Administrative Program Specialist (QA Document Control Specialist) – PVL 91310

Education: A Bachelor's degree is required. A degree in Biochemistry, Chemistry, Biology, Bacteriology, Virology or a related field is preferred.

Appointment Percentage: 100%
Full-time Salary Rate: Minimum: $42,167 Annually; Depending on qualifications

Job Summary:
The Waisman Center is dedicated to the advancement of knowledge about human development, developmental disabilities, and neurodegenerative diseases throughout the lifespan. One of only 14 centers of its kind in the United States, the Waisman Center encompasses laboratories for biomedical and behavioral research, a brain imaging center, and a clinical biomanufacturing facility for the production of pharmaceuticals for early stage human clinical trials. In addition to its research efforts, the Center provides an array of services to people with developmental disabilities, offers numerous educational and outreach programs to young children and their families, and trains scientists and clinicians who will serve our nation in the future.

Waisman Biomanufacturing (WB), at the University of Wisconsin-Madison is a clinical manufacturing facility that produces biotherapeutics (gene therapeutics, cell therapeutics, recombinant proteins and vaccines) for Phase I/II Human Clinical Trials in compliance with current Good Manufacturing Practice (cGMP) guidelines. Clients include clinical investigators at UW-Madison, NIH, other universities, and the biopharmaceutical industry. Waisman Biomanufacturing is located within the greater Waisman Center. The QA Document Control Specialist's primary responsibilities will include QA documentation and record keeping, QA raw material control, quality systems (documentation control, failure investigation, deviation reporting, etc.) and training documentation. They will also provide backup support for external audits.

Minimum Qualifications:
Well-qualified applicants will have the following **preferred** experience and knowledge:

- One to two years of work experience in a manufacturing environment. Undergraduate research experience will be considered.
- Experience performing QA duties is highly preferred.
- Experience working under current Good Manufacturing Practices (cGMP).
- Experience in documentation control including documentation initiation, review and approval as well as review and approval of manufacturing batch records.
- Experience reviewing documentation, performing inspections, completing QA documentation and releasing GMP raw materials.
- Experience providing support during audits by regulatory agencies and prospective clients (e.g., interacting with auditor(s), responding to resulting observations, providing documentation, etc.)

Principal Duties:

70% Quality Assurance Documentation and Recordkeeping:

- Prepare, organize and review cGMP documentation including SOP's (Standard Operating Procedures), Quality Control (QC) test procedures and manufacturing process batch records. This requires a level of scientific knowledge sufficient to assure that the documentation is accurate and technically sound.
- Audit completed manufacturing records, which are comprised of the documentation of detailed chemical and biological processes. Audit and approve test data and reports for a variety of chemical, biological and microbiological assays.
- Assure proper filing and retention of manufacturing records.
- Work with internal project leaders and clients to generate GMP documentation for both manufacturing and QC testing that is scientifically accurate and complete. Assure that documents are routed for approval in a timely manner.

15% Departmental Training Documentation:

- Assure training requirements are met for all personnel in the facility, both Manufacturing and Quality Scientists.
- Assure documentation of training is complete and accurate.
- Notify personnel when re-training is due and monitor for completion.

5% Quality Systems:

- Assure schedules for appointment calibration and preventive maintenance are met and that appropriate records are maintained. Review and approve calibration and preventive maintenance records to assure that technical specifications are met and the equipment is suitable for use.
- Assure deviations and CAPA's (Corrective and Preventive Action) are investigated and closed within time requirements.
- Review deviations and CAPA's to insure that the investigations are technically accurate and that the conclusions are sound and justifiable.

5% Quality Assurance Raw Material Control:

- Inspect and release incoming raw materials to insure that biological and chemical specifications are acceptable and the quality of the material meets client and regulatory requirements.

5% Auditing:

- Provide backup support during audits by regulatory agencies and prospective clients. Serve as a contact for internal audits requested by potential clients, including interacting with auditor(s) throughout the process and ensuring a timely response to all resulting observations.
- Serve as the QA backup for performing audits and maintaining records for audits of material suppliers and contract laboratories to assure that they are capable of meeting the technical and regulatory requirements.

How to Apply:
Please click on the "Apply Now" button to begin the application process. You will be asked to upload a resume and cover letter. http://jobs.hr.wisc.edu/cw/en-us/job/495989/quality-assurance-document-control-specialist

Questions about the position can be directed to Melissa Henning, Human Resources Assistant, at 608-890-1388 or melissa.henning@wisc.edu.

To ensure consideration applications must be received by September 5, 2017

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If you need to request an accommodation because of a disability you can find information about how to make a request at the following website: http://www.oed.wisc.edu/478.htm

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NOTE: Please indicate in writing if you request that your identity be kept confidential. If you do not indicate your preference to remain confidential, the University may be required to disclose your identify and/or application materials. The identity of finalists and successful candidates will be revealed upon request. See Wis. Stat. sec. 19.36(7).

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UW-Madison is an equal opportunity/affirmative action employer.
We promote excellence through diversity and encourage all qualified individuals to apply.
A criminal background check will be conducted prior to hiring.
A period of evaluation will be required