



## VALIDATION ENGINEER

Gala Biotech, a Catalent Pharma Solutions (CPS) Company, is a biotechnology company engaged in the production of recombinant proteins in cell culture systems for pharmaceutical and biotechnology applications. We are seeking a high caliber individual to fill our Validation Engineer position in our Middleton facility.

### OBJECTIVE:

The Operations Department is responsible for materials management, which includes warehousing and control of material movement, calibration and validation activities and cGMP activities. cGMP manufacturing includes cell banking, upstream (cell culture) and downstream (protein purification) activities.

### RESPONSIBILITIES:

The Validation Engineer has the primary responsibility for protocol development and execution of validation qualifications. Where applicable, oversight of contractor validation may be necessary. The Validation Engineer will conduct validation activities, based upon engineering specifications that include: authoring and editing protocols, executing validation protocols and writing reports. The Validation Engineer will identify deviations from test plan and will work with functional groups to resolve deviations.

- Perform all necessary activities to execute IQ, OQ and PQ protocols in a timely manner.
- Coordinate the collection of necessary documentation for the development of validation protocols.
- Execute various engineering studies and pre-validation testing to ensure proper execution of validation plans.
- Develop and write Standard Operating Procedures.
- Coordinate efforts with various departments to determine appropriate validation requirements.
- Generate conclusions based on the review and analysis of pertinent test data.
- Write validation protocols and reports.
- Analyze problems utilizing linear logic and apply solutions to achieve an acceptable resolution.
- Make simple repairs and adjustments to equipment and instrumentation.
- Other duties as assigned.

#### QUALIFICATIONS:

- Have knowledge of GMP regulations, specifically 21 CFR - parts 210 and 211, ISO Standards and EU Regulations.
- Excellent English verbal and written communication skills to present problems, solutions and ideas.
- MS Word, Excel, Access experience including revision control and tracking.
- Ability to self-start and follow through with initiatives and tasks.
- Excellent workload management and organization skills to reach deadlines and goal.
- The ability to read/decipher schematics (engineering drawings).
- Mechanical and electrical aptitude.

#### EDUCATION/EXPERIENCE:

- BS degree in scientific or engineering fields or a minimum of 5 years of relevant experience in the pharmaceutical industry.
- Previous calibration experience preferred.

#### APPLICATION PROCESS:

Join an exciting organization! If you would like to apply for this position with Gala Biotech, please send your cover letter, resume, and salary requirements by mail or by email to:

By mail:                      Human Resources  
                                    Gala Biotech  
                                    PO Box 620160  
                                    Middleton, WI 53562

By e-mail:                    [gala.hr@catalent.com](mailto:gala.hr@catalent.com)

Gala Biotech is an Equal Opportunity Employer

We offer a competitive salary and benefits package including comprehensive health, life and disability insurance, 401(k), vacation and holidays.