

## Medical Device and Pharmaceutical Consulting and Training

Winovia provides consulting, training, and implementation of *self-sustaining*, and *effective* quality systems and processes customized to our global clients' needs. Winovia helps companies *improve*, *change* and *transform* their quality systems and processes.

- **Regulatory expertise** — medical device and pharmaceutical quality systems (FDA 21 CFR Parts 210, 211 and 820; ISO 13485; ICH Q7, Q8 and Q10)
- **Due diligence and audits** — assessments, development and remediation of quality systems
- **Training** — quality systems, current good manufacturing practices, design control, new product development, process validation, six sigma, design for six sigma, test method validation, quality risk management, change management
- **Product development** — product life cycle, quality by design, design controls, and design for six sigma
- **Validation** — strategies, planning, procedures, protocols and templates
  - Design qualification and validation
  - Process validation
  - Test method validation
- **Manufacturing** — process and quality improvement; six sigma
- **Quality risk management** — ISO 14971, ICH Q9, risk prioritization, hazard analysis and critical control points (HACCP), fault tree analysis (FTA), preliminary hazard analysis (PHA), hazard operability analysis (HAZOP), failure mode and effects analysis (FMEA)
- **Complaint handling and corrective and preventive action (CAPA)**
- **Documentation and technical writing** — customized quality manuals, procedures, protocols, reports and templates
- **Project management** — managing validation and remediation projects



### Call Today!

Find out how customized quality systems, procedures and processes can result in effective and sustainable compliance, growth, revenue and profitability.

Winovia LLC  
136 Chestnut Street  
Albany, New York 12210-1906 USA

Phone: +1-518-436-8110

[info@winovia.com](mailto:info@winovia.com)

Compliance makes good business sense