evidence become audit- and submission-ready?

SUBMISSION SUPPORT

Submission planning · Evidence and traceability matrix · Query management · Responses to findings and nonconformities

TECHNICAL DOCUMENTATION, RISK & AI

Consistent, traceable and review-ready.

From evidence planning to the final review for Notified Body submission.

TECHNICAL DOCUMENTATION

- Creation, review and remediation in accordance with MDR Annexes II and III
- Submission readiness review for the Notified Body
- Gap, consistency and traceability review across the complete technical file
- Resolution of findings, nonconformities and missing evidence
- Technical file and DHF remediation
- UDI

SAFETY, SOFTWARE & USABILITY

- Risk management according to ISO 14971
- Electrical safety and EMC according to the IEC 60601 family
- Software lifecycle according to IEC 62304
- Usability engineering according to IEC 62366-1
- Cybersecurity lifecycle according to IEC 81001-5-1

AI IN MEDICAL TECHNOLOGY

- Regulatory assessment of AI-enabled medical devices
- Interaction between the EU AI Act and MDR/IVDR
- Data governance, bias, human oversight, robustness and cybersecurity
- Verification, validation, change control and post-market monitoring
- Implementation of an AI management system according to ISO/IEC 42001
- Controlled use of generative AI for research, evidence mapping and documentation review

Use AI responsibly: analyse faster, document clearly, and retain controlled accountability and approval.

QUALITY MANAGEMENT & AUDITS

A QMS must work in practice - not only in the quality manual.

Structures, processes and evidence are aligned so that decisions remain traceable and deviations are closed effectively.

QMS ACCORDING TO ISO 13485

- QMS structure, process map, SOPs, work instructions and templates
- Alignment with MDR/IVDR and FDA QMSR
- Document and records control, training and management review
- Validation, calibration, nonconforming products and release controls

QMS HEALTH CHECK CHECK

Effectiveness · Accountability · Evidence · Improvement

GAP ANALYSIS | RISK | ROADMAP | PRIORITIES

CORE PROCESSES

- CAPA, NC/NCR and effectiveness verification
- Change management and regulatory impact assessment
- Complaint handling, PMS interface and vigilance
- Process metrics, trend analysis and continual improvement

AUDITS & REMEDIATION

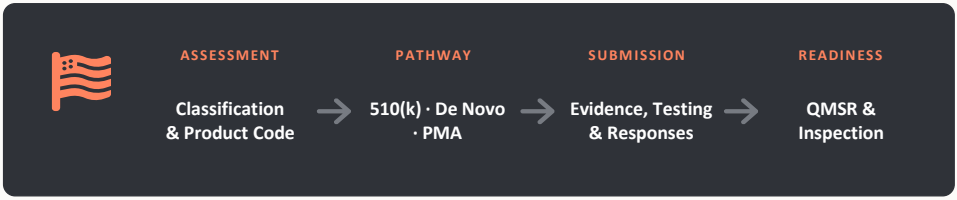
- Internal, external and supplier audits
- Mock audits for Notified Bodies, FDA and MDSAP
- Audit plan, checklists, interviews and evidence review
- Finding analysis, CAPA, action plan and effectiveness verification

Objective: less friction, clear responsibilities and robust evidence for every assessment.

FDA: MARKET ACCESS & INSPECTION READINESS

Integrating US strategy and the quality system consistently.

From the appropriate submission pathway to robust inspection readiness.



Regulatory Strategy

Device classification, product code, predicate and pathway assessment. Planning for 510(k), De Novo or PMA, including Q-Submission strategy.

Submission Support

Content and evidence plan, test matrix, software, cybersecurity, human factors and technical evidence. Support with deficiency responses.

QMSR & Inspection

QMSR and ISO 13485 integration, design and development records, complaint/MDR and CAPA interfaces, and mock inspections.

TYPICAL DELIVERABLES

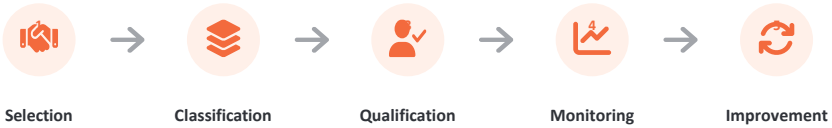
Regulatory assessment · Submission roadmap · Gap and DHF remediation · Evidence matrix · Mock inspection · Observation/finding response · CAPA plan

SUPPLIER QUALITY & GMP

Quality begins in the supply chain.

Risk-based supplier controls and controlled production processes reduce deviations, failures and audit risks.

SUPPLIER QUALITY MANAGEMENT



- Supplier selection and risk-based supplier classification
- Qualification, audits, quality agreements and approval criteria
- Performance monitoring using KPIs, scorecards, deviations and complaints
- SCAR, change notifications, requalification and escalation management

GMP / CGMP & PRODUCTION COMPLIANCE

- Documentation compliance, records review, data integrity and traceability
- Cleanroom and contamination control, e.g. according to ISO 14644 where applicable
- Equipment qualification and process validation: IQ, OQ and PQ
- Deviation, change and release management, including training
- Control of critical production, cleaning and sterilisation interfaces

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Let us discuss your next regulatory step.

A clearly defined starter package quickly provides transparency on risks, priorities and the most effective path to implementation.

REGULATORY GAP ASSESSMENT

Product status, market pathway, gaps and a prioritised roadmap.

TECH DOC REVIEW

Submission readiness, consistency, traceability and findings.

QMS HEALTH CHECK

Process effectiveness, audit risks, CAPA and required improvements.

AUDIT READINESS SPRINT

Mock audit, evidence review, action plan and closure plan.

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Project support · Interim management · Review & audit · Coaching & training

Regulatory status: July 2026. Binding requirements are assessed for each product against the applicable legislation, guidance and standards.