BOP, DOT, FDA... Oh my!

Know your medicine, know your pharmacist? Often times in nuclear pharmacy, “Know your regulations, Know your regulatory affairs gurus” seems much more fitting. And when I think of a guru in this area, I think Rich Nickel.

Mr. Nickel’s passion for nuclear pharmacy began in pharmacy school at Duquesne University, where he received his AU training, and in graduate school at University of Pittsburgh where he studied health physics. After graduation, he started his career as a clinical nuclear pharmacist where he wrote Investigational New Drug Applications, prepared radiopharmaceuticals, and worked alongside physicians to implement new protocols for the use of radiopharmaceuticals in the hospital. He explains that while this first job was both challenging and humbling, it was one of the highlights of this career. (Oh, and I should also mention it’s where he met the love of his life.) He practiced as a clinical nuclear pharmacist for 5 years, then moved across town and first served as the Pharmacy Manager for Mallinckrodt for 3 years, followed by the Regional Operations Manager for 14 years.

So how exactly did he get involved in regulatory affairs? Rich explains that he always had an interest for regulatory affairs, but didn’t have time as a manager. Fortunately, he was able to secure another position with Mallinckrodt that would afford him the opportunity to become more involved with this unique area within nuclear pharmacy. He adds, “I saw a need and I was finally able to do it.” From here, he started attending rule-making meetings in the early 1980s, including a meeting in 1987 where the Massachusetts Board of Pharmacy was adding language to include and finally recognize nuclear pharmacy as part of pharmacy practice instead of strictly manufacturing. Mr. Nickel continued fighting for the practice of nuclear pharmacy on a federal level by petitioning the National Institute of Occupational Safety and Health (NIOSH) to remove radiopharmaceuticals from their Hazardous Drugs List. Also, along his journey, he has served on the board for the National Association of Nuclear Pharmacies (NANP), served as co-chair of the nuclear pharmacy committee for the Council on Radionuclides and Radiopharmaceuticals (CORAR), and last year he was appointed by the Society of Nuclear Medicine’s

Did you know...

Did you know that in 1958 William H. Briner started the National Institutes of Health Radiopharmacy and that he is considered one of the fathers of radiopharmacy?

Know your MEDICINE. Know your NUCLEAR PHARMACIST.
As you may have guessed, no day is like the previous when you’re in this area of practice. Writing procedures, enhancing quality systems for the pharmacies, and keeping abreast of the latest BOP and FDA changes were only part of his role. The other time was spent auditing the pharmacies. Rich describes his time allotment as “50% support and 50% oversight and enforcement, with an emphasis on support.” Mr. Nickel explains that before new regulations can be implemented, it is important to educate team members on the why... why the new rules or guidelines were created and why they are crucial to best practices. Hint, hint: don’t forget there’s a patient on the other end of that pig!

When inquiring about the pros and cons of his job, Rich proudly admits that the best part about his role was educating and working with his peers on implementing best practices in nuclear pharmacy (think radiation safety, aseptic techniques, etc), as well as informing colleagues on the newer regulations that may affect them. In addition to educating others, he also enjoyed the challenges of answering regulatory-type questions that pharmacists often present. However, Rich’s tone gets a bit more somber when he depicts his least favorite aspect of his job - “getting people out of trouble and helping protect licenses” when the proper regulations were not followed. Can’t say that I blame him.

So where does Mr. Nickel see nuclear pharmacy in the future? He thinks that PET will likely play a bigger role in the future, but that the next 6 months will be a critical turning point for PET pharmacies, as they become manufacturers and their drug products obtain approval by the FDA. And although the switch from pharmacy to manufacturer is a major change, Rich speculates that the role of the pharmacist will only become stronger.

If you’re thinking that a job like this requires all work and no play time, Rich would prove otherwise. Outside of meeting with the FDA, updating quality systems, and learning all the details of new regulations, he still has time to volunteer with the health ministry at church, serve as an officer with the Knights of Columbus, and even tour new places on his BMW motorcycle. (Yes, that’s him in the above left photo, standing between his prized bike and the giant chicken.)

As we finish our talk, he offers some much-appreciated advice to students and new practitioners. He encourages us to become familiar with all the regulations and standards of practice; to reach out to others who know more about an area than you do; to strive for quality; and to “keep an open mind and have a thirst for knowledge.” So when you’re in the pharmacy and nothing seems to be going right — your generator doesn’t come in on time, your QC doesn’t pass, or your cyclotron seems to have a mind of its own - remember the why of all the regulations and remember to keep the patient mind. “After all,” Rich tells me, “the job is what you make it; have a lot of fun with what you do!”

Until next time,

Ashley Mishoe

Upcoming Events:
March 1-4, 2013
APhA Annual Meeting & Exposition
Los Angeles, CA

“Keep an open mind and always have a thirst for knowledge.”

Ashley Mishoe, PharmD - Chair
Erika Podzielinski, P3 - Co-chair