Hughes IT Consulting

Certified CBAP | Pharma Business Analyst | Validation & Requirements Expert

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Who I Train

Life sciences professionals, business analysts, and project teams who need:

- Practical, real-world Business Analysis skills tailored to **regulated Pharma environments**
- Strong foundations in **GxP validation documentation**
- Confidence with leveraging LIMS and EDMS platforms

Training Topics Offered

1. Business Analysis in Pharma

- Role of the BA in SDLC & CSV workflows
- Stakeholder analysis in regulated settings
- Requirements gathering & documentation best practices
- Use cases, process modeling, traceability matrices

2. GxP Validation Documentation Essentials

- Writing URS, FRS, and ATP documents
- Validation strategy for 21 CFR Part 11
- How to support audit trails, access control, and metadata integrity
- Risk-based validation techniques

3. SOP Development for Regulated Systems

- How to structure GxP-compliant SOPs
- Aligning SOPs with automated workflows
- Change control and document lifecycle best practices

Why Me?

- 20+ years in pharmaceutical IT with **Merck, Teva, Pfizer, and Centocor (JnJ)**
- CBAP-certified with hands-on validation experience across multiple systems
- Expertise with using **LIMS & EDMS systems and JIRA & Confluence**
- Proven ability to turn complex technical workflows into clear, testable documentation