

Jobs That Crossed My Desk Through Sept. 15, 2010

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Sept. 15, 2010

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.

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 in free. See details at www.bio2devicegroup.org.

I have three openings in Southern California

Director Q/C salary \$125K to \$135K Manufacturer of Pharmaceutical API's

Director/Vice President Manufacturing salary \$150 to \$180K (see description below)

Vice President Q/A Q/C salary to \$180K (see description below)

Please send resumes to the contact information listed below. Call me with any questions.

Thanks for your help,

John Colantoni

JWC Associates

Phones: 732-792-2933 and 609-921-9090

E-mail: jwchh500@aol.com

Job Title: Director, Manufacturing Operations

Job Overview: Responsible for the strategic and operational leadership of Manufacturing Operations at the site. Direct the production management and staff in meeting custom, commercial and clinical manufacturing customer orders. Work with site as well as sales and marketing management in planning for the continued growth of the site operations which include a potential site expansion. The Director will provide effective communication within department, site and Group to achieve results, meet opportunities and solve issues. Assure compliance with FDA and EMEA regulations, ICH guidelines and State of California regulations. Lead the lean manufacturing efforts underway at site. This position will be based in **Southern California** directly reporting to the **Chief Operating Officer**.

Essential Job Responsibilities:

- Maximize the efficiency, quality and capacity utilization of the operations. Develop the methodology and framework for the operations staff to utilize to embrace lean manufacturing.
- Provide the leadership in department to set aggressive objectives, insure performance standards, conduct performance appraisals and employee development.
- Lead optimization of our production processes using both organic chemistry and chemical engineering to improve quality, yields and cycle time of products.
- Ability to handle multiple production projects simultaneously in a batch production facility in terms of management of resources, scheduling of facility and on-time high quality delivery.

- Partner with Product Development, Engineering, Quality, Regulatory Affairs, Marketing as well as the manufacturing teams within the Group.
- Insure robust technical transfer system to handle multiple technical transfers to and from site.
- Manage the manufacturing relationships with regulatory authorities, pharmaceutical and biotechnology customers.

Required Skills/Qualifications:

- Minimum undergraduate degree in Chemical Engineering or Chemistry. A Masters or PhD is strongly preferred.
- Minimum of ten years in cGMP API manufacturing experience with progressive management and supervision promotions.
- Experience in API bulk chemical batch operations, both in clinical development and NDA commercial, operations.
- Peptide manufacturing experience is strongly preferred.
- Experience in FDA, EMEA inspections with documented successful outcomes.
- Demonstrated achievements in lean manufacturing, process, yield and productivity improvements.
- Ability to juggle multiple tasks, deadlines and priorities. Must collaborate across organization and functional boundaries including customers as a team player and occasional team leader.

Job Title: Vice President, United States Quality Assurance & Control

Job Overview: Maintain, develop and implement all aspects of the Quality Assurance and Quality Control Systems at our two Southern California sites, as well as quality policies and procedures to adhere to FDA and global regulatory organizations. Assure compliance with FDA regulations, ICH guidelines and State of California regulations. This position will be based in Southern **California** directly reporting to the **Chief Operating Officer**.

Essential Job Responsibilities:

- Manage through team functions such as quality agreements, supplier audits, batch record review, annual product review, CAPA, complaint handling, document control systems, cGMP training of employees, clinical and commercial product release.
- Insure Quality System, cGMP and ICH guidelines are followed on site. Conduct annual analysis of upgrades to Quality System in terms of both Operations efficiency as well as new FDA or ICH regulatory changes.
- Partner with Regulatory Affairs, Manufacturing, Development, Marketing as well as Corporate Quality on customer projects, regulatory submissions, and harmonization of the Group's Quality standards across all Group sites.
- Establish career development and training plans for direct reports. Establish and monitor employee's annual objectives with goal of succession planning across Quality activities.
- Maintain our successful track record with FDA with both US sites.

Required Skills/Qualifications:

- Minimum undergraduate degree in Chemistry, Biology or Chemical Engineering. Prefer a Masters, PhD or PharmD in chemistry, biology, pharmacy or engineering.
- Minimum of five years at a Director or Senior Director level overseeing in-house quality programs of at least one FDA inspected and approved active pharmaceutical ingredient facility and the QA/QC staff.

- Minimum of twenty years of experience in quality assurance, quality control and compliance in the cGMP active pharmaceutical ingredient contract manufacturing industry or pharmaceutical company that internally produces their APIs.
- Experience in FDA, EMEA inspections with documented successful outcomes.
- Demonstrated ability to apply comprehensive, in-depth understanding of pharmaceutical industry regulatory compliance with emphasis on cGMP, IND, and NDAs.
- Effective management of relationships with FDA, pharmaceutical and biotechnology customers
- Experience in all aspects of Quality Assurance from preclinical to commercial product phases.
- Ability to juggle multiple tasks, deadlines and priorities. Must collaborate across organization and functional boundaries including customers as a team player and occasional team leader.

New Career Opportunities at careers.ModernMedicine.com

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- [Columbia University Dept of Urology](#), Urologist
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- [Yale New Haven Hospital](#), Women's Center Physician
- [Top's Medical Arts Center](#), Emergency And Internal Medicine
- [PracticeMatch Services LLC](#), Adult Urgent Care Physician
- [Source One/Allegiance Health](#), Dermatologist
- [Island Eye Center](#), Glaucoma Specialist
- [Holzer Clinic](#), Urologists

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This job came from Fred of Bio2Device Group Sept. 13
 Contact <http://ncompassinc.com/jobs/1136.html> for reply.

Position Title: Sr. Optical Engineer- Job Order #1136
 Reports To: Director of Product Develeopment
 Location: South Bay
 Company: Private
 Salary Range: DOE

Summary

Our client is looking for an individual to support the development and manufacturing of its expanding line of innovative instruments. Duties will include: designing and testing hardware; integrating optical and opto-mechanical components; developing and executing test plans; troubleshooting prototypes; and maintaining quality control of production parts. The individual will support design verification through optical bench testing and tolerance studies and will work in a multidisciplinary team environment including electrical, optical, and mechanical engineers.

Skills/Experience Requirements:

- o Requires high degree of problem solving, communication skills and teamwork
- o Proficiency with optical design tools such as OSLO, ZEMAX (or equivalent)
- o Track record of optics designs that were launched into the marketplace
- o Experience in lens design, systems design, geometrical and physical optics.
- o Five years in an optical systems product development setting. Key participation in the test and integration of successfully shipped products is strongly preferred.
- o Experience with optical alignment and metrology techniques, including the use of autocollimators, alignment telescopes, and interferometry.
- o Experience with radiometric & photometric measurements using photodiodes, spectrometers, laser & white light sources, and integrating spheres.
- o Skills in optical mounting and opto-mechanical assembly as demonstrated by successful programs or shipped products are required.
- o Understanding of optical drawing standards and Geometric Dimensioning and Tolerance. Knowledge of SolidWorks is desired.

Responsibilities:

- o Applies optical engineering principles and concepts in the design, test and system integration of high performance optical and opto-mechanical systems and sub-systems for near-infrared (NIR) ultrafast laser beam shaping and delivery
- ? telecentric beam scanning
- ? optimized 3D beam delivery
- ? optical coherence tomography (OCT) and video microscopy
- ? optics as surgical elements (bio-compatibility/sterilization/disposable)
- ? Comfortable making complex, multidisciplinary tradeoff recommendations in the face of incomplete information typical to new product development
- o Delivers robust designs accounting for cost, component variability, vibration & shock
- o Contributes as technical expert on manufacturing techniques, optics vendor qualification, and transfer to manufacturing
- o Collect & review data and communicate status of technical issues by preparing technical reports and presentations.
- o Initiates, executes & reviews changes via Company's ECO process.
- o Provide incoming optical component inspection, tracking of component issues, and vendor interfacing to assure product quality.
- o Develop tooling along with assembly, alignment, and optical test procedures.
- o Creates intellectual property
- o Reports to Director of Product Development

Education Requirements:

- o B.S or M.S. in Optics, Laser Physics (or equivalent) and more than six (6+) years of relevant experience required
- o Advanced degree and Medical Device experience preferred

FYI, this Process Technician II, BioAnalytical, was just posted. Apply to Genencor at http://www.genencor.com/wps/wcm/connect/genencor/genencor/jobs_and_careers/jobs/jobs_en.htm

Process Technician II, BioAnalytical
Genencor, A Danisco Division Location: Palo Alto, CA
Posted Date: Sep 09, 2010
Position Type: Full Time Job Code: Process Technician II, BioAnal
Required Education: High School (or equivalent)
Areas of Expertise Desired: Bioanalytical Services
Biochemistry
Chemistry

Description? This position will provide an integral role in supporting the Process Analytical group, which plays a key role in providing analytical support for development and scale-up of our many products.

- Core responsibility will be to provide assay support to our fermentation, recovery and formulation groups, through the use of primarily colorimetric and HPLC assays.
- Operate and maintain automated enzymatic assay equipment, HPLC systems, and other analytical instruments as needed.
- Support assay development and assay transfer to and from our global R&D and manufacturing sites.
- Data analysis and interpretation are important parts of this position, as is communication of results to scientists and collaborators.
- Participate in continuous team efforts to improve process analytical capabilities, team efficiency and data quality. Requirements? Minimum education of Associates Degree in Science required. Bachelors Degree in Chemistry, Biochemistry or Biology preferred.
- Possess basic lab skills, basic problem solving skills and strong communication skills in order to be able to consistently generate and deliver high quality analytical data.
- A desire to learn and excel, be independently motivated , have mechanical aptitude, strong problem solving skills.
- A familiarity with computer-based systems, display strong attention to detail, and must be able to work effectively and safely in both individual and team environments.
- A familiarity with UV-vis spectrometers, HPLCs and other analytical instruments is a plus.
- Must be able to work weekends and overtime as required.

Other positions at Genencor are:

- Senior Regulatory Specialist, Food Denmark, Aarhus Other EN-02345 APPLY BY 14 september 2010 We are currently seeking an outstanding individual to join our new global Genencor regulatory team based in Brabrand, Denmark Genencor, a division of Danisco A/S.
- Research Assistant, Molecular Biology USA, California, Palo Alto Research & Development EN-02289 APPLY BY 15 september 2010 We are currently seeking a dynamic individual to join our Expression & Molecular Biology Group.
- Research Assistant, Formulation & Integrated Systems USA, California, Palo Alto Research & Development EN-02286 APPLY BY 15 september 2010 We are seeking a highly energetic researcher to join our R&D Formulation and Integrated Systems Group in Palo Alto, CA.
- Scientist II- Microbial Physiology USA, California, Palo Alto Research & Development EN-02361 APPLY BY 30 september 2010 The successful candidate will work with a team of scientists, focused on the understanding and controlling of microbial physiology for the production of chemical products.
- Research Associate/Senior Research Associate, Chemical Engineering USA, California, Palo Alto Research & Development EN-02363 APPLY BY 30 september 2010 We are looking for an outstanding individual to join the Research and Development team in Palo Alto, CA.

- Senior Scientist, Chemical Engineering USA, California, Palo Alto Research & Development EN-02365 APPLY BY 30 september 2010 We are looking for an outstanding individual to be a part of an exciting Research & Development collaboration for a breakthrough bio-based process to manufacture Biolsoprene™ products using renewable raw materials.
- Sales and Marketing Development Program, Grain Processing USA, Iowa, Cedar Rapids Sales & Marketing DW-CR-10 APPLY BY 30 september 2010 If you're just about to graduate and you're looking for a challenging role where your business and technical skills can be applied in a leading industrial biotechnology company, Read On!
- Process Technician: 14L USA, California, Palo Alto Research & Development Process Technician: 14L APPLY BY 30 september 2010 As a Process Technician in Genencor's Operations group, you will play an integral role in supporting the development, scale-up, and transfer of production processes for our new biotechnology products utilizing state-of-the-art facilities which range in scale from 14L to 3,000L capacities.
- Process Technician: Pilot Plant USA, California, Palo Alto Research & Development Process Technician: Pilot Plant APPLY BY 30 september 2010 As a Process Technician in Genencor's Operations group, you will play an integral role in supporting the development, scale-up, and transfer of production processes for our new biotechnology products utilizing state-of-the-art facilities which range in scale from 14L to 3,000L capacities.
- Process Engineer USA, Iowa, Cedar Rapids Technology ENG-CR-10 APPLY BY 11 oktober 2010 Excited about large scale process development and looking to be an integral team member at our Cedar Rapids facility? Read on!
- Process Technician USA, Iowa, Cedar Rapids Operations TRA-CR-10 APPLY BY 11 oktober 2010 With your excellent teamwork and communication skills, you will play an integral role in supporting the development, scale-up, and transfer of production processes for our new biotechnology products utilizing state-of-the-art facilities.
- Environmental, Health & Safety Representative USA, Iowa, Cedar Rapids Operations JO-CR-10 APPLY BY 11 oktober 2010 An outstanding opportunity to apply your knowledge and skills in EH&S within a team driven, biotechnology environment!
- Maintenance Technician USA, Iowa, Cedar Rapids Operations BRP-CR-10 APPLY BY 11 oktober 2010 An exceptional position if you enjoy the challenge of maintaining industrial plant equipment and working in a team driven environment.

Potentially interesting job on Craigslist for someone in transition:

Questcor Pharmaceuticals, Inc. is a specialty pharmaceutical company located in Union City that markets and sells brand name prescription drugs through a direct sales force and international distributors. We focus on the treatment of central nervous system diseases which are served by a limited group of neurologists. Both positions are located in Union City, CA.

Part-time, **Temporary Administrative Assistant** (approximately 30 hours per week);

possible temp to regular employment

The successful candidate will provide part-time, temporary administrative support to teams within the Commercial Operations department, with a specific focus to Marketing. The position will require good interpersonal skills and a willingness to learn in a fast paced, team oriented work environment.

Responsibilities:

Provide administrative and project support to the Commercial Operations team
Coordinate meeting and event logistics for professional conferences and vendor meetings, as well as internal sales & marketing meetings
Provide support to inbound Questcor phone line and assist with outbound support for team by faxing, printing, scanning, and mailing documents
Provide support with vendor management, including processing contracts and properly triaging calls when necessary
Assist with purchasing/financial process including obtaining approvals on purchase orders, invoices, data entry, and assistance with maintaining reports
Assist with special projects as needed

Skill Set/Qualities:

Demonstrated ability to work in a fast-paced environment
Strong organizational skills and interpersonal skills
Good verbal and written communication skills
Computer literacy (word processing, graphics and database)
Strict attention to detail; work well under pressure while meeting tight deadlines
Ability to prioritize workload and manage multiple tasks simultaneously
Desire and ability to communicate/interact with others and promote teamwork; enthusiastic and cooperative attitude

Requirements:

?Bachelor degree or equivalent experience
?Minimum 3 years administrative experience, preferably in Marketing

Temporary Project Coordinator/Admin Assistant (approximately 30 hours per week) ? 4 to 6 month assignment

The successful candidate will provide part-time, temporary administrative support to personnel in the Medical Affairs department. The position will require good interpersonal skills and a willingness to learn in a fast paced, team oriented work environment.

Responsibilities and Skill Set

?Similar to those outlined in the Admin Assistant role listed above but at a higher level of proficiency

Requirements:

?Bachelor degree or equivalent experience
?Minimum 5-7 years administrative experience, preferably in the pharmaceutical industry
?Science background or degree a plus

Include your name and the position title in the subject line of your email and send your resume and salary requirements to: hr3@questcor.com.

Please contact Julie@JGBBioPharma.com if you are interested and qualified. Julie Bukar
Managing Director
JGB BioPharma Consulting Inc.
650-520-3433
Julie@JGBBioPharma.com
www.JGBBioPharma.com

Clinical Accounts Payable Clerk -- 3 - 6 month Contract; 15 - 20 hrs/week (San Francisco Bay Area)

DESCRIPTION:

Input Invoices into accounts payable system in order to insure timely payments to vendors

EXPERIENCE AND QUALIFICATIONS:

Attention to detail is essential
Good computer skills
Accounts payable experience is a plus
Previous work in the pharmaceutical industry, especially clinical research is a plus
College Degree is a plus

GCP Auditor – 3 month Contract or Contract to Permanent (San Francisco Bay area) 19TYZ

Please contact Julie@JGBBioPharma.com if you are interested.

DESCRIPTION:

Reports to VP Quality
Plan and implement global audits of clinical trials and pharmacovigilance activities.
Responsibilities include, but are not limited to:

- Perform compliance audits of clinical sites, CROs, vendors, clinical systems, pharmacovigilance, master files, and clinical study reports
- Identify compliance issues and recommend corrective actions
- Analyze compliance and auditing data to assess the overall scope of compliance/noncompliance and identify opportunities for process improvements
- Act as a resource for GCP compliance questions and issues that arise
- Assist with GCP training activities
- Assist with regulatory agency inspection activities
- Ensure standard operating procedures are in place and provide input to SOPs from other related functional areas
- Conduct internal audits to ensure compliance to internal procedures and to current regulatory requirements.

Ensure proper filing, archival and storage of Clinical study documentation
EXPERIENCE AND QUALIFICATIONS:

Bachelor of Science or equivalent
3-5 years experience in pharmacovigilance and GCP auditing
Experience in regulatory authority inspections is a plus
In-depth knowledge of GCP regulations and ICH guidelines
Good interpersonal, written and verbal communication skills
Strong problem solving and organizational skills
Capable of working in a team environment and independently
Ability to manage multiple tasks in a changing environment

Contact:

Jessica Leveille
Manager, Biomedical Delivery Services at Orbis Clinical
Direct line (781) 496-3133
Direct fax (866) 855-5872
Email JLeveille@orbisclinical.com
Web www.orbisclinical.com
100 Unicorn Park Drive
Woburn, MA 01801

Regulatory Medical Writers (Clinical) – Northern NJ, On site

Length of Assignment: 6 months contract-to-perm

Start Date: As soon as possible

Client: Our client is a multi-billion dollar company and a worldwide leader in the field of pharmaceutical and medical products. They are a research-based company whose purpose is to bring diagnostic and therapeutic innovations to the healthcare community with a commitment to advance patient care and to shape the future of medicine. Their focus lies in the areas of Women's Healthcare, Oncology, Diagnostic Imaging, and Neurology markets.

Position: The Scientific Writer is the medical writing expert responsible for the research, writing and editing of regulatory documents. This person will provide full lifecycle support from clinical study protocols through regulatory dossier preparation and submission.
Please note: We are not looking for manuscript writers, tech writers, drug safety specialists that have written sections of submissions, no writers that only do slide kits and presentations, etc. Must be regulatory/clinical writer. Also, editing/review experience is not enough.
Must have written at least 2 different types of documents (protocols, IBs, CSRs, etc)
It's ok if they haven't authored a full submission.

Responsibilities:

Assuring quality and timely preparation of regulatory documents across all therapeutic areas.

Required Skills:

BS or equivalent with 6 years experience in a scientific discipline and a minimum of 4 years in Medical writing
OR MS, PhD, or equivalent with a minimum of 2 years previous industry writing experience

AND

Excellent written and oral communication (English)

Demonstrated working knowledge of scientific principles

Familiarity with all phases of medical research and ability to learn new medical concepts quickly

Familiarity with statistics and experimental design

Ability to summarize complex data and identify relationships

Medical Writing Coordinator/Specialist- Northern NJ, On site

Length of Assignment: 6 months contract to perm

Start Date: As soon as possible

Client: Our client is a multi-billion dollar company and a worldwide leader in the field of pharmaceutical and medical products. They are a research-based company who's purpose is to bring diagnostic and therapeutic innovations to the healthcare community with a commitment to advance patient care and to shape the future of medicine. Their focus lies in the areas of Women's Healthcare, Oncology, Diagnostic Imaging, and Neurology markets.

Position: The Medical Writing Specialist is responsible for tracking, quality control, and timely completion of the document components for complex medical writing projects, including Clinical Study Reports (CSRs), protocols, and other regulatory documents. This individual will not be writing the content of the submissions, but will review, edit and compile the components prior to publishing.

Responsibilities:

Work together with key interface partners (ex: Study Management, statistics, and Programming) to facilitate the completion of clinical study reports and their appendices. Using project management skills to track, review and ensure timely completion of high quality regulatory documents

Ensure the study file components (ex: Investigator CVs, protocol and amendments, sample case report form) needed for CSRs are checked into the electronic archive on a timely basis and meet all global standards and regulatory requirements

Act as a resource on all format and style related issues to ensure consistency within submission related documents prepared by Medical Writing or external partners. Maintaining departmental and project-specific style guidelines to reflect new agreements and changes due to SOPs and regulatory guidelines

Assisting scientific medical writers in the review of protocols and case report forms to ensure that methods are clearly presented, data categories are clear, and terminology is consistent

Performing real-time edits to clinical documents during comment review and resolution meetings

Proofreading, reformatting and editing document text, as required, to ensure that all documents for a writing project meet all formatting and publishing requirements prior to final QC, compilation and electronic publishing

Managing the review and approval of documents in the document management system using standard procedures

Required Skills:

BS or AS degree

Strong electronic documentation and word processing skills

Excellent written and oral communication (English)

Excellent interpersonal skills

Familiarity with clinical research, statistics, and regulatory submission requirements

Understanding of regulatory guidelines (ICH, FDA, etc)

Experience in a Medical Writing group would be a plus!

This is a document formatting position, and 90% of it is formatting in *Word*

Must be an expert in *Word* and formatting in *Word*, no exceptions - should know all the ins and outs, can format, style, design templates, etc.

Document management system knowledge is important

Adobe experience is important Med Writing experience would be extremely helpful

New Career Opportunities at careers.FindPharma.com

Pfizer, Astellas, Med Exec International, i3 and ClinForce are just a few of the industry leaders using careers.FindPharma.com every day to find professionals like you. Check back often for new job postings!

If interested, contact Gail Williams at (206) 708-1326 The same company is also seeking Director Engineering for same team. The company will cover relocation.

The Director, Development - Molecular Biology – San Diego- manages staff engaged in advanced product development and systems integration/support.

Additionally:

- Oversee multiple projects and system interfaces.
- Manage a technical group and associated resources responsible for the definition, development, and approval of high impact product designs or processes.

Responsible for implementing and maintaining the effectiveness of the quality system.

- Monitor projects across multiple product development groups or disciplines to ensure major milestones are met.
- Make final decision on project resource or capacity issues; initiate and coordinate planning and action to address those issues.
- Prepare, consolidate and manage budgets.
- Determine and approve actions to deal with variances.
- Define long term strategy for functional area.
- Review and approve proposals ensuring system integration requirements are met.
- Keep abreast of developments in technology or design methods and forecast future trends.
- Design and implement an organization that responds to the needs of the business and provides a meaningful work experience for employees.

Working knowledge and hands-on experience with of microfluidics, systems integration and miniaturization, and device manufacturing is preferred.

Previous management experience and skills in project management and planning are preferred.

Skills/Experience Requirements Basic Qualifications:

B.S./M.S. in Engineering, Life Science or a closely related discipline and 6+ years technical experience with 8+ years of supervisory or management experience, or a Ph.D. in Engineering, Life or Physical Science, or closely related discipline and 3+ years technical experience with some supervisory or management experience.

Knowledge of regulations and standards affecting IVDs and Biologics.

Demonstrated advanced product development, systems integration, process design, project leadership experience and a demonstrated record of research which advances technology within the division.

Must be US citizen and able to pass background investigation for eventual US Government security clearance.

Preferred Qualifications:

Working knowledge and hands-on experience with of microfluidics, systems integration and

miniaturization, and device manufacturing is preferred.
 Previous management experience and skills in project management and planning are preferred.
 Ability to learn new techniques quickly and stay informed of new research and technologies.

Education Requirements

B.S./M.S. in Engineering, Life Science or a closely related discipline

From Stryker online:

http://jobs.brassring.com/1033/ASP/TG/cim_jobdetail.asp?SID=^6R_slp_rhc_sitrxKWeQzaYY4tt_slp_rhc_R9jXgyEp//1xTXBFENbePS5Hf0atTYjq0MJJdPDCB7NwOEO1ymeR0w/E_C_R_L_F_3BuCYgKFFFujlEp7S4u2YQUIdek6ZkY=&jobId=1250665&type=search&JobReqLang=1&recordstart=1&JobSiteId=78&JobSiteInfo=1250665_78&GQId=70

Job Title	International Marketing Associate
Division	Stryker Endoscopy
Location (Country - State)	United States - California
City or Sales Region	San Jose
Business Function	Marketing
Shift	N/A
Education and/or Special Training	<ul style="list-style-type: none"> •B.A. or B.S. degree required; M.B.A. or Master's degree preferred •3.0 Minimum GPA Required
Job Description	<p>GENERAL DESCRIPTION: Assists in the implementation and execution of the marketing and sales support program of Stryker Endoscopy to the International Markets.</p> <p>ESSENTIAL FUNCTIONS:</p> <ul style="list-style-type: none"> •Will provide sales support by answering and/or resolving customer questions and /or issues on assigned products both telephonically and in person. •Will process and /or follow up on customer sales orders and requests for emergency equipment loans. •May develop and/or initiate the development and production of marketing support material (e.g. product brochures, mailers, product update memos, etc.). •Will assist in the marketing of our products through exhibits, trade shows and educational lab execution. •Will travel extensively to International locations, providing marketing or sales training •May provide input in the new product development process. •Will submit periodic reports on assigned topics.
Qualifications/Work Experience	<ul style="list-style-type: none"> •0-2 years in a marketing, sales or related position.
Percent Travel Required	50-75
Requisition ID	12825BR

Apply online or to inhouse recruiter
Email: christy@tuescher.org
Phone: 408-523-6935

Job Title : Consumer Marketing Manager
Job Number : 397141
Location : Sunnyvale, CA
Full/Part Time : Full-Time
Shift : Regular

Primary Function of Position:

Intuitive Surgical is looking for a marketing manager experienced in both consumer and B to B. This person should be experienced in on/offline marketing, promotions and PR for national campaigns. Individual must be self-driven 'go-getter', organized, a problem-solver, creative and analytical. This person will report to the Director of Marketing and work closely with the sales, product marketing, design, copywriting and PR teams.

Roles and Responsibilities

This position has responsibility and authority for:

- Oversee direct to patient marketing to specific medical specialties/service lines.
- Manage short and long term programs to drive consumer acquisition.
- Oversee partnerships/sponsorships and execute against contractual commitments.
- Drive critical relationship with content syndicators, and information websites to influence online content.
- Lead research qualitative and quantitative research programs.

Provide general support to the consumer and B2B marketing team.

Competency Requirements

Competency is based on: education, training, skills and experience. In order to adequately perform the responsibilities of this position the individual must:

- Savvy online marketer with 9+ years of consumer and/or B2B experience.
- Online marketing experience, email, and social media programs.
- Experience with offline marketing media campaigns and events.
- Excellent and creative written and oral communication skills.
- Proven ability to meet and exceed quantitative goals and consistently meet deadlines.
- Self-starter who takes ownership of projects.
- Excellent problem solving abilities and time management skills.
- Ability to manage multiple tasks in a time sensitive environment.
- Strong interpersonal skills; ability to work with and manage cross functional teams to reach common project goals.
- Healthcare industry experience a plus, not a requirement.
- College degree required.
- 15% travel required.

Four positions have been posted since July 15 on CACO Free Job Links website (<http://www.caco-ca.org/asp/jobs.aspx>). The summary of those positions is found on the website.

Employer	Position
SRI International	Supervisor - Analytical Chemistry
University of California San Francisco	Bioanalytical/HPLC-Mass Spectrometry Scientist
University of California San Francisco, Institute for Neurodegenerative Diseases	Bioanalytical

Researcher " LCMS Focus
ChemoCentryx Inc. DMPK Consultant / Part-time contractor

Jobs That Crossed My Desk Through Sept. 4, 2010

Contact:

E-mail your CV/resume to
hchenconsulting@gmail.com
and/or telephone Hiram Chen at 416-627-7462

Senior Medical Writers – Greater Boston Area

A large multinational pharma/biotech company based in the Greater Boston Area is seeking senior-level Medical Writers. Experienced candidates must have scientific, analytical and strategic skills working both independently, proactively and as team members preparing all types of clinical regulatory submission documents.

Qualifications:

Minimum BSc (MSc or PhD preferred); experience in multiple therapeutic areas, however, background in oncology and biologics drug development strongly preferred.

Jane Pondel
Sr. Clinical Recruiter
Delta Pharma, a Randstad company
Four Parkway North, Suite 120
Deerfield, IL 60015
T 847 527 6118
F 847 317 9543
jpondel@delta-pharma.com
www.delta-pharma.com

Senior Medical Writer, Contract – Leiderdorp, Netherlands

The individual is required to have at least a BA/BS degree or equivalent with 7+ years relevant experience (5 years with MS/MA). The individual must be able to perform independently without appreciable direction regarding technical aspects. The individual needs effective oral and written communication skills and effective interpersonal skills. The individual must be proficient with MS Word and the use of styled templates. The individual should be familiar with guidelines and regulations that apply to the assigned document type(s) (e.g., ICH E3 and FDA guidance on study tagging files/Comprehensive Table of Contents Headings and Hierarchy for study report).

Preferred: The individual has at least 5 years experience in writing regulated documents and would be considered a technical expert for the assigned regulated document

Key Tasks and Competancies: The individual must successfully interact with in-house medical writing contact and multifunctional team members (e.g., statistics, clinical, medical, regulatory, etc) and successfully complete the assigned writing responsibility.

The individual must be able to correctly use provided templates and follow provided writing guides.

Tasks may include:

Formulating a document plan in collaboration with company's scientific team (concept meeting).

Incorporating the scientific team's concepts and strategies into the provided document architecture.

Assembling and compiling information into the provided document architecture.

With direction of company or designee, building persuasive and scientific-based arguments that support the regulatory or other purpose of the document.

Adhering to principles of content re-use.

Producing a draft document that is consistent with the document plan.

Productively interacting with company scientific reviewers in review and editing of draft document.

Revise document drafts based on the review comments, addressing all comments in collaboration with responsible content authors and document scientific lead (primary conceptual leader).

Ensure data consistency and document integrity by critically evaluating comments, in collaboration with responsible content authors and primary conceptual leader as necessary, and incorporating them appropriately.

When authoring team or reviewers are in disagreement, work with primary conceptual leader to facilitate and negotiate issue resolution and decision-making and incorporate outcomes into the draft/final document. Document the resolution and the rationale of significant decision(s).

Edit document to ensure document quality in regard to correctness of structure, content, language, and/or style.

Facilitating document approval and finalization.

Contact:

Contact:

Elizabeth Caselton, Principal
Marcom Choices Staffing
Executive Search and Contract/Temporary Staffing High Tech Product Marketing & Corporate
Communications PO Box 620632
Woodside, CA 94062
elizabeth@marcomchoices.com

Phone: 650-851-9055

My agency, Marcom Choices Staffing is conducting executive search for a pharmaceutical company on East coast. Location is outside of New York City.

Pay range for the Senior Director will be \$165-175K, but for the right person may consider a salary close to \$200,000. Also they can offer relocation package if needed.

Feel free to pass this job description on to colleagues who may be interested from your network. Resumes submitted to elizabeth@marcomchoices.com

The Senior Director Communications and Media Relations, is responsible for all communications (external and internal) related to the pharmaceuticals business and its products. This position is responsible for all communications/public relations and the results of those efforts, including media strategy, programming, issues management and media relations. Further, this position will ensure consistent messaging internally and externally to achieve business unit and company objectives.

- Responsible for all strategic development and implementation of proactive product communications and public affairs programs:
 - enhances awareness and acceptance of key brands/franchises among external and internal stakeholders (i.e., physicians, patients, caregivers, payors, advocates, legislators, employees) and the general, trade and on-line media;
 - develops integrated campaigns to create and manage stakeholder perceptions and influence healthcare choices that support business goals and brand sales targets;
 - successfully navigates media for new product entries;
 - designs and implements proactive and reactive social media plans for brands, including issues management
 - manages issues associated with products to protect the company and brand reputation.
- Serves as the primary communications counsel to the Chief Commercial Officer, brand teams; overseeing strategic direction, execution, message delivery and results
- Ensures close coordination and consistent strategic communications through internal vehicles; partners closely with Internal Communications to business goals; provides oversight and strategic guidance to internal communications strategy as it relates to commercial operations business and products
- Oversees the strategic direction, execution and results of outside public relations/public affairs agencies and teams; responsible for overall ROI.
- Works with little supervision, supervises communications professionals and coordinators, as needed; and contributes to the professional development of staff, including training, coaching, reviews and performance measures.
- Operates in a matrix environment with key interfaces to other communications colleagues, U.S. Marketing and Medical Affairs, U.S. Government Affairs and Public Policy and Strategic Advocacy, External Global Marketing, Global Product Communications, Corporate Media Relations and Investor Relations.

- Develops and implements a strong, positive news flow for the clients business initiatives
- Anticipates, prepares for and manages media issues with the press
- Provides senior counsel and oversight on brand communication strategy and programming
- Understands commercial, governmental and legal strategies, and advising of appropriate communications tools to achieve objectives
- Ensures close coordination and timely reporting with Corporate Communications in Paris

Key Internal and External Relationships:

External - Business, consumer, trade and online media, government officials, patients, KTLs/investigators and third-party groups.

Internal - Commercial Operations, Internal communications; Regulatory; Medical Affairs,; Global Marketing; Corporate Communications; Legal

- Bachelor of Science/Bachelor of Arts, specifically in Communications, Journalism and/or Public Relations.

- Seven to 10 years in a Corporate Communications or Agency environment, with an emphasis in Internal Communications and writing.

The client will relocate the right person.

FYI. Submit qualified resumes to Careers@Freeslate.com.

Location: Sunnyvale, CA

Posted Date: Sep 01, 2010

Position Type: Full Time

Job Code: 000112

Required Education: Masters Degree

Areas of Expertise Desired: Biochemistry

Chemistry

Clinical Research

Research

Description WORKFLOW ARCHITECT

JOB SUMMARY:

The position will be working in a fast-moving, innovative environment, and has particular responsibility for working with customers to understand their current lab and scientific workflow needs and configuring solutions and proposals that provide step-change impact based on Freeslate offerings. This position requires an individual who can interface with customers working in a broad array of areas including catalysis, industrial formulations, home and personal care, polyolefins and polymer, refining and biomass.

JOB RESPONSIBILITIES:

- Triage and qualify early stage leads and opportunities
- Provide technical and applications expertise to sales team to interface with customers, including at their sites

- Scope and understand specific customer applications to define project concepts and scope
- Generate configuration and concept options for qualified opportunities
- Generate technical proposals in the voice of the customer

-
Work with the marketing and strategic teams to define general application needs for target segments (catalysis, industrial formulations, home and personal care, polyolefins and polymer, refining and biomass)

Freeslate is a privately held company of ~100 employees that provides products and related services for high throughput research. Based on its proprietary laboratory automation technology, high-throughput pressure reactors and integrated LEA (Lab Execution and Analysis) software suite, the company enables step-change gains in its customer's productivity and innovation by delivering seamlessly integrated workflows. Relying on an experienced team of engineers, software developers and scientists, Freeslate works closely with their customers to design, develop and implement automated solutions that transform their approach to critical R&D work processes, accelerating innovation. Serving customers for more than a decade, our business has provided high-throughput solutions to a wide range of industries including pharmaceuticals, energy, chemicals, and consumer products. Freeslate is headquartered in Sunnyvale, California, with direct sales and service presence in North America, Europe and Asia. We have comprehensive and competitive compensation and benefits offerings with a comfortable and collegial work environment. If you are interested in working with leading edge technologies with the brightest minds in high throughput research, Freeslate is the place for you.

Freeslate is an Equal Opportunity Employer that is committed to diversity and inclusion. Our hiring decisions are made without regard to race, color, religion, creed, disability, genetic information, national origin, gender, gender identity and expression, age, sexual orientation, marital status, or veteran status.

Submit qualified resumes to Careers@Freeslate.com. **Requirements REQUIRED** EXPERIENCE AND SKILLS:

- Relevant domain expertise in the field, and ability to talk with and guide customers in technical discussions
- Experience in applied lab automation
- Experience in developing novel methods or work processes
- Experiences generating proposals
- Successful track record of delivering quality work product in terms of proposals, developed systems, or novel work processes

ADDITIONAL REQUIREMENTS:

- Masters in Chemistry, Chemical Engineering, or Materials Science. PhD preferred

-
5+ years relevant experience in industrial experience with an ability to interface with customers and the market as an authority in the field

- Travel approximately 25-40% to support pre-sales discussions
- Must be well organized and enjoy working in a dynamic work environment
- Must be an excellent communicator with strong presentation skills

Please contact Julie@JGBBioPharma.com if interested.

Julie Bukar
www.JGBBioPharma.com
650-520-3433

I am looking for a Contract Clinical Operations person for a Client. This will be a 4 - 6 month contract; 40 hr/week. Work on site (but 1 day from home office OK). Very little travel. In-house position managing the CROs.

Desired characteristics are:

- Experience conducting complex in-patient studies, such as in an acute care or surgical setting
- Experience in study start up
- Experience in small / start - up companies
- Minimum of 5 years direct clinical operations experience with a minimum title of Clinical Research Associate II.
- Must be able to commit for 4 - 6 months as this is a key position

Contact: Dan Newhall
Managing Partner – Client Services
NCompass Recruiting Services, LLC
www.ncompassinc.com
Office: 415.738.7878 x 102
Mobile: 415.637.1974

Job Order #1144
Position Title: Manufacturing Engineer – Disposables
Reports To: Director of Operations
Location: South Bay
Company: Private

Position Overview

This individual contributes the engineering necessary to support the manufacturing of disposable products. S/he develops internal processes and procedures for manufacturing/service; works cross functionally to effect design requirements for manufacturability and cost optimization, performs validation functions and researches and resolves quality issues. Additionally, coordinates with suppliers and outside contractors to achieve company manufacturing and quality goals. The ideal candidate is a self-starter that exhibits good judgment and can pursue projects with little instruction from day-to-day.

Job Functions

- Plans engineering program support and performs engineering tasks to support assigned product.
- Supports manufacturing in all engineering issues including documentation, test, component evaluation, Product Verification, Process Validations, customer failures, performance issues and processing engineering change orders.
- Assists in achieving cost-of-goods reduction objectives.
- Resolves engineering problems and performs testing to evaluate and analyze engineering issues with products.
- Prepares and approves design changes.
- Coordinates engineering product support with Production, R&D engineering, Quality, Planning and Purchasing.
- Works with R&D engineers and suppliers to concurrently develop products for manufacturability and involved with new product introductions.
- Generates manufacturing work instructions and tracking documents to meet QSR and ISO requirements.
- Designs and manufactures or procures fixtures, equipment and other devices as required. Performs and documents all IQ, OQ and PQ activities as required on production fixtures and

equipment.

- Defines, authors, and releases new procedures, work instructions, travelers and/or tracking documents to control and define manufacturing and service functions and to validate processes, equipment, and/or fixtures.

Collects and reports on product failure/root cause data collected during production activities to support current product improvement and future product development.

Requirements / Skills

To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill, and/or ability required. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Education/Experience:

- BS in Mechanical or Materials Engineering is preferred but equivalent work experience is acceptable.
- Familiar with Injection molding processes, ultrasonic welding, and UV cure adhesives.
- 4 years experience in a medical devices environment.
- Working knowledge of manufacturing of medium to high volume disposables and related automated processes.
- Strong knowledge of FDA and ISO Quality System Regulations
- Excellent written and oral communication skills
- Excellent team-work skills and ability to work well with a multicultural workforce.
- Proficient in MS Office (Word, Excel, Power-point)
- In addition, this person must be high-energy, enthusiastic, creative, and willing to drive projects through to completion on schedule and within budget.

Language Ability:

Ability to read, analyze, and interpret common scientific and technical journals, financial reports, and legal documents. Ability to respond to common inquiries or complaints from customers, regulatory agencies, or members of the business community.

Math Ability:

Ability to apply advanced mathematical concepts such as exponents, logarithms, quadratic equations, and permutations. Ability to apply mathematical operations to such tasks as frequency distribution, determination of test reliability and validity, analysis.

Reasoning Ability:

Ability to define problems, collect data, establish facts, and draw valid conclusions. Ability to interpret an extensive variety of technical instructions in mathematical or diagram form and deal with several abstract and concrete variables.

Computer Skills:

To perform this job successfully, an individual should have knowledge of Development software; Design software; Project Management software and Manufacturing software.

Physical Demands:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions. While performing the duties of this Job, the employee is regularly required to sit. The employee is frequently required to use hands to finger, handle, or feel and reach with hands and arms. The employee is occasionally required to stand; walk; climb or balance; stoop, kneel, crouch, or crawl and talk or hear.

NOTE: This job description is not intended to be all-inclusive. Employee may perform other related duties as negotiated to meet the ongoing needs of the organization.

Process Development Chemical Engineer
Codexis, Inc.-Redwood City,CA

Process Development Chemical Engineer
Codexis is searching for a process development chemical engineer to support R & D in separations, extractions, and gas absorptions operations.Codexis serves major worldwide markets where clean ...

Scientist, Biocatalyst Evolution and Development
Codexis, Inc.-Redwood City,CA

Scientist, Biocatalyst Evolution and Development GroupCodexis seeks a highly motivated Staff Scientist to join the Biocatalyst Evolution Research and Development department.Codexis serves major worldwide markets where clean technology can ...

Scientist, Bioprocess Development
Codexis, Inc.-Redwood City,CA

Scientist, Bioprocess Development
Codexis seeks highly motivated scientists to join the Bioprocess Development Department.Codexis serves major worldwide markets where clean technology can make a positive economic and environmental impact. ...

Scientist, Molecular Biology
Codexis, Inc.-Redwood City,CA

Scientist, Molecular Biology
Codexis seeks highly motivated scientists to join the Molecular Biology Department.Codexis serves major worldwide markets where clean technology can make a positive economic and environmental impact. Our focus ...

Scientist, Fermentation
Codexis, Inc.-Redwood City,CA

Scientist, Fermentation R & D
Codexis seeks highly motivated scientists to join the Fermentation Research and Development Department.Codexis serves major worldwide markets where clean technology can make a positive economic and ...

Associate Director/Director, Fermentation
Codexis, Inc.-Redwood City,CA

Director/Associate/Director, Fermentation R & D
Codexis seeks an experienced fermentation engineer with a proven record of success to lead the Fermentation Research and Development Department.Codexis serves major worldwide markets where ...

Contact Joy Bridges at
Joy@legacymedsearch.com

Sales Representative – San Francisco - Patient Monitoring (241 Sales SF)

COMPANY SUMMARY: Founded in 2004, our client recently received FDA clearance for a pioneering signal-processing technology that allows for contact free patient monitoring. The system reports real time vital signs and corresponding trend-lines in clinical settings.

This is a start-up opportunity to join a seasoned group of executives looking to capitalize on their past success leading medical device companies worldwide.

PRIMARY RESPONSIBILITIES

- Drive sales of disruptive Patient Monitoring solutions in assigned hospital and extended care facility accounts
- Grow market share by introducing product through all areas of the hospital (patient floors, critical care, ICU/CCU/PCU).
- Calling of all levels of assigned accounts; Nursing Administration, Department Managers, Purchasing/Materials Management, Biomedical Engineering, Information Technology, etc.
- Manage product demonstrations required to close the sale
- Initiate lead generation by analyzing customer information and support of Sales
- Partner with Field Service Management on issues of installation and applications
- Research product field intelligence in accordance with marketing initiatives.
- Manage personal expenses within assigned guidelines
- Position requires frequent lifting of equipment that may weigh up to 50 lbs.

EXPERIENCE REQUIREMENTS

- 3+ years medical capital equipment sales experience (Sorry, No exceptions)
- Thorough understanding of hospital and extended care facility sales cycles
- Ability to work at the department level and C-level customer management and the ability to communicate with executive management
- Sales experience with Critical Care, Monitoring, Respiratory or similar capital equipment products
- Overnight Travel within the Region required

I want to inform you of a new and exciting position at UCSF to facilitate academic-industry interactions. The new position of Assistant Vice Chancellor, Office of Technology, Innovation, Industry, and Partnerships (OTIIP) will report to the Associate Vice Chancellor, Research, (Susanne.Hildebrand-Zanki@ucsf.edu <mailto:Susanne.Hildebrand-Zanki@ucsf.edu>) who reports to Jeff Bluestone (Executive Vice Chancellor). My understanding is that the new position is to bring together the OTM, CBE, and other units under one umbrella. Basically, they are searching for a high-level leader with both industry and academic experience who is proficient at IP, making deals, forming partnerships, and business development. Please forward this job announcement widely.

https://sjobs.brassring.com/1033/asp/tg/cim_jobdetail.asp?jobId=1151487&PartnerId=6495&SiteId=5226&type=mail&JobReqLang=1&recordstart=1&JobSiteId=5226&JobSiteInfo=1151487_5226&gqid=0

Jobs That Crossed My Desk Through Aug. 25, 2010

To apply for this position, please send your resume to Claire Barnes, Claire@brecreuiting.com

A well funded startup company in Santa Clara looking for a temporary Research Associate. The successful candidate will become a member of a multidisciplinary team of scientists and aid in the discovery and characterization of novel polymer-based therapeutics.

RESPONSIBILITIES:

- Prepare chemical libraries and scale-up materials
- Implement current screening protocols
- Design, develop and implement new screening protocols
- Assist in translational studies including drug-drug interactions, mechanism of action studies, and polymer properties

SKILLS/EXPERIENCE:

- Must be self-motivated, detail oriented and flexible towards handling project assignments
- Must display strong communication, organizational and interpersonal skills for a team-oriented and dynamic environment
- Previous experience in polymer science or high through put screening preferred
- Proficiency in Microsoft Excel, PowerPoint, and Word

QUALIFICATIONS:

- BS/MS in a relevant biological or chemical field
 - Minimum of 3-5 years of biotech/biopharmaceutical experience
-

A well funded startup company in Santa Clara has several positions open from Research Associate to Scientist level in the Analytical Group supporting late stage drug development. These positions are temporary/ temp to perm.

RESPONSIBILITIES:

- Develop and validate analytical methods for release and stability testing
- Evaluate and improve existing tests and assays
- Identify impurities using advanced structural elucidation techniques
- Conduct routine analysis following SOPs
- Establish reference standard programs
- Write/review analytical test methods, protocols, reports and regulatory sections
- Compile, analyze and present analytical data for specification settings; document their justifications
- Coordinate analytical activities at CRO and CMO (method transfer, stability coordination, data review and approval)

SKILLS/EXPERIENCE:

- Hands-on experience in wide range of state-of-the-art analytical techniques is a must (LC, LC/MS, IC, GC, GC/MS, SEC, IR, NMR, XRD, DSC, TA, Light Scattering)

- Excellent working knowledge of the ICH Guidelines regarding Quality and Stability Testing, GMPs and GLPs and other regulatory requirements from IND to NDA stage and beyond
- Experience with providing analytical support to process and formulation development (e.g. in-process monitoring, impurities assessments, excipient compatibility, bio-equivalency studies)
- Familiarity with approach to extractables using ultra sensitive chromatographic sampling and detection methods
- Ability to exercise independent judgment in developing methods and evaluation criteria for obtaining results
- Strong communication and interpersonal skills for a team-oriented environment, along with the ability to be flexible and collaborate on projects
- Experience with polymeric drugs is a plus

QUALIFICATIONS:

- BS, MS or PhD degree in Analytical Chemistry or related disciplines with 5+ years in analytical role supporting late stage drug development (recent Phase 3, NDA and drug product launch experience)

Local east coast candidates only. Apply online below:

<http://www.on24.com/company/careers/job-opportunities/ON24>

Senior Account Executive – Pharmaceutical/Medical Devices-New York, Pennsylvania, New Jersey

The Senior Account Executive is responsible for the sale of ON24’s webcast and virtual events solutions. These product/services are sold to enterprises, institutions, and VARs specific to the Pharmaceutical and Medical Device industries. The Senior Account Executive is responsible for achieving all individual sales targets set by the company. This position is responsible for accounts in the northeast.

JOB RESPONSIBILITIES

- Identify lead sources and sign contracts with c-level and VP-level executives, such as CMO, CEO, CIO, VP Marketing, and VP, Corp. Communications, within targeted market segments.
- Prepare and present proposals, quotes and recommend solutions based on customer needs and sell appropriate solutions.
- Attend sales seminars, sales meetings or educational activities to stay up-to-date on the latest developments, trends, and regulations in the market place.
- Keep current with all ON24 product information, pricing and contract terms.

IDEAL EXPERIENCE

- Experience working in and/or selling to companies in the Pharmaceutical, Medical Device, Medical Institutions space.
- Experience working with or sell to Agencies, Publishers, Associations specific to Life Sciences.
- Excellent writing skills / experience responding to major enterprise RFPs.

- Experience closing and managing major strategic accounts with penetration into multiple client groups within the organization.

If you have those skills, please contact Ruba at

Ruba Khenaisser
 Senior Engineering Recruiter
 Medical Devices & Biotech
 Aerotek Inc.,
 395 Oyster Point Blvd. Ste. 119
 South San Francisco, CA 94080
 Tel: (650) 825-2932
 Fax: (650) 825-2992
 Email: <mailto:rkhenais@aerotek.com> rkhenais@aerotek.com

Medical Device Positions at Aerotek

- Sr. Electrical Engineer/Manager, Redwood City (very hot)
- Sr. Mechanical Engineer, Redwood City (very hot)
- Sr. Process/Supplier Engineer x 4 (very hot)
- Sr. Manufacturing Engineer, Redwood City & Santa Clara (medium urgency, wants to hire by end of month but process will probably delay start date to first week or two of September)
- Assembler X 2, Lead Assembler, San Carlos (start Monday)

Current RA, R&D and Quality Pharma Opportunities

Below are the positions that are currently available. Please contact me at hans@protechpharma.com or at 973-838-7500 Ext. 205 if you match ALL the qualifications that my clients are searching for.

RESEARCH & DEVELOPMENT:

MANAGER, PRODUCT AND PROCESS DEVELOPMENT, OH (2 Positions) (HOT JOBS)
 Candidates must have strong formulation OR analytical R&D experience
 Experience with sterile, sterile liquids, parenterals, biologics, or diagnostics
 Strong drug development experience
 Job title could be upgraded for the right candidate (ex. Assoc. Dir. or Director)
 Strong leadership and managerial skills are required
 Steady pharmaceutical or biotech experience
 Sponsorship is possibly provided to an ideal candidate on a case by case basis to Canadian Cit. and H1B Visas (this is the only position for which any of my clients would provide sponsorship)
 BS or advanced degree in the science and 8+ years of relevant industry experience

SR. FORMULATION SCIENTIST, OH (several positions)

Strong formulation experience with parenterals, sterile liquids or biologics(as long as there is some small molecule experience)
 PhD and 5 yrs, MS/MA and 8+ yrs or BS and 15+ yrs of industry experience is required
 Knowledge of emulsion, suspension, and liposomal product development is desirable
 Experience training and managing technical staff is desirable

Process development experience is also required

SR. ANALYTICAL SCIENTIST, OH (several positions)

high proficiency with HPLC, GC, IR, UV, KF and TLC as well as wet chemistry techniques.

Advanced degree preferred and 8+ yrs or 15+ yrs with BS degree.

Pharmaceutical or Biotech experience is required

Method development, validation and transfers

Expertise in parenteral , sterile liquids or biologics development is desirable.

Knowledge of small molecules is highly desirable

Technical leadership of all analytical development activities within a project team including technical direction, training, and mentoring of more junior staff

FORMULATION SCIENTIST III/IV, (PPD), OH

Experience with formulation and lyophilization cycle development and process scale-up to production size

PhD with 1+ years of relevant experience, Master's Degree with 3+ years experience in related scientific discipline or Bachelor's Degree with 7+ years experience in related scientific discipline

Expertise in some sub-category of parenteral formulation/development is desirable, such as lyophilization, microencapsulation emulsion technology, biochemistry methods development, analytical methods development.

SCIENTIST III/IV, PPD, OH

Requires a PhD with minimum 2 years of related experience or a Masters of Science degree with minimum 6 years experience, or a Bachelor of Science degree with a minimum 10 years experience in a related field.

Working knowledge of ANDA, AADA and NDA filings with the FDA and other applicable regulations.

Proficiency with HPLC, GC, FTIR, NMR, and MS as well as wet chemistry techniques

Experience including formulation and lyophilization cycle development of small molecules

Development of parenteral (or similar but not solids or topicals) products from pre-formulation through transfer to manufacturing

SCIENTIST I/II, PPD, OH

B.S. degree in a science discipline (Chemistry preferred)

Minimum of 4 years of pharmaceutical product development experience

Analytical R&D candidates that provide support to product development will also be considered

HPLC, GC, FTIR, MS, wet chemistry

SCIENTIST II/III, SOUTHERN CA (Generic solid dosage)

Analytical method development and validation experience in a generic pharma environment is a must

Strong technical strengths in HPLC, GC, MS, FTIR, UV and other related technologies.

PhD with lab experience in school setting or M. S. with 3 plus years pharmaceutical analysis; or

B.S. with 6 plus years pharmaceutical analysis.

RESEARCH SCIENTIST, PROCESS CHEMISTRY, RI

BS/MS in chemistry with 2 plus years of experience in pharmaceutical development (no PhD's please)

Responsible for conducting laboratory studies to verify chemical processes for the production of target molecules.

Develop chemical processes for the manufacture of API's

PRINCIPAL SCIENTIST, SPECTROSCOPIST, RI

Ph.D In Chemistry with 15 years of experience in pharmaceutical analysis is a must.

Broad knowledge of chemical analysis, organic chemistry, strategies and techniques, such as: TLC, GC, HPLC, NMR and IR, RAMAN, & X-Ray diffraction, LC/MS, GC/MS.

Interpretation of the results of the above analytical methods.

Broad knowledge of the hazards of working with organic materials, reagents and solvents.

Working knowledge of synthetic organic and mechanistic organic chemistry.

Experience in development of API's. Familiarity in working in a manufacturing setting.

Strong hands-on leadership skills are required

Experience supporting both organic and analytical scientists

QUALITY CONTROL:

QC SCIENTIST III, HUDSON VALLEY, NY

Strong testing experience in a QC lab setting

Process validation experience is a must

SOP, GLP, GMP and FDA regulations

Bachelor's degree in Chemistry or related scientific field or Master's degree in Chemistry or related scientific field and 4 to 6 years of pharmaceutical industry experience

Dissolution, assays, impurities, content uniformity, particle size distribution, density, water determination by KF, preparation and standardization of solutions is required

(Relocation or sponsorship are not offered)

REGULATORY AFFAIRS:

SR. ASSOCIATE LABELING COMPLIANCE, HUDSON VALLEY, NY

Bachelor degree or equivalent in a scientific or related discipline and 5 to 7 years of experience in pharmaceutical labeling compliance and/or operations

Knowledge of Proof review of all labels and labeling materials at all stages of the development process is required

REGULATORY AFFAIRS MANAGER, GENERIC, SOUTHERN CA

Strong familiarity with FDA, ICH and cGMP standards, guidelines, regulatory compliance regulations and the overall regulatory environment as related to the pharmaceutical industry.

Bachelors of Science Degree and 3 to 5 years Regulatory Affairs pharmaceutical technical work experience or an equivalent combination of education and experience.

Develops submission strategies for manual and electronic submissions of new ANDAs

Determines necessity for communication with FDA for CMC and/or Bioequivalency issues

Provides draft labeling (labels, package inserts, carton) for submission

REGULATORY AFFAIRS ASSOCIATE II/III, GENERIC, SOUTHERN CA

Prepares, reviews and submits Abbreviated New Drug Applications, amendments, all post-approval submissions such as supplements, annual reports and adverse reaction reports to the Food and Drug Administration

Familiar with current Food and Drug Administration (FDA) regulations, guidelines/guidances and

current FDA/Regulatory Affairs submission requirements.
Bachelor of Science Degree from an accredited college or university and one (1) to three (3) years regulatory pharmaceutical work experience is desirable
Factors such as similar pharmaceutical work-related experiences (such as QA and Analytical RA support) will be considered

Contact Claire Barnes
E-mail cbarnes@alexza.com, Claire Barnes, Staffing Consultant.

QC Stability Supervisor (Temporary)
Job ID 0271-Mountain View

Alexza Pharmaceuticals is a pharmaceutical company located in Mountain View, California. We are developing breakthrough therapies for the treatment of acute and intermittent medical conditions, with a focus on the CNS therapeutic spaces. Alexza has filed its first NDA and has five additional product candidates in various stages of clinical development. All the the product candidates are based on Alexza's proprietary technology, the Staccato system.

Alexza was founded by Dr. Alejandro Zaffaroni, who is one of the most successful serial entrepreneurs in the biomedical industry with a long list of successful companies to his credit, including ALZA, Affymax, Maxygen, Symx and Affymetrix Corporation.

We have a temporary assignment for a QC Stability Supervisor. This person will work closely with our multi-disciplinary team of scientists and engineers who are dedicated to the development of novel drug delivery technologies with the potential to revolutionize the treatment of several common diseases.

Responsibilities:

- Maintain Alexza stability program including stability protocol writing, stability specification setting, stability planning and set-up, stability sample pulling and distribution for testing, stability report writing/updating, and stability data trending
- Perform daily QC testing activities to support the development and manufacture of drug/device products
- Write and implement protocols for design verification and other quality processes
- Deliver timely, accurate and reliable sample testing results following standard operating procedures in a cGMP laboratory to support product development and release of preclinical and clinical materials. Primary analytical techniques are HPLC, GC, UV, FT-IR, and other wet-chemistry related tests. Conduct routine and non-routine analysis of raw materials, in process, and finished formulations according to standard operating procedures
- Compile data for documentation of test data and prepare reports
- Develop and refine testing methods and compile data for documentation of test procedures
- Revise and update standard operating procedures as needed
- Conduct stability data trending analysis
- Perform special project work on analytical and instrument problem solving issues
- Apply knowledge of Good Manufacturing Practices and Good Laboratory Practices on a daily basis

Skills Required:

- Must be highly organized, detail oriented and able to manage multiple projects
- Ideal candidate will have laboratory skills that include computer controlled HPLC, GC, UV, IR, workstation software, office software (MS Excel, MS Word, etc) and compliance level record keeping
- Solid communication and presentation skills required
- Holds oneself and others to Alexza's values and standards

Education and Experience:

- Requires a Bachelors degree in a scientific discipline
- 3 - 5 years experience in a cGMP quality control laboratory
- Prior project lead experience desired
- Analytical method validation experience preferred
- Experience working in a matrix managed team environment and an ability to work effectively with all departments within the company
- Experience with USP testing methods a plus
- Prior experience in device development or pharmaceutical environment preferred

Alexza Pharmaceuticals is an Equal Opportunity Employer.

A Bio2Device Group member sent out this list of jobs at Cepheid a few days ago. Check out descriptions at www.Cepheid.com under Employment Opportunities.

<u>Project Manager</u>	US-CA-Sunnyvale	8/16/2010
<u>Machine Operator (Grave Shift)</u>	US-CA-Sunnyvale	8/4/2010
<u>QA Product Specialist</u>	US-CA-Sunnyvale	8/9/2010
<u>Test Operator (Swing Shift)</u>	US-CA-Sunnyvale	8/4/2010
<u>Sales Operations Administrator</u>	US-CA-Sunnyvale	8/11/2010
<u>Software Development Test Technician</u>	US-CA-Sunnyvale	8/12/2010
<u>Oncology Marketing Manager</u>	US-CA-Sunnyvale	7/21/2010
<u>Reagent Fill and Pack Assembler</u>	US-CA-Sunnyvale	8/16/2010
<u>QC Chemist</u>	US-CA-Sunnyvale	7/15/2010
<u>Manufacturing Equipment Engineer</u>	US-CA-Sunnyvale	7/19/2010
<u>Sr. Scientist</u>	US-CA-Sunnyvale	8/5/2010
<u>Document Control File Clerk</u>	US-CA-Sunnyvale	8/2/2010
<u>Molecular Systems Specialist</u>	US-CA-Sunnyvale	7/20/2010
<u>Sr Scientist / Development Manager</u>	US-CA-Sunnyvale	7/2/2010
<u>Executive Assistant</u>	US-CA-Sunnyvale	7/28/2010
<u>Sr. HR Business Partner</u>	US-CA-Sunnyvale	6/28/2010
<u>Sr. Software Engineer</u>	US-CA-Sunnyvale	6/29/2010
<u>Scientist</u>	US-CA-Sunnyvale	7/7/2010
<u>Research Associate</u>	US-CA-Sunnyvale	7/2/2010
<u>Field Service Engineer</u>	US-CA-Sunnyvale	6/23/2010

Qualified candidates please reply to:
 Cindy Johnson
cjohnson@chozeninc.com
 tel: 925-242-1010 x 101

Most Urgent Positions:

- **Quality Systems Manager**
- **Sr. Quality Engineer**
- **Sr. Mechanical Design Engineer**
- **Director of Quality**

- **Design Assurance Quality Engineer (TX)**

REGULATORY, QUALITY & CLINICAL AFFAIRS

See descriptions for all positions from Cindy Johnson separated by solid lines

The positions are located in the San Francisco bay area unless noted otherwise.

Director of Quality Assurance

- 15 years minimum medical device industry experience in Quality Engineering
 - BSME, BSEE or related engineering degree
 - 5+ years quality management experience, exceptional verbal & written communication skills
 - Experience in larger organizations building and developing talent is required
 - Proven leadership and people development skills
 - FDA MDR/Compliant expertise
 - Laser safety compliance desirable
-

Quality Systems Manager

- Quality systems management experience required
 - CAPA, complaint handling & document control experience
 - Product development engineering experience required
 - Audit experience
 - Strong mentoring and leadership skills
-

Principal/Sr. Quality Engineer

- Strength in design control required
 - Strong product development quality engineering background
 - 7 - 10+ years of medical device quality engineering experience
 - Excellent written and verbal skills required
-

Sr. Software Quality Engineer

- Bachelors in computer science, software engineering or electrical engineering
 - 10+ years direct experience with software testing, software validation and software quality engineering in medical device environment
 - Embedded firmware testing experience
 - Experience testing applications developed in C and Visual Basic is required
 - Use of software development tools is highly desirable (bug tracking, configuration management and requirements management)
-

Design Assurance Quality Engineer – Texas

- BSEE, Software Engineering or related field and 5-8 years experience or MS and 3 years experience
 - Prior experience in the medical device industry.
 - Working knowledge of CFR 21 Part 820 (QSR), ISO 13485 and IEC 62304.
 - Experienced in design controls.
 - Excellent written and verbal communications skills. Proficient in MS Office.
 - Knowledge of other domestic and international regulations that may apply.
 - Experience with Medical Device Software Validations. C/C++
 - Experience in ASIC and microcontroller design.
 - Experience with IDE studies.
-

Quality Engineer - Texas

- BS in related discipline and 5-8 years experience or MS in related discipline and 3 years experience
 - Prior experience in an FDA manufacturing environment
 - Proficient in MS Office including Word and Excel
 - Strong interpersonal skills
 - Good written and verbal communication skills
 - Knowledge of Statistical Process Control
-

Clinical Trials Associate

- Minimum 3+ years ongoing clinical trials experience in the medical device industry
 - Cosmetic or aesthetic industry experience preferred
 - BS/BA degree
 - Demonstrated proficiency in knowledge of GCPs and knowledge of other pertinent regulatory requirements
 - 10% - 40% travel required
-

R&D, MANUFACTURING & OPERATIONS ROLES

Sr. Mechanical Design Engineer/Manager

- BSME required, MSME preferred
 - Proven track record of successful product development, strong emphasis on Design for Manufacturability
 - Strong hands on mechanical design skills required, preferably with small, handheld battery operated devices
 - Experience with molding small parts and industrial design experience would be a plus
 - Some supervisory experience required
-

Sustaining Manufacturing Engineer (Consumables)

- BS in Mechanical or Materials Engineering
- Familiar with Injection molding processes, Glue and UV cure adhesives.
- Minimum 2 years experience in a medical devices environment.
- Working knowledge of manufacturing of medium to high volume disposables and related automated processes.
- Strong knowledge of FDA and ISO Quality System Regulations
- Excellent written and oral communication skills
- Proficient in MS Office (Word, Excel, Power-point)
- In addition, this person must be high-energy, enthusiastic, creative, and willing to drive projects through to completion on schedule and within budget.

SALES, MARKETING, BUSINESS DEVELOPMENT & CUSTOMER/PRODUCT SUPPORT

Managing Director, Global Marketing

- BS/BA required, MBA preferred
- ***Extensive Direct to Consumer (DTC) experience required***
- Experience launching medical devices internationally (Asia, Europe, Latin America, etc)
- Strong leadership, mentoring and management skills (at least 3+ yrs operating at Director level w/direct management responsibilities)
- Strong ability to lead marketing communications efforts

Product Support Manager (technical support)

- Bachelor of Science degree or equivalent experience
- Minimum of 5 years Product or Technical Support Experience in a Medical Device Company
- Minimum of 3 years supervisory experience leading and supervising employees in a product or technical support environment
- Strong written and verbal communication skills, especially as it relates to communicating technical instructions and analysis to a variety of audiences
- Previous experience working with tier II customer relationship management systems
- International support experience strongly preferred

Contact Information:

TVG
Nadine Freihofer, HR Generalist
5200 Soquel Avenue, Suite 202
Santa Cruz, CA 95062 USA

Position Title: Executive Assistant/Project Manager

About Technology Vision Group LLC (TVG)

Technology Vision Group LLC (TVG) is a leading global life science networking company that is built on industry expertise and long-standing relationships. We provide our clients with the connections, the venues, and the access they need to succeed in a global life science world.

Since 1992, TVG has been connecting innovators and leaders in the life science industry across the US, Canada, China, Europe, Australia, Latin America, India and Asia. TVG facilitates a global network which supports life science companies as they build new relationships, enter new markets, and create new products. Our 19-year track record of success (1992-2010) is founded on deep industry knowledge, integrity in business, and our powerful network of valuable relationships. We are judged by the company we keep and have helped over 3,200 life science companies achieve their business goals. We continue to expand into emerging markets in Latin America, China, and India – fulfilling our vision to be Your Global Life Science Network™.

Position Summary: We are looking for a top notch Executive Administrative Assistant who can perform Project Management duties to assist our senior level partner. This person must be skilled at managing business relations and special projects at the senior executive level, have excellent communication, problem solving abilities and be successful handling complex business situations for a small organization. Entrepreneurial self-starters should apply for this position.

Job Duties:

- ✓ Work closely with TVG Partners, Sales and Logistics to move projects through the pipeline.
- ✓ Assist in coordinating top speakers from the life sciences industry for panel presentations at TVG conferences.
- ✓ Track meetings, scheduling, orchestrate communication within a global network, represent TVG management and create agendas.
- ✓ Follow up with corporate sponsors, assess needs, create proposals and coordinate with stakeholders.
- ✓ Create and deliver reports, letters and memos.
- ✓ Take ownership of special projects to assist senior management in developing new emerging biotechnical international markets.

Minimum Qualifications:

- ✓ Must be detail oriented, able to multi-task and balance competing priorities.
- ✓ Strong organizational skills, ability to network and establish strong business relationships with internal and external partners.
- ✓ Must process information efficiently, assess project needs, evaluate and take next steps toward project completion.
- ✓ Must be comfortable working in a virtual environment with some knowledge of the life sciences industry.
- ✓ Excellent verbal and written communication skills.
- ✓ Familiarity with computer software applications and state-of-the art communication technology.

- ✓ 3+ years work experience as an executive assistant with project management duties.
- ✓ Ability to speak, read foreign languages a plus.

For more information about TVG go to www.techvision.com. Qualified candidates may apply on-line by submitting a resume and cover letter with salary expectations to hr@techvision.com.

If you are interested in applying for this position, please send your resume, salary history, and contact information to: careers@portola.com

Protein Analytical Scientist
 Portola Pharmaceuticals, Inc.
 Location: South San Francisco, CA Posted Date: Aug 24, 2010
 Position Type: Full Time Job
 Code: 351-001 Required Education: Doctorate
 Areas of Expertise Desired: Analytical Chemistry
 Protein Chemistry

Description

Portola Pharmaceuticals Inc., is a biopharmaceutical company focused on the discovery and development of the novel therapeutics for the treatment and prevention of severe cardiovascular diseases. With one of the most experienced discovery and development teams in the areas of vascular thrombosis and inflammation, Portola is applying an integrated discovery and development approach to a comprehensive understanding of platelet physiology and vascular thrombosis, with an eye toward developing new therapeutics where current antithrombotic therapies are inadequate.

The Analytical Development group is seeking a temporary assistance (6-month assignment) with establishing, developing, and/or optimizing analytical methodology to test the identity, purity, potency and stability of protein products (in-process and final). Help with troubleshooting established test methods used in development and release testing.

Provide analytical support in troubleshooting process and formulation problems. Manage CRO in method transfer, assay qualification/validation, lot release and stability testing of protein API and formulation. Take part in writing CMC section for IND. Requirements We require that you have -

- Ph.D in Analytical Chemistry or related field.
- MS/BS with extensive relevant experiences will also be considered.
- Minimum 5 year experiences in analytical laboratory in pharmaceutical industry.
- Proven experience with method development and validation in a cGMP setting.

- Hands on experiences with HPLC, SEC, IEX, IEF, Gel electrophoresis, ELISA, Western blot, and other state of the art analytical methodologies for protein quantitation and characterization. Be able to execute and troubleshoot a variety of methods used for analysis and characterization of proteins.

- Hands on experience with mass spectrometry for protein characterization is a plus.
- Excellent oral and written communication skills

-
You are able to work safely in an analytical/bio-analytical laboratory with inherent safety concerns such as chemicals, glassware, infective agents, etc

Contact Ron Coelyn
E-mail: rcoelyn@coelyngroup.com
Phone: 817-424-3652
web: <http://www.coelyngroup.com>

Our Firm is currently working on several executive search projects for LifeScience industry clients. We would value your help in identifying some exceptional candidates for one in particular.

Senior Vice President, Marketing & Sales –Southern California

The client is a privately-held Company with a novel interventional spine technology.

The specific applications represent a significant breakthrough in this technology space and a very prestigious group of venture capitalists believe the future potential is enormous.

The candidate-of-choice does NOT need to relocate unless he/she wishes.

Our client requires that the candidate-of-choice must have meaningful experience in orthopedics, ideally with several years specifically in spine.

We are seeking individuals with impeccable personal and professional reputations and unquestioned integrity; people who are relentless in the pursuit of lofty goals; and finally, people whose track record of accomplishments and contributions are unambiguously clear.

Contact Louise at ljohnson@bcg-usa.com

I have a friend in San Diego who is looking for mid-level staff in QA and Regulatory. These are full-time positions at CliniComp, an electronic health record company.

If you know anyone with experience in electronic medical records (software systems), military (DoD), VA and healthcare who wants to work in San Diego, please have them contact me.

Other Information for Those in Transition

Upcoming course designed for life science professionals who want to quickly learn how to do research and analysis for making recommendations and critical decisions in their field and sector. I

share my years of experience in bioscience marketing and business research and developing critical business and marketing documents.

Bioscience Business and Marketing Essentials, Thursday and Friday, Oct. 7-8, 2010

2-Day Intensive Course: Bioscience Business and Marketing Essentials, Thursday and Friday, Oct. 7-8, 2010 with 2 months to complete project

Lead Instructor: Audrey S. Erbes, Ph.D., Principal, Erbes & Associates and www.audreysnetwork.com

Expert Guest Speakers:

- Donald Holsten, Pharm. D., Regulatory Consultant and Educator
- Bev Hudson, MBA, Senior Vice President, Business Development, OmniComm Systems, Inc
- Julie Tompkins, MBA, Senior Vice President, Timely Data Resources (TDR)

Please see www.ucsc-extension.edu/BBME for details

Date & Time: Oct. 7-8, 2010, Thursday and Friday, 8:30am-5pm

Location: UCSC Extension in Silicon Valley, 2505 Augustine Drive, Santa Clara, CA 95053

Fee: \$800; \$720 through Sept. 23

Topic Description

The bioscience industry is like no other. Lengthy timelines and unique financial, legal, regulatory, social and political challenges impose constraints that impact every aspect of the business. This course helps participants gain: a practical understanding of the bioscience industry landscape, key business drivers and challenges; insight into the critical roles that business and marketing disciplines play at all stages of a bioscience company's development; and hands-on experience implementing important bioscience business processes that are essential to success within the industry. Two days of intensive classroom are followed by 2 months to complete individual project with guidance of instruction and access to research resources. For more information: See course listed under certificate program at www.ucsc-extension.edu/biobusiness.

Instructor:

Audrey Erbes, Ph.D., Principal, Erbes & Associates, is a marketing professional with more than 25 years of managerial experience in marketing and business development in the biotech and pharmaceutical industry. She is also a recognized speaker and industry blogger at www.audreysnetwork.com. She was Executive Vice President and cofounder of Kowa Research Institute, a biopharmaceutical licensing and investment subsidiary of Kowa Company Ltd., Japan. Prior to that, she held management positions at Syntex Corp. (acquired by Roche) in market research, product management, strategic marketing and planning, and business development in the U.S. and abroad, with a special emphasis on Europe and Asia/Pacific/Canada.

Guest Speakers:

Donald Holsten, Pharm D., a regulatory consultant and educator with over 20 years of national and international experience as a senior regulatory affairs and quality assurance executive, has expertise in food, drug/biopharmaceutical, medical device and cosmetic products. He has an intimate knowledge of the FDA approval cycle and has helped prepare numerous biotechnology and pharmaceutical companies for FDA interactions and panel reviews. Don has held management positions at several companies, including Liposome Technology, Inc and Oclassen Pharmaceuticals, Inc. where he was Director of Regulatory Affairs/Quality Assurance and Director of Regulatory Affairs, respectively. Earlier in his career he held a senior level position as Assistant Chief, Food and Drug Branch, Department of Health Services for the State of California. Topic: "Operating in the U.S. Regulatory Environment: Is Product Approvable."

Bev Hudson, M.B.A., is the senior vice president, Business Development, OmniComm Systems, Inc., a Web-based electronic data capture (EDC) and eClinical (eClinical) software and services company with products that streamline the clinical research process. Previously, she was VP and General Manager of Clinical Research Services at MedPoint Communications, Inc. and earlier ran sales and operations for Mayo Clinical Trial Services. She spent eleven years at Genentech in sales and marketing management roles. Topic: "The Impact of U.S. Health Care System on Marketing Biotech Products."

Julie Tompkins, M.B.A., is senior vice president at Timely Data Resources (TDR), a healthcare market research and consulting firm. She has nearly 30 years experience in the pharmaceutical and biotech arenas, including more than 12 years in industry and more than 20 years in market research consulting, and has worked with pharmaceuticals, diagnostics, and drug delivery systems. At Syntex (now Roche), Julie worked in both R&D and Marketing. After leaving Syntex, Julie was President and Founder of MedSearch, a primary market research company that merged with TDR in January 2000. Topic: "The Role of Market Research in Product Planning, Development and Marketing".

Free Newsletters to Keep You Informed

Check out free newsletters delivered to your email box:

- "Biospace"s "Genepool," "Deals and Dollars," and "Clinical Focus"
- "FierceHealthCare," "FierceHealthIT," FiercehealthFinancial", "FierceHealthPayer," "FierceEMR," "FierceBiotech," "FierceMedicalDevices" and "FiercePharma"
- "Drug DiscoveryOnline,"
- "IN VIVO Blogspot," "Pharm Exec blog"
- "QMed Daily" (formerly DeviceLink.com)
- "PRWeek Healthcare Newsletter"
- "enewsletters@fdanews.com "

Paula Rutledge, President of Legacy MEDSearch, has provided the following Job Search and Interview Preparation Resources to share with you:

- Interview Preparation Resources: Interview Prep Guide
- Medical Device Research Forum Medical Device Guru
- LinkedIn Medical Device Group LinkedIn Medical Device Group
- Interviewing Videos on YouTube Medical Career Magazine

Although the above was developed with medtech professionals in mind, the processes outlined are also useful for other industry professionals.

Ken Wu advises "I found this article titled, 7 Mistakes Job-Seekers Over 50 Make, via the American Society of Quality (ASQ) daily email update. It's worth reading if you're considering how to reposition your self for the upturn in the job market."

The link; http://internsover40.blogspot.com/2009/09/7-mistakes-job-seekers-over-50-make.html?WT.mc_id=EM3965M&WT.dcsvid=1541418993.

Job Sites

The most known site for career and job listings is www.biospace.com which focuses on biotech and pharma.

A newer website which includes jobs but also a virtual exhibit hall for companies—this one is dedicated to pharma entitled ePharmaExpo.com at <http://www.epharmaexpo.com/job.php>

There's another site which is focused on life science recruitment and placement; note featured company listings each week—www.beaker.com

There's website with jobs specific to medical device area at the www.legacymedsearch.com .

Another new site with listings of interns, consultants and some jobs is www.deviceland.com

I've just received information on another new site with sole focus on medical devices and most in the Bay Area is <http://www.mdrecruit.com/careers.html> I'm told they had 97 placements last year. Check this one out and let me know if you have good results.

You can look up pharmaceutical jobs in your area by zip code at <http://jobs.findpharma.com/careers/jobsearch>. They include all functions in pharmaceutical companies.

Other Helps

I received Biotech Ink Insider from Susan Caldwell, a local medical writer. She always has great insights as well as jobs at times to share. I've pasted in some videos mentioned by Susan that might be of interest for your job search:

Writing a Resume: When seeking a job, the resume is of considerable importance--it's your calling card and door opener. Here's a video that helps you create the right resume and minimizing the stress while you do it. Includes ten rules for how to approach your resume, interview, and job search. Very good basic advice.

Writing Your Resume Cover Letter: Same instructor as for Writing a Resume (above). Gives good basic advice on how to craft your cover letter and get the job interview you seek.

The Art of Medical Writing: Short video on the Masters in Medical Writing program at the University of Philadelphia, the only such training program in the world.

Susan Caldwell wrote an article regarding writing a resume as well.

"10 Tips for Creating a Door-Opening Resume" by Susan E Caldwell

If you're a medical writer, how can you make sure that you still have work in these tough economic times? Important for staff and freelancers alike, marketing your name and abilities can be done in many ways. One way is to develop and maintain a living resume that speaks to the best you have to offer employers.

As an experienced worker, you likely have a professional reputation. Maybe it's good, or maybe it's not so good. How can you enhance or improve your resume so that your best shines through? Here are a few suggestions:

1. Resume Format. Your resume's format should be simple and pleasing to the eye. Because resumes are often input into databases, the simpler the format, the better. Using a simple format should help avoid the need to reformat before your resume is uploaded into a database. When you submit your resume to a recruiter or job board, you should submit it as a Microsoft Word file, but without special formatting. Avoid bullets, bolding, italics, indents, and other formatting that are lost in plain text files. If you do use special formatting, your resume may look like alphabet soup after it's put in a database.

Organize your resume in sections, each with a heading that tells the reader what is in that section. Here are some sections typically found in resumes and their approximate order of appearance:

Introduction or Career Goal

Summary

Work History or Professional Accomplishments (if candidate has work history)

Academic Background

Skills

Honors and Awards

Publications

There are many variations on the organization and section labels listed above, and you should use what is appropriate for your career stage. Points 7-10 (below) specifically address what content should be included in some of your resume's major sections.

When you are ready to format your resume, consider looking at the many examples of resumes available online. Seeing the structures of other resumes may help you decide on your own resume's format and organization.

2. **Job Targeting.** Decide what your target job or assignment is, and tailor your resume to that job. How do you do that? For one thing, you can pepper your resume with the key concepts, terms, and abbreviations for your target job in your resume; this will show that you know the language in that field. Examples include the terms ICH Guidelines, investigator brochure (IB), style guide, and eCTD. Another way to target your resume is to rewrite portions of your resume to match the target job description. This strategy sounds like a lot of work, but it can pay huge dividends. When you submit a targeted resume, it's more likely you will be considered a great match for the position.
3. **Resume Emphasis.** Emphasize your best accomplishments (for example, an approved eCTD submission that you worked on). Make it clear that you got the job done in an effective way, particularly if it saved time or money. You can do this by positioning these stellar achievements toward the resume's front, writing more about those accomplishments, and/or including specific comments about them in your resume. If there's a web site or information on the web that illustrates or supplements information about your accomplishment, link that information to your resume.
4. **Lying on Your Resume.** This one is simple: don't lie on your resume. It's a bad idea for several reasons. Not only is it wrong, but if you exaggerate or lie, you may be in over your head if you do get the job. In addition, employers do check resume facts, and they are likely to identify any lies or inconsistencies.
5. **Errors in Your Resume.** If you're seeking a new job or contract assignment, your resume should be flawless. That is, it should have no typos, misspellings, incorrect grammar, or other writing errors. If you want to open the door to a job interview, show the reader that you are careful about your writing. As a medical writer, the writing that appears in your resume will be the first writing sample an employer sees. Be sure that it will stand up to scrutiny.
6. **Resume as Living Document.** Ensure that your resume is always current and well crafted; it should be a living document. Update it every time you have new material to add to it. Again, the resume's purpose is to get your foot in the door for an interview. If you don't keep your resume current, you may miss a chance to include vital information, especially if you need it on short notice. For this reason, you should always be ready to send your resume to recruiters or employers on a moment's notice.

The remaining points in this article address issues within your resume's sections:

7. **Summary.** At the start of your resume, include a short (usually 1 to 2 paragraphs) thumbnail summary of your work experience and academic background. It's also appropriate to have a statement that tells the reader what you want to do in your next job.

8. **Academic Background.** The academic background section should include your earned degrees, the name of the institution where you earned the degree, and the dates when they were conferred. If you have earned an advanced degree, this section may be a good place to list the title of your thesis or dissertation, if any. (Alternatively, your dissertation's citation can be included in your resume's Publications section.)

A separate section following your academic background can include the continuing education and training courses you've taken. The list should include the subject matter (or course title) and date(s) when you had the training. And here's an important tip: whenever possible, include specific dates for the education and training. The dates add to your credibility, and their absence can be conspicuous.

As you advance in your career, your academic background generally becomes less important than your work history. After you have a work history, especially in medical writing, consider moving the academic background information in your resume to a location following your work history.

9. **Work History or Professional Achievements.** In this section of your resume, include specific details about your work history. The reverse chronological work history format often works well, with your most recent job listed first. The work history section should describe your milestone accomplishments for each job or contract assignment. As with the academic background section, include the start and stop dates for the jobs and/or contract work that you've done. The dates will give you added credibility.

10. **Publications.** If you've authored any publications, put a list of them in your resume with the full citations in a consistent reference format. For publications with multiple authors, you should include all of the authors' names in the order that they appeared in the publication. Finally, try to get access to electronic copies of your publications on the internet. Consider hyperlinking those citations in your resume to the actual articles. In so doing, your reader can easily find and read examples of your work. You can also prepare a set of publication samples as a zipped file to provide to prospective employers.

Done well, your resume will open many doors for you, including some you may want to walk through. There are many resources on the internet that will help you create an excellent resume. Take the time to use them, too! You'll be glad you did.

About the Author

Susan Caldwell is a medical writer, PhD scientist, and entrepreneur. After 10 years of laboratory research, she made a major career course correction and never looked back. She found she could make a career of doing what she loves--writing--and applied it to her background in biomedical research. Since 1995, she has directed medical writers at five life-science companies, including her company, Biotech Ink, LLC. Her specialty is writing regulatory documents for clinical, preclinical, and manufacturing activities that support the development of biotechnology, pharmaceutical, and medical device products. She also has considerable experience writing book chapters, newsletters,

brochures, white papers, web content, and many other document types. Susan has been writing and publishing the Biotech Ink Insider newsletter since October 2008.

You can email Susan at caldwell@biotechink.com, phone her office (650-286-9300), see her LinkedIn profile, follow her on Twitter, and you're invited to join her Medical Writers Twibe (for which you have to have a Twitter account).

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*****Su

san E. Caldwell a local medical writer shares some insights into finally mastering touch typing. As writers, we must type to do our work, at least if we're using Microsoft Word or other word processor. Many writers become writers without knowing how to touch type (typing without looking at the keys). Touch typing at 40-60 average words per minute, which is industry standard, is roughly 3 to 4 times faster than you can write by hand. The links below are offered so that you can learn and practice touch typing for free (and they aren't presented in any particular order):

1. <http://www.sense-lang.org/typing/>
2. <http://play.typeracer.com/>
3. <http://10-fast-fingers.com/>
4. <http://www.learn2type.com/>
5. <http://www.touch-typing-tutor.com/>
6. <http://www.nimblefingers.com/>
7. <http://www.alfatyping.com/>
8. <http://www.typeonline.co.uk/typingspeed.php>

Salary Surveys

- See free downloadable annual Salary Survey from Contract Pharma at <http://www.contractpharma.com/articles/2009/06/2009-annual-salary-survey>
- Salary surveys are regularly published Medical, Marketing Media each year in September
- See 2009 Medtech salary survey at Source: http://www.devicelink.com/mddi/current_salary_survey.html

Given the current economic climate, this is a wonderful time to prepare for a career transition and to reassess your career path so that it is aligned with your personal and professional goals. Career Opportunities in Biotechnology and Drug Development, www.careersbiotech.com, published by Cold Spring Harbor Laboratory Press, is a comprehensive, in-depth exploration into the many careers found in the life sciences industry (biotech, pharma and medical devices), based on interviews with over 200 industry executives. It covers 20 vocational areas and over 100 careers. The book was written with the goal of helping readers identify career areas that best suit their interests, values, skills and goals. Each chapter explores the many in-depth nuances of each vocational area. Additionally, there are chapters on resume preparation, job search strategies, informational interviewing and more. A free sample chapter on careers in Project Management is available at www.careersbiotech.com.

This insightful and extremely helpful book was researched and written by Toby Beth Freedman, Ph.D., President, Synapsis Search (www.synapsissearch.com) and local guru on life science careers. Toby freely shares her experiences acquired as a researcher, business development manager, recruiter and her indepth research with local industry organizations, such as, local AWIS, the Bio2Device Group and universities.

The target audience for this book is people working in academia or in industry who are considering a career transition. It has a broad appeal to scientists, doctors, nurses, lawyers, engineers, business executives, high tech professionals, etc. The book is available on Amazon and a paperback version will be available soon.

These job postings are listed on my blog accessed at www.audreysnetwork.com along with my suggestions for local industry meetings for networking and expanding your knowledge and skills. Please direct other interested parties to my email address at audreyerbes@aol.com if they wish to receive these mailings directly.
