Job Opportunity

We are looking for a **Validation Manager** to spearhead the repositioning of our capabilities to achieve new heights for the exciting growth journey of the organisation. The primary function of the role is to provide validation, cross contamination, and New Product Introduction (NPI) expertise for the site and to direct and manage validation requirements and activities.

Responsibilities

- Provide advice and expertise to Validation, Production, Analytical Development and Quality teams in relation to validation requirements.
- Ensure validation procedures are in place and complied with as per current Regulatory and Corporate requirements.
- Lead the Validation team members, providing technical advice and performance feedback to achieve individual, team, and site goals and objectives.
- Provide advice and expertise to Business Development, Project Management and CDMO Steering Committee in relation to phase appropriate manufacturing, cross contamination and segregation requirements and NPI processes.
- Collaborate closely with cross-functional teams to ensure alignment and timely execution of validation plans.

Requirements

- Bachelor's or master's in a scientific or engineering discipline.
- Minimum 7 years (10 years preferred) of working knowledge and practical experience with validation principles across equipment, process, method, cleaning, and computer system validation
- Experience working in utilities and general production systems used in the manufacture, testing, and holding of bio-pharmaceutical products.
- Strong knowledge of cGMP including ICH Q7 and international codes of GMP (FDA and EU).
- Working knowledge of the GAMP good practice guides and experience in phase appropriate manufacturing requirements.
- Expert knowledge of validation principles including user requirements, functional specifications, commissioning, FAT, SAT IQ, OQ, PQ, and process validation.
- Exceptional attention to detail regarding documentation.
- Excellent communication skills and ability to work as part of a highly skilled Validation team.
- Experience using the Microsoft Office suite, in particular MS-Word and MS-Excel.
- Experience working in a CDMO environment is preferred.

Why work with BioCina?

- Competitive remuneration and benefits: We offer a competitive salary, comprehensive benefits package, and recognition for exceptional performance.
- Career growth opportunities: We believe in growing our people and provide ample opportunities for career development and advancement.

- Innovation and impact: Be part of a company that goes beyond the boundaries of science and making a positive impact on patients' lives.
- State-of-the-art facility: Utilise cutting-edge technology and work in a modern, well-equipped facility that fosters creatively and productivity.

- Collaborative environment: Work alongside with passionate and expert professionals who are dedicated to excellence and shared a common goal.

Join our team and help shape the future of biopharmaceuticals. Together, we can make a difference.

To apply, please submit your resume and a cover letter outlining your qualifications, relevant experience and why you are the right fit for this role. We thank all applicants for their interests, but only shortlisted candidates will be contacted.

As part of our commitment to create a diverse and inclusive workplace, BioCina is an equal opportunity employer and seeks to have a diverse candidate shortlist for this vacancy. All experienced candidates from a range of backgrounds, including genders, people with disabilities, and indigenous and ethnically diverse candidates are encouraged to apply.

To apply, please submit your resume and a cover letter outlining your qualifications, relevant experience and why you are the right fit for this role to HRrecruitment@biocina.com. We thank all applicants for their interests, but only shortlisted candidates will be contacted.

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