

Jobs That Crossed My Desk Through April 23, 2017
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April 23, 2017

If interested in a listed position, contact the person whose information appears at the top of each listing. Individual listings of each executive search person are separated by string of stars. Multiple listings submitted by one recruiter are separated by straight lines.

Remember I'm not a recruiter and only distribute this listing to help bioscience industry professionals identify potential positions with contact person information provided where possible. These positions originated with individuals in my network. Note that recently I've begun to receive many listings via Linked In and in such cases, I've listed company website if not person who sent listing to me.

Jobs are materializing but with such a large pool of qualified professionals at this time, they fill up fast. Always be sure to check the website of recruiter or company to learn what jobs have popped up in between my publications. Unfortunately, I'm not able to post these every day but this tip should help you find newly posted jobs from the contacts sending the jobs below.

Be sure to join the Bio2Device Group (includes professionals from all life science sectors and functions) to access their list of positions which includes different universe of jobs. You must attend one of B2DG meetings to become member but application is free. See details at www.bio2devicegroup.org.

Nancy Cody
Wirth & Associates
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Director, Quality Micro
NC

This person assures systems and procedures for regulatory compliance are established and deployed. They periodically review the suitability and effectiveness of the quality system with executive management and manages regulatory inspections.

Qualifications

In depth knowledge of the regulatory environment for manufacture of medical products

Strong leadership skills and demonstrated success in managing a large team

Strong analytical and problem solving skills

Excellent verbal and written communication skills

Success working with multifunctional, global teams

Excellent interpersonal/communication/influencing/negotiation skills required

Demonstrated problem solving skills

Education and Experience

BS in science or engineering; advanced degree helpful

7 years management experience

Minimum of 10 years experience in Quality, Manufacturing or related field in the medical products industry

Manager II, Quality - Micro/Chem Lab
NC

This person will manage through subordinates the coordination of the activities of several sections or departments in the Quality organization. They are responsible for results in

terms of product quality and conformance to regulations and quality policies. In some instances, this manager may be responsible for a functional area and may not have subordinates.

Qualifications

Thorough knowledge of applicable procedures, specifications, regulations and standards

Ability to manage/supervise a large team of employees

Strong analytical and problem solving skills

Strong communication and leadership skills

Strong interpersonal/communication/influencing/negotiation skills

Strong project management skills

Education and Experience

BS in science or engineering; advanced degree helpful

7 years in Quality, Manufacturing, Engineering or related field

5 years of management experience.

Associate Director, Packaging Engineering, Commercial Manufacturing team

CA

10+ years of experience.

A Bachelors degree in science or related fields is required.

An advanced science degree such as MS, MD, PharmD, PhD or an advanced business degree such as an MBA is desirable.

Prior people management experience strongly preferred.

Manager, Quality Assurance

Pacific Northwest

Bachelor's degree at minimum

5+ Years work experience in the pharmaceutical industry strongly preferred

Demonstrate high standard of ethics, integrity and professionalism

Must be able to work while wearing personal protective equipment

Sr. Manager, Quality Control

Pacific Northwest

BS or MS in Chemistry, Pharmaceutical Sciences, Life Sciences or equivalent; PhD preferred

15+ years of relevant experience in QC or equivalent experience in commercial

pharmaceutical industry; 5+ years in a management role, particularly in a commercial GMP environment

Expertise in analytical method development, analytical method validation, and statistical quality control

Excellent knowledge of GMP, ICH, USP and global compendial regulations and guidance

Strong leadership and project management skills required to support a multi-client environment from small biotech through big pharma

Interact, cooperate and motivate across department and functions in a multi-client pharmaceutical manufacturing environment

Work in a fast paced pharmaceutical environment, able to work flexible schedules on short notice

Director, Packaging Design & Development

CA

Experience leading and managing packaging development teams for pharmaceutical applications.

Able to work with cross functional teams including R & D, Manufacturing, Marketing, Regulatory, etc.

Project management competencies in budgeting and resource planning and management.

Working knowledge of "Design of experiments" and other analytical tools.
Willingness and ability to travel both domestic and international up to 25% of the time.
Education

B.S. Degree in Packaging, Mechanical, or Materials Engineering with minimum 15 years of experience or an advanced degree with minimum 12 years of experience in the Pharmaceutical, Biologics or Medical device field for package design and development.

Analytical Chemistry Supervisor
Pacific Northwest

Bachelor's Degree in Science (at minimum)

2+ years' experience as an Analyst or Chemist

Minimum of 1 year experience in a GMP environment

Demonstrated ability to perform hands-on, detailed work, in a fast-paced manufacturing environment

Will handle hazardous materials and occasionally work in confined spaces

Must be able to work while wearing personal protective equipment

Principal Scientist, R&D

Pacific Northwest

PhD in Chemistry, Biochemistry, Engineering, or Pharmaceutical Science with a minimum of 5 years relevant experience or equivalent combination of education and work experience in a research and development setting

Broad knowledge in the field of DMPK and be able to confidently represent DMPK on multidisciplinary project teams

Proficiency in specialized software packages, e.g. WinNonlin, GastroPlus, MATLAB, is desirable

Background in fundamental physical and biological sciences

Is recognized as an expert in own area within the organization

Requires specialized depth and/or breadth of expertise

Interprets internal or external business issues and recommends solutions

Works independently, with guidance only in the most complex situations

May oversee activities of lower level personnel but primary role is individual contributor

Director, Quality Micro/Chem Lab

NC

Supervise, plan, organize, direct and evaluate all activities of the Quality Laboratory to ensure the safety and reliability of products, and to comply with quality and regulatory requirements. Making critical decisions to release raw materials, in-process testing and final release of finished products in a timely manner.

Qualifications

Must know quality laboratory operations and government regulations pertaining to pharmaceutical and medical device manufacturing labs. very well. Must have the ability of managing complex projects and resolving complex lab. issues. Must possess excellent supervisory and interpersonal skills, and be able to communicate with all level personnel and regulatory authorities. Should have advanced knowledge in Statistical Analysis, QSR, cGMP, CFR, USP and GDP. Strong leadership, project and people management skills, and ability to make critical decisions. Strong understanding of business and/or industry.

Bachelors Degree in biological science with 9-13 years' experience, or Master's Degree in microbiology with 7-11 years' experience, PhD in relevant scientific field with 4-8 years experience.

Minimum 5 years of management experience.

Medical Director, Pharmacovigilance Safety Physician, Corporate Drug Safety
CA

Minimum of 5 years pharmacovigilance drug safety experience including benefit/ risk analysis and safety evaluations required.

Experience with CNS therapeutic area is desired but not necessary preferred.

Product launch experience is desired preferred.

Experience with pharmacovigilance audit process. Prior experience in interactions with regulatory authorities on drug safety aspects as well as risk management strategies and pharmaco-epidemiology preferred.

Familiarity with common adverse event management databases (e.g. Argus) is preferred

Knowledge of MedDRA and WHO Drug coding dictionaries preferred

Ability to write SOPs and other working practices and documents within the context of clinical and post-marketing drug safety reporting required.

Ability to write risk management plans and periodic safety reports. Excellent clinical judgment and ability to communicate complex clinical issues in a scientifically sound and understandable way required.

Comprehensive experience with obtaining, analyzing, disseminating, and reporting safety information in compliance with safety regulations, including periodic safety reports, is required.