



WHEN YOU'RE READY FOR A NEW JOB

HOW TO WRITE A RESUME THAT GETS ATTENTION

**PROFESSIONAL
PLACEMENT
SPECIALISTS, INC.**



Your Regulatory, Clinical, and Quality Experts

Phone: (877) 667-9699

Website: www.gotopps.com

THE PURPOSE OF YOUR RESUME

Your resume is your first chance to make an impression on a potential employer. Careful thought should be put into this very important document. Your resume not only informs the employer about your background, but also your communication style, writing (and spelling) ability, organizational skills, and ability to briefly and concisely convey information.

It is also important to be truthful on your resume. Your industry is smaller than you might think and you may run into people with whom you have worked at other companies. They might even be someone with whom you worked on a project and knows your contributions, or knows someone that has worked with you in the past. Either way, if you have lied or exaggerated about your level of contribution, you will be found out and your reputation ruined. Also, with the number of companies doing background and education verification checks, it isn't worth the humiliation of being caught in a lie and ruining your reputation for solid, quality work. Be proud of your accomplishments and state them honestly.

SETTING UP YOUR RESUME FOR MORE IMPACT

Now, about the layout of your resume: I'm sure you have been told that your resume should only be 1 or 2 pages. That is only partially true. If you have 5 years or less of experience, yes, it should only be a 1-2-pager. If you have more experience than that, you may short-change yourself by trying to keep it to 2 pages. It is better to give your potential employer (or Recruiter) a good idea of what you have done, and are capable of doing, than to have a short resume. Under no circumstances should you go over 4 pages. Beyond that and you risk having your resume find the bottom of the pile to be read "when they have time". The key is to make sure EVERYTHING on your resume sells you to a potential employer, and gives them a clear picture of what you are capable of doing for them.

If you are someone who has done a number of publications or presentations, you can simply state on your resume: "Extensive publication and presentations experience. A detailed list is available upon request", and place it under a heading of "Publications and Presentations".

Most hiring managers and recruiters focus on your most recent 3-5 years of experience. For positions held within that time period, you should make sure to put your most relevant bullet points to describe what you've done. For position beyond the 5 year mark, try to pick the most important 3-5 bullet points to list. This will help keep your resume more concise without filing it with information that is not as relevant to the reader.

Also try to eliminate any date gaps in your resume. If you have taken an extended leave, or have been unemployed for more than 6 months, you may need to list this time gap on your resume. Many employers become suspicious of big time gaps and may wonder what you are hiding. If they are wondering about these gaps, they are not concentrating on your accomplishments. If what they remember about your resume is that it had "curious" time gaps, you may not fare too well against your competition.

I have collected thousands of resumes during my Recruiting career. Some layouts are very difficult to follow and read, and leave the reader confused about what the job candidate has done, or can do. A chronological resume layout is easier to follow as it uses bullet points to highlight accomplishments and responsibilities. This is the format used by a majority of the people in the market, and is very good, but there are options to help you stand out even more.

A key component to any effective resume is having a “Skills Summary” or “Significant Accomplishments” section at the very top of the first page. This is your chance to shine and get your reader’s attention right off the bat. Most people write their resumes like a job description; listing how they spent time during their days. Employers don’t hire people to come in and spend time, they hire them to get things done and accomplish something. That’s what your resume needs to list.

Anything you can list that had a big impact on your group or company should be listed in your Skills Summary or Significant Accomplishments section. If you streamlined a process, completed a clinical trial ahead of schedule, or got a submission in and approved quickly, those are the kind of things a hiring manager wants to know about. You may be uncomfortable bragging about your accomplishments, but if you don’t brag a little, the reader of your resume will never know how good you are.

A SLIGHTLY DIFFERENT RESUME

Using the same chronological layout, you can take it one step further to really give your resume some impact. This extra step is the information I can use as a recruiter to really get the attention of the hiring manager, and will set you way ahead of other resumes/job candidates they are considering.

This is a step using the PPR approach. **PPR stands for Project, Participation, and Results.** The **Projects** portion is simply facts about significant projects you’ve worked on. This part should be pretty easy since that is what resumes are made up of anyway. The **Participation** portion lists significant, measurable results you personally achieved on these projects in your previous positions, and the **Results** portion specifies what this project achieved for the company, and let’s the potential employer know what you think you can do for them if they hire you, based on what you’ve done in the past. Here’s an example of how that might look.

2007 - 2010 **Senior Manager, Regulatory/Clinical Affairs**, 123 Surgical, San Jose, CA
Provide leadership for regulatory policy and strategy through example, guidance, internal communication, follow-up and verification for corporate operations and operations of corporate partners. Formulate global clinical development plans, monitor clinical trials and manage the Clinical Research Department.

Project Regulatory filings

My Role Develop content for regulatory filings, ensuring quality of content, approving minor or routine submissions and meeting predetermined timelines for all submissions.

Results Consistently met all deadlines

Project Manage clinical trials

My Role Responsible for all facets of development including discovery, development and clinical trials

Results Trial approved by the FDA on the first pass, including 25 sites in the US and 5 in Europe; enrollment completed 9 months ahead of schedule.

By doing this you are answering the basic question of the hiring manager that is at the core of the entire interviewing process: **What’s in it for me?** The potential employer is looking at your resume to decide what’s in it for them to bring you on board. The hiring manager is trying to fill a position to solve a problem they have, and they are looking at your background and capabilities to see if you are someone that can help them accomplish the goals they have for their department. That’s what’s in it for them.

As the process continues, and you learn more about the opportunity, you can determine what's in it for you. Once you get in the door to interview, you can learn a lot more about the company, culture, and people you would be working with. This information can turn a pretty good opportunity into a great one, or let you know it might not be quite right for you. But unless you can get in the door to interview, and eventually get an offer, you will never know what's in it for you.

As a Recruiter, it is my job to present you in the best possible light, and to do a first stage screening to make sure you have the background the employer is looking for. That is a service I provide my client companies, and they have come to expect from me. Your resume is still a very key component. I can give my contacts within the company a lot of detailed information about you to entice them to look further at your background, but resumes get passed internally to other members of the interviewing team to see if it's worth bringing you in. Since I am not part of these conversations, **your resume needs to stand on its own.**

I hope this information and the following sample resume is helpful in giving you the best resume possible to help you advance in your career. If you ever have any questions, please feel free to contact me.

Jeff King

President/Principal Recruiter

Professional Placement Specialists

SAMPLE

Standard Chronological Style Resume

NAME
ADDRESS
PHONE NUMBER(S)
EMAIL ADDRESS

Summary:

- Over 30 years experience in a variety of management and staff positions within the medical device (Class II and Class III) and biotechnology industries.
- Excellent management skills, and extensive experience in quality systems management, auditing, regulatory affairs and compliance, manufacturing, process engineering, supplier management and procurement.
- Hands-on experience in statistical techniques, validation, sterilization, biocompatibility and inspection and test methods has allowed me to effectively guide product development activities.
- Effective leader and mentor, and am frequently the “champion of change”.

Key Accomplishments:

- Developed and implemented Quality Systems Integration plan for site within newly developed business group
- Hosted successful California State FDB inspection and Notified Body Recertification audit to 13495 and MDD requirements
- Provided quality engineering R&D and product manufacturing support resulting in significant reduction of customer reported failures
- Prepared and successfully gained 510(k) approvals for various indications for use
- Transitioned quality systems and business processes from Startup/Clinical mode to Commercialization

Work Experience:

Company Name, Location (optional)

5/09 – Present Plant QA Manager

- Developed and implemented Quality Systems Integration plan for site within newly developed business group
- Hosted successful California State FDB inspection and Notified Body Recertification audit to 13495 and MDD requirements
- Submitted and received approval for technical file for (product name)
- Established quality metrics reporting systems
- Supported product scale-up of the (product) device to meet needs of European launch
- Prepared site for closure and supported manufacturing transfer

Company Name, (location)

10/08- 5/09 Director QA/RA

- Provided quality engineering R&D and product manufacturing support resulting in significant reduction of customer reported failures
- Provided quality and regulatory leadership for private funded company
- Presented quality and regulatory status/history for prospective buyers
- Initiated and implemented improvements in Customer complaint/MDR reporting, CAPA and Product Development processes

Company Name, (location)

10/07 – 8/08 Senior Compliance Manager

- Site Management Representative – successfully hosted Regulatory/Notified Body audits
- Provide compliance guidance for product development activities
- Created and implemented systems for management of external product development alliances and international distribution entities
- Responsibilities included management of CAPA system, postmarket surveillance, documentation and records management, internal and external audits and training
- Established and implemented the quality system integration strategy subsequent to sale of company

Company Name, (location)

3/07 – 08/07 Director of RA/QA

- Head of Quality and Regulatory functions – Management representative
- Primary contact with FDA for submissions and Clinical Trials
- Prepared and successfully gained 510(k) approvals for various indications for use
- Established and maintained quality systems certified to ISO 13485:2003 and CMDCAS
- Transitioned quality systems and business processes from a Startup/Clinical mode to a Commercially ready mode
- Established and implemented Risk Management processes
- Provided Supplier quality management support for supply chain including external contract manufacturer and Service facility
- Established a quality metrics reporting system in support of continuous improvement
- Provide guidance and training in matters of regulatory compliance
- Oversee the Document Services and Quality Control test functions

Company Name, (location)

11/04 – 3/07 Director of QA/RA,

- Leader of corporate quality assurance and regulatory affairs
- Management Representative; FDA inspection 2005 with no FD483
- Developed and implemented quality systems for ISO 13485:2003 and CMDCAS certification
- Initiated and directed project to implement Agile product management documentation system across multiple company sites
- Developed quality planning process Integration of company acquisitions
- Provided regulatory support enabling product distribution within the US and other international markets, including Japan, Australia, Canada, and the EU.
- Established customer focus teams to address product performance issues resulting in reduction of field failures and complaint rates.
- Implemented a formal quality reporting systems and developed corporate quality goals and objectives
- Provided Supplier quality management support enabling successful product transfers to contract manufacturers
- Developed and implemented a process to establish and maintain worldwide authorized service centers
- Provided regulatory and quality support and guidance for new product development activities in headquarters facility and within subsidiaries. and intercompany
- Established comprehensive quality systems training program and conducted training to all employees.

Company Name, (location)

6/03 – 11/04 Plant Quality Manager II

- Quality Systems Management Representative for the Bay area Site
- Support New Product Development Teams and Manufacturing Operations
- Member of Corporate Sterilization and Biocompatibility Council
- Coordinated a facility relocation including ISO facility audit and State FDA inspection

11/02 – 6/03 Senior Quality Engineer

- Provide Quality Engineering/Statistical support for new product development teams
- Facilitate the implementation of the Product Development Process (PDP)

Company name, (location)

4/01 – 7/02 Director of Quality Assurance,

- Overall responsibility for Quality Control, Quality Assurance, Quality and Reliability Engineering, Document Control, Regulatory Compliance, Customer Complaint Analysis and Supplier Quality
- Organizational focus on Product Design and Development activities

Company name, (location)

- 4/00 – 4/01 Senior Quality Assurance Engineer,
- Developed and Implemented Supplier Management Program
 - Managed Supplier and Material Qualification activities

Company name, (location)

- 7/98 – 4/00 Reagent Supply Team Manager,
- Managed Supplier Quality Engineers,Commodity Managers and Buyer/Planners
 - Responsible for Chemical and membrane Procurement and material quality
 - Supply Chain Optimization and Cost reduction

- 1/97 – 7/98 Supplier Quality Engineering Manager,
- Supported mechanical, electronic, PCBA, Plastics, Print/Package
 - Established and managed Supplier Quality System Audit program
 - Lead Supplier Selection and Qualification efforts
 - Develop and Manage Quality of Contract Manufacturers of medical devices

- 1/94 - 1/97 Senior Regulatory Compliance Specialist,
- Conducted Internal audits in compliance with Quality System requirements
 - Conducted Quality System audits at Medical Device Contract Manufacturer facilities
 - Perform Preproduction Quality Assurance audits
 - Developed and conducted compliance training programs (GMP/GLP/ISO...)
 - Provided support for FDA, Corporate QA and ISO 9001 Surveillance audits

Company name, (location)

- 1/96 - 6/96 Quality Assurance Manager,
- Managed QC Inspection department for Infusion Therapy products
 - Developed GMP/ISO 9001 training materials and provide compliance training

Company name, (location)

- 12/91 - 1/94 Supervisor, Chemical Quality Control,
- Managed QC department Analytical Chemistry Lab for Reagent Operations
 - Component and finished product Inspection and testing
 - Establish quality improvement teams, infrastructure, and provide quality training to teams
 - Initiated Supplier Quality System Audit program

- 5/85 – 5/90 Process Development Chemist/QA product Test Supervisor,
- Primarily supported Reagent and Consumables division

Company name, (location)

- 5/90 - 12/91 Quality Engineer,
- Quality and regulatory compliance support for new product development teams
 - Established Risk Analysis System for new product introduction
 - Developed Quality Metrics Reporting System including Quality Costs Analysis
 - Conducted Internal Audits

Education, Certifications and Training:

B.S XXXXXXXXXX, University of XXXXXXXXX
ISO Certified Lead Assessor (ISO 13485:2003)
Member ASQ, Formerly ASQ Certified Quality Engineer and Certified Quality Auditor
Active Member Regulatory Affairs Professional Society (RAPS)
“Train the Trainer” for enhanced training skills
Extensive training in applied and theoretical statistics