
AZBIO RESOURCE NETWORK MEMBER

**QMR, LLC*****Quality Management Resources***

With almost 30 years of diversified experience, QMR provides practical and cost-effective solutions for all your life-sciences quality assurance and regulatory affairs needs. Areas of specialization include:

- Audits, gap assessments and mock inspections.
- Device, Software and IVD product submissions, FDA and CE Mark.
- Electronic records and signatures.
- Responses to and FDA representation for Form 483s, Warning Letters and Consent Decrees.
- Implement start-up and re-engineer existing quality systems. FDA and ISO.
- Design controls, including software, risk management, human factors engineering and V & V.
- Enterprise-wide risk management solutions.
- Process, software, quality system change control and validations. Document change controls, automated systems.

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