ZIFO RnD SOLUTIONS

Job Title:	Validation Specialist	Job Category:	Full-time
Domain:	Validation and Compliance	Date Posted:	24-Jan-2018
Location:	Boston	Zifo Contact:	hr@zifornd.com

Q. What is the job description?

» The Validation Specialist will be responsible for authoring, review and approval of SDLC / Validation deliverables by ensuring the documentation meets the regulatory requirements and applicable quality procedures in the life sciences industry (pharmaceutical/biotech/medical device companies). The Validation Specialist will act as a liaison between the remote validation team and the client's QA/Compliance group to deliver the required deliverables.

Q. What are the job responsibilities?

» Customer orientation

- Understand the requirements and business needs of the customer
- Work with the remote team to translate the needs of customer into Validation deliverables
- Work closely with the customer QA/compliance group to assure quality, defect free deliverables
- Analyze trends in customer feedback, ensure correction and corrective actions are taken towards areas of development, and that these actions are effective

» Process awareness and adherence

- Ensure compliance with the regulatory requirements, Zifo' process and customer's process requirements
- Assure the deliverables from Zifo adheres to customer's requirements

» Validation Deliverables

- Create, Review and Approve all deliverables not limited to URS, FRS, Risk Assessment, Validation Plan, Test Protocols, Traceability matrix and Validation Summary Report
- Perform Risk Assessment and propose risk mitigation strategies

- Execute protocols in the customers GLP/GMP environment
- Proactively communicate the compliance gaps and system issues by working with customer's QA/compliance, remote team and vendors
- Adhere to follow customer's change control process for the validation deliverables

» Business Development
- Establish and manage the relationship with customers
- Identify and develop new opportunities in existing and new accounts by promoting Zifo as a Validation partner

Q. What are the required skills?

» Strong Written and Oral communication skills
» Interpersonal and Problem solving skills
» Strong Domain and Regulatory Knowledge
- 21 CFR Part 11, EU Annex 11
- GLP, GCP and GMP
- 21 CFR Part 58 (GLP), 210, 211 (GMP), 820 (QSR)
- SDLC, GAMP5, Risk Assessment Methodologies

» Project Management skills
- Define Scope, track and manage schedules
- Vendor Management
- Risk Management

Q. What are the desired competencies?

» Independent, Self-Motivated & Results driven individual
» Willingness & Ability to acquire quickly new Technical Skills & Business Principles
» Experience (3-5 years) with Customer/Client focused delivery model
» Strong regulatory knowledge and technical writing Experience (3-5 years)
» Previous experience (3-5 years) with Productivity tools such as VISIO, Excel, PowerPoint, Word, Microsoft Project
» Strong Understanding of SDLC models, Risk Assessment Methodologies

Q. What is the required education/work experience?

» Bachelor's/Master's degree or equivalent in a scientific or health care field preferred
» 3-5 years of experience as a Validation Analyst or Specialist, preferably in the pharmaceutical / medical devices industry
» Strong experience in R&D or manufacturing systems such as ELN, LIMS, EDC, Mobile Medical applications and other GxP Systems.

Q. What is Zifo?

Zifo works with customers from more than 20 countries, including 7 of the Top 10 global Bio-Pharmas. It has been ranked as one of the Fastest Growing Technology Companies for 6 consecutive years (2012 – '17) by Deloitte, and has been recognized as one of the Best Companies to Work For in India 2016 by the Great Place to Work Institute and as one of India's Great Mid-Size Workplaces – 2017 - A study conducted by Great Place to Work® Institute India in association with MINT, by HT Media.

Looking for a long-term enriching career with us? Send in your resumes to 'hr@zifornd.com'

We look forward to meeting you soon!