



Ideal Knowledge Transfer™

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Commissioning and Validation Engineer
Reports to Vice President, Midwest Operations

Salary: Commensurate with qualifications and experience

Bonus: Eligible for bonus program

Educational Background:

Bachelors of Science in Engineering from an accredited institution; Chemical Engineering preferred. Experience, training and/or certificates may be substituted for engineering degree in some circumstances.

Experience and Skill Set:

cGMP experience in validation, commissioning, technical services, manufacturing and/or manufacturing sciences. Basic understanding of process equipment used to manufacture pharmaceuticals, biopharmaceuticals and biotech products (e.g., bioreactors, centrifuges, filtration systems, chromatography systems, etc.). Excellent writing and documentation skills required including the use of MS Word and MS Excel. Experience with cGMP facilities, clean utilities and equipment desired. Experience with automated equipment (e.g., PLC, DCS, SCADA, etc.) desired. Understanding of GAMP4 desired.

Job Description:

Author and execute DQs, IQs, OQs and PQs for various commissioning and validation projects. Execute and manage change control during project execution. Summarize and analyze test data. Author final summary reports based on actual execution results. Author or revise procedures and templates for commissioning and validation activities. When applicable, provide point-of-contact leadership at client sites. Subject areas include but are not limited to: HVAC, WFI, CIP, SIP, CSV, bioreactors, chromatography, filtration, Kaye Validators, refrigerators, freezers, incubators, cold rooms, autoclaves, automation, process, cleaning and document management systems.

Travel: 5-10% travel; frequent travel to customer sites in greater Chicagoland.