



# 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:



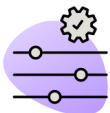
## QUALITY ASSURANCE & REGULATORY COMPLIANCE

- 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



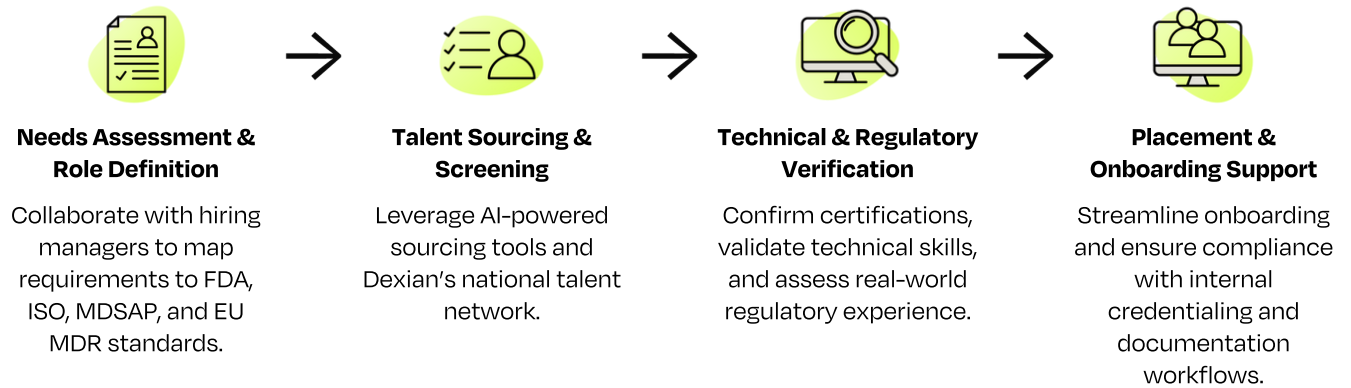
## Technology Expertise

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



## 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.**