



## Nontraditional Patient Care

Regulatory affairs positions offer alternatives to bedside care

By Rosina Robinson, MEd, RN, RAC

I believe that I have never had a greater impact on the health of patients and their health care providers than I do today. I recently have traded my scrubs for a business suit. I am now I am a nurse and a regulatory affairs professional in a small consulting company that helps medical device manufacturers obtain the marketing clearance or approval for their medical devices or combination products in the United States, Canada and Europe. (See figure for more information about regulatory affairs.)

### The Beginning

In June of 1969, I solemnly professed the Florence Nightingale Pledge at the commencement exercises for the Ravenswood Hospital School of Nursing in Chicago.

Almost 10 years later, I returned to school to work toward a bachelor's degree in psychology. It wasn't that I was unhappy with clinical work, I just wanted to explore some new ideas. It was during that pursuit that my life changed and I started on an exciting journey that led me to where I am today.

### What A Nurse Can Contribute

I recognize that most nurses do not know what a circuit schematic for a microprocessor like engineer counterparts is, let alone can read one. Many may not have a grasp of organic chemistry like the pharmacy and chemistry professionals practicing in regulatory affairs. With a nursing background, however, a nurse provides a uniquely human perspective to the issue of medical devices from the perspective of a consumer, a health care professional and patient advocate.

A nurse with clinical experience has a health care provider's perspective on the general acceptability and limitations of the design and features of a new product. Use of similar products can identify past and potential problems in device design and operational characteristics.

Experience with patients provides knowledge of the degree of simplicity required or level of complexity acceptable for patient training in safe use of a medical device.

In the implementation of the design control elements, the regulatory professional with a nursing background can provide invaluable design inputs.

A working knowledge of anatomy, physiology, pathophysiology, psychology and human factors can contribute significant information to the hazards analysis for any given product and techniques for mitigation and amelioration of those hazards.

Because of the nature of the work environment, nurses are masters of time management and bring good organizational skills to their work.

Years of communicating about patients and clinical findings, both verbally and in writing, are good experience for the clear and concise writing required in submissions and communication with regulatory agencies. Nurses practice their interpersonal skills every day, translating medical jargon into lay-terms and communicating clinical findings.

### Positive Impact

The regulatory affairs profession has offered me many new personal and professional challenges. I have been given many opportunities to make a positive impact on patient care, not on the one-to-one basis of nurses in clinical practice, but on a different scale.

Innovative devices make significant impacts on patient care, while "me too" devices may provide less expensive alternatives to existing products without sacrificing safety or effectiveness, thereby reducing health care costs.

As a staff member of a consulting company that assists medical device manufacturers, I am involved with a wide variety of products and projects. My activities take place during numerous stages in a device life cycle. There is no time for boredom.

In any single day, I perform any of a number of activities ranging from helping a manufacturer determine the regulatory status of their device even while it still in the concept stage, writing a premarket notification, helping a company design a clinical study, interpreting the results of a clinical study, or helping a company through the premarket approval process. In addition, I am required to stay informed about legislative activities affecting my regulatory practice and my nursing practice.

Working in industry I have learned to reframe problems into challenges and opportunities and not to delay meeting challenges head-on.

I have never felt more involved in the care of "my" patients than I feel today. My current night and evening shifts are generally limited to working over the keyboard on my laptop computer, rather than performing chest physiotherapy. The most hazardous conditions that I have spread to my home environment from work are not microbes, but rather an explosive growth of computer technology and stacks of reading that never seem to get any shorter.

### **Getting There From Here**

Regulatory affairs professionals are not only nurses. We come from backgrounds in engineering, medicine, pharmacy, law, technical writing and clinical laboratory science.

Unlike our first professions where educational preparation was structured and formalized, there has not been and there continues to be no direct and standardized path to the regulatory affairs profession. Each of us comes to it with a different perspective on the practice of regulatory affairs. But this non-structured manner of education is slowly changing and can offer new and expanding horizons to nurses in the future.

There are many new academic programs being developed to prepare individuals with undergraduate or graduate degrees in other science or medical disciplines for regulatory affairs or clinical research careers, including graduate certificate programs, domestic and international regulatory affairs at Northeastern University, University College; masters of drug regulatory affairs and health policy at the Massachusetts College of Pharmacy; and a PhD program in drug regulatory affairs at the University of Rhode Island.

Online programs in regulatory affairs are also being developed.

To those nurses who are looking for a new challenge, working in regulatory affairs may give you the opportunity to become every patient's most vocal advocate. Like me and many others, we continue to "devote ourselves to the welfare of those committed to our care."

*Rosina Robinson is senior regulatory consultant for Medical Device Consultants Inc., North Attleboro, MA. An RN since 1969, Robinson spent 2 years as an Army nurse and worked in large inner city hospitals, in the community hospital setting and in outpatient facilities.*

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