

Features

- Online ICH E6 R2 awareness and certification courses
- Quality management capability maturity assessment
- SOP / QMS gap analysis against the new ICH E6 R2 guidance
- SOP / QMS updates and additions for alignment with ICH E6 R2
- Training development and delivery for QMS awareness and compliance certification
- Risk assessment approach and training
- Risk detection and KRI / KPI design
- Central monitoring and risk management guidance and support
- Functional plan development
- Quality management / RBM technology implementation
- Study set up and ongoing support

Benefits

- Understand what ICH E6 R2 is and how it will impact your company – quickly and cost effectively
- Understand the gaps in your quality management capability to enable the fastest route to compliance
- Utilize our experience and IP to ensure your QMS meets the needs of ICH E6 R2 quickly and cost effectively
- Ensure your organization is trained and certified quickly by through e-Learning or Webinar based training courses
- Understand the concept of risk assessment and simple, pragmatic approaches, including the use of Transclerate RACT and MCC RAMMT
- Learn how to design and utilize KRIs and KPIs for risk detection and quality management, using your own data sources
- Put everything into practice with guidance and ongoing support in central and risk-based monitoring
- Be inspection ready, with clear, relevant and well defined functional plans, and evidence of usage

Using the OPRA quality management platform, our clients can:

- Show evidence your compliance with ICH E6 R2
- Generate quality management reports for your CSR
- Centralize risk assessment, risk detection, risk management and risk reporting
- Gain efficiency and quality through RBM

Engage with one of our specialists to find out how we can help your firm become ICH E6 (R2) compliant.

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