Hughes IT Consulting

www.hughesitconsulting.com

Specialized Services for Life Sciences – GxP Documentation & Validation for Regulatory Readiness

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Who I Help

Biotech, Pharma, and CROs who need to:

- Deliver GxP-compliant documentation
- Transform raw stakeholder inputs into structured requirements, traceability, or SOPs
- Fill critical documentation and validation gaps during or after system implementation

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Services Offered

1. Validation & Regulatory Documentation

- GxP Validation Packages (Functional Specifications, Acceptance Test Plans, SOPs)
- CSV deliverables for LIMS and EDMS systems
- Installation & Operational Qualification (IQ/OQ) documentation

2. SOP Development & Revision

- Author or revise SOPs and Work Instructions
- Align to 21 CFR Part 11 and ALCOA principles
- Support for regulated document workflows

3. Requirements Finalization & Traceability

- Translate workshop notes and user interviews into formal, testable requirements
- Build Use Cases, Process Flows, and Acceptance Criteria
- Develop and maintain Requirements Traceability Matrices

About Me

I'm a **Certified Business Analysis Professional (CBAP)** with over 20 years of experience supporting validated systems in the Life Sciences sector. I've supported **Merck, Teva, Pfizer, and Centocor (JnJ)** in bringing electronic systems into regulatory compliance. I blend strong documentation and analysis skills with hands-on delivery of GxP-ready packages that reduce inspection risk and speed up system on-boarding.