# Medical Device Quality & QMS Talent Solutions

## COMPLIANCE-DRIVEN TALENT FOR AN INNOVATION-INTENSIVE INDUSTRY

## Executive Summary

In the highly regulated world of medical devices, **quality assurance is not a function—it's a mandate.** Failure to meet regulatory standards like FDA 21 CFR Part 820, ISO 13485, and EU MDR can result in operational shutdowns, delayed product launches, or costly recalls.

Dexian brings **Talent + Technology Solutions** to medical device manufacturers by connecting them with **top-tier quality and compliance professionals** who understand the complexity of global quality standards and product lifecycle regulations. Whether you're scaling post-market surveillance, validating a new software platform, or preparing for an audit, Dexian delivers skilled talent—**on demand, with speed and precision.**

dexian®

# Core Offering

Dexian provides end-to-end recruiting solutions for contract, contract-to-hire, direct-hire, and consulting roles within:

## QUALITY ASSURANCE & REGULATORY COMPLIANCE

- Quality Engineers (Design Controls, Risk Management)
- Regulatory Affairs Specialists (EU MDR, FDA 21 CFR Part 820)
- Supplier Quality Engineers & Auditors
- Quality Systems Auditors (FDA, ISO, MDSAP)

## QMS INTEGRATION & OPTIMIZATION

- QMS Implementation Specialists (ISO 13485, FDA compliance)
- Document Control & Change Management Experts
- CAPA & Non-Conformance Investigators
- Post-Market Surveillance & Complaint Handling Specialists

## VALIDATION & CONTINUOUS IMPROVEMENT

- Process Validation Engineers (IQ/OQ/PQ)
- Software Validation (CSV, IEC 62304)
- Lean Six Sigma Black Belts
- Internal & External Compliance Auditors

# Technology Expertise

Dexian specializes in placing talent experienced with leading QMS platforms:

- MasterControl
- Greenlight Guru
- TrackWise
- EtQ Reliance
- Arena QMS
- Pilgrim SmartSolve
- Veeva QualityOne
- AssurX

These professionals are not just system operators—they are change agents who understand compliance and process optimization inside and out.

# Our Process:
# Built for Regulated Environments

**Needs Assessment & Role Definition**

Collaborate with hiring managers to map requirements to FDA, ISO, MDSAP, and EU MDR standards.

**Talent Sourcing & Screening**

Leverage AI-powered sourcing tools and Dexian's national talent network.

**Technical & Regulatory Verification**

Confirm certifications, validate technical skills, and assess real-world regulatory experience.

**Placement & Onboarding Support**

Streamline onboarding and ensure compliance with internal credentialing and documentation workflows.

# Why Dexian?

**NICHE EXPERTISE**

Deep knowledge of medical device quality roles and compliance mandates.

**SPEED TO VALUE**

Rapid placement with pre-screened candidates ready to contribute.

**MARKET INSIGHT**

Strategic workforce partner for navigating the FDA, EU MDR, and QMS modernization trends.

**FLEXIBLE MODELS**

From short-term audit support to long-term quality team buildouts.

# Business Impact

Clients engage Dexian to:

- Accelerate product launches without regulatory delays
- Prepare for FDA, ISO, and MDSAP inspections with confidence
- Strengthen post-market and complaint-handling programs
- Replace inconsistent offshore quality resources with U.S.-based or nearshore talent
- Reduce the burden on internal HR and compliance teams

## Let's Build Quality Into Everything You Do

The future of med device innovation depends on the quality of the people behind it. With Dexian as your workforce partner, you gain **strategically vetted talent** and **seamless QMS integration** that powers **operational excellence** and **regulatory resilience.**

**Let's connect and build a smarter, safer, more compliant tomorrow—together.**