RQM+

Share your email address to receive occasional updates.

Scan Now

Regulatory Affairs

RQM+ supports every clinical specialty and device classification of medical devices and IVDs.

- Worldwide regulatory strategies
- Regulatory submissions
- EU MDR and IVDR implementation
- New product development and sustaining regulatory support
- Acquisition due diligence and implementation
- Strategic direction

Design and Manufacturing Quality Engineering

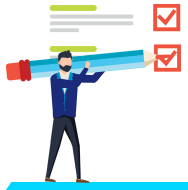
RQM+ quality engineers are rooted in new product development and help you create and manufacture the best device while ensuring compliance to the latest regulations.

- Product development support
- Safety risk management
- Health hazard evaluation
- DHF gap analysis and remidiation
- Manufacturing site transfer
- Manufacturing process validation

Quality Management Systems

RQM+ uses a customized, business-balanced approach to develop and optimize quality systems.

- Worldwide quality management solutions
- Gap analyses to new regulations
- Audit and inspection support
- Remediation of audit findings
- Acquisition integration
- Internal and supplier audits worldwide



Regulatory Compliance

RQM+ provides an all-encompassing compliance solution that includes strategic leadership, program management, and a tactical team to address all challenges.

- FDA 483 and warning letter strategy and response
- EU notified body non-conformity strategy and response
- CAPA/NCR leadership and support
- Recall strategy

Leverage the Unrivaled Collective Knowledge of RQM+

- Impacts every client and project
- Integrated and scalable team of 450+
- Former FDA, competent authority, and notified body leadership with connections
- Strategic implementation of complex regulations across various clinical specialties
- Best-in-class project management
- ISO 9001:2015 certified

Clinical Regulatory Affairs

RQM+ supports every clinical specialty and device classification of medical devices and IVDs.

- Worldwide regulatory strategies
- Regulatory submissions
- EU MDR and IVDR implementation
- New product development and sustaining regulatory support
- Acquisition due diligence and implementation
- Strategic direction

Post-Market Surveillance

RQM+ quality engineers are rooted in new product development and help you create and manufacture the best device while ensuring compliance to the latest regulations.

- Product development support
- Safety risk management
- Health hazard evaluation
- DHF gap analysis and remidiation
- Manufacturing site transfer
- Manufacturing process validation

Complete Solutions

RQM+ uses a customized, business-balanced approach to develop and optimize quality systems.

- Worldwide quality management solutions
- Gap analyses to new regulations
- Audit and inspection support
- Remediation of audit findings
- Acquisition integration
- Internal and supplier audits worldwide

RQM+ is the leading international provider of regulatory, quality, and compliance consulting services for medical device and diagnostics manufacturers.

RQMplus.com

RQM+