What You Must Know About Medical Device Job Interviews
10/3/2011 7:10:25 PM

By Shula Stokols Pollard, PhD

Medical Device Jobs – Shine in an interview and hit the ground running

You may already have experience in the medical device industry or you may be brand new to it. You may be applying for a job as an engineer, manufacturing tech, sales associate, or manager. Whatever your case may be, make sure you know the basics of the industry before you start interviewing. If you don’t have the time or resources for formal education, you can learn a lot via online research and readily available educational materials (see www.meddevprimer.com). The more knowledgeable you are on both the company and the industry, the more you will shine in an interview and hit the ground running in a new job. This article will get you started.

Know the Industry:

If you are applying for jobs in the medical device industry, you should know a bit about how medical devices are brought to market, including the testing and regulation of medical devices. Medical devices are regulated by the Food and Drug Administration (FDA), which is one of eleven operating divisions within the Department of Health and Human Services. The FDA consists of nine centers and offices; the center responsible for regulating medical devices is called the Center for Devices and Radiological Health (CDRH). The CDRH homepage, which offers a tremendous amount of guidance, databases, and general information for the medical device industry as well as educational material, can be found at: www.fda.gov/MedicalDevices.

The FDA classifies and regulates devices based on risk; class I devices are the lowest risk devices and subject to the least degree of regulatory control, while class III devices present the highest risk and are subject to the most stringent regulatory control. Most class I devices are exempt from premarket notification and FDA clearance is not required before marketing the device. Examples include bandages and enema kits.

Most medical devices on the market are class II devices. Class II devices require premarket notification via a 510(k) submission. To meet the requirements for 510(k) clearance, a medical device must be substantially equivalent to another device that has been already approved through the 510(k) pathway. 510(k) submissions typically do not have to include clinical trial data. Examples include physiologic monitors and surgical tools.

Class III devices require a submission for premarket approval (PMA), which is significantly more demanding and expensive than a 510(k) submission. In addition, class III devices require postmarket surveillance, which is the monitoring of the safety of the device after it has been approved for commercial use. Class III devices account for less than 10% of all medical devices.

The majority of medical devices are approved without any clinical trial data; instead, preclinical data (bench top and animal studies), reports from the literature, and data from substantially equivalent devices can be used to demonstrate product safety. However, clinical trial data is required for novel or high-risk technologies. Particularly if you are hoping to work for a company that is developing or manufacturing a device that does require clinical data, you should have some background on how and why clinical trials are conducted.

From the perspective of the FDA, the purpose of clinical trials is to demonstrate the safety and effectiveness of a device in a target population under specific conditions of use. Device manufacturers may also use clinical trials to establish product differentiation claims in a competitive market.

Medical device clinical studies are typically classified as pilot/feasibility, pivotal, continued access, or postmarket.
Pilot/feasibility studies are often conducted to enhance the design of pivotal clinical research, but are not a criterion for approval of a device. Unlike drug studies which require both a Phase II and Phase III study, medical devices require only one well-controlled trial - the pivotal study - to demonstrate safety and effectiveness. Continued access studies can be performed during the time between completing a pivotal study and device approval. Postmarket studies are performed after the device has been approved.

A good trial design can reduce selection and observer bias, minimize variability and confounders, and increase efficiency and usefulness of results. Given the large number of clinical trials conducted, care must be taken when interpreting the results of any one trial. The strength of the evidence from a clinical study is proportional to not only the magnitude of the observed effect, but also how well bias and variability were controlled when the study was conducted.

The statistical significance of a study is a measure of how confidently the observed difference between the study groups can be attributed to the treatments vs. random chance. Most commonly, the p value is used to report statistical significance. Of note, statistically significant differences are not necessarily clinically significant, in that they may not be large enough to provide practical relevance.

ClinicalTrials.gov, a registry of federally and privately supported clinical trials, is an excellent source to learn more about clinical trials and also provides a searchable database. On the advanced search page, include search terms of interest and “device” in Interventions field. The advanced search page can be found at: www.clinicaltrials.gov/ct2/search/advanced.

Know the company:

Research, research, research. “Research the company you are interviewing with before the interview” is sound advice for any company in any industry, and it is true when pursuing medical device jobs as well. The resources that follow can help you research not only the interviewing company, but also its competitors; knowledge of competitor products and technologies often help distinguish one candidate from the next. And if you’ve already nailed the interview, you can still use these resources to impress your coworkers and hit the ground running once you start the job.

Of course the company’s website is a great place to start. Often times a company website will provide recent news releases, investor information, and descriptions of currently marketed as well as pipeline products. At a minimum, you should be up to date on everything presented in the company website.

If the company is one of the larger medical device companies or is developing a novel or high-risk device, be sure to check out clinicaltrials.gov to get a feel for the company’s clinical trial program. You can learn about what studies they have planned, how many they have completed or have in progress, and the types of interventions they are pursing, but may not yet be discussing on the company website.

Perusing a company’s intellectual property may sound tedious and daunting, but can actually provide a wealth of useful information. Pay particular attention to the Background section of patents; this section is easy to read and often highlights the problems with the existing technology and the differentiating features of the company’s technology. There are a number of websites that can be used to search patents; the U.S. Patent and Trademark Office publishes all patents and patent applications online at www.uspto.gov/patents.

Finally, looking up recent news for the company you are interviewing with not only provides you with the most recent information pertaining to the company and its competitors, but shows you are in tune with the industry and up to speed on the company’s latest achievements (or problems). Two noteworthy sites for medical news are www.medscape.com and www.salesandmarketingnetwork.com.

Find more in depth coverage of the information you need when starting a career in the medical device industry - including FDA regulation, clinical trials, preclinical testing, quality & risk control, and intellectual property - in the Medical Device Primer series, found at www.meddevprimer.com.

Check out the latest Career Insider eNewsletter - October 20, 2011.
Sign up for the free weekly Career Insider eNewsletter.