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***Stay compliant. Stay competitive.
Start your QMSR journey with us.***



New FDA QMSR guideline!

Compliant QMSR



New QMSR. New challenges.

*Your pathway to U.S. compliance
starts here.*

WQS GmbH and WQS INC has
implemented and established QMSR
and ISO 13485:2016 requirements in
many companies.

QMSR SERVICES

With the new FDA QMSR legal obligations we, the WQS Group offer a thorough set of QMSR compliance services tailored to support you in navigating and adhering to the new regulatory requirements.

Our approach is tailored precisely to your needs and can include, but is not limited to:

Regulatory Gap Assessment

- WQS is conducting an in-depth analysis of your current quality management system against the QMSR, identifying gaps and areas for improvement.

Customized Compliance Strategy including Risk Assessment

- Based on the gap analysis, we develop a tailored strategy to address identified gaps, ensuring your systems are fully compliant with the QMSR requirements.

Documentation Updates

- We assist in reviewing and updating your documentation, including SOPs, Quality Manual, and records to meet the stringent documentation requirements of the QMSR and ISO 13485:2016.

Employee Training and Development

- We provide targeted training programs to ensure your team is well-versed in the QMSR changes, their roles, and responsibilities within the updated system.

Preparation for FDA Inspections

- With anticipated changes in the FDA's inspection approach under the QMSR, we prepare you for inspections through mock audits and readiness assessments, ensuring your team is confident and prepared.

WQS services are designed to address the specific challenges inquired by the QMSR. You will be leveraging our expertise to facilitate a smooth transition.

Our consultants offer an objective evaluation of your quality management system, identifying potential non-conformities and improvement opportunities.

Ready for QMSR?

We guide you through every step.