



## ONE YEAR OF REGULATORY TRAINING ABROAD: **KOREAN MFDS STAFFER WORKING AT U.S. CRO SHARES HER EXPERIENCE**



*Interviewer*

**Patrick JP Burke**

Senior Director, Business  
Development



*Interviewee*

**Na Ry Woo**

Korean Ministry of Food  
and Drug Safety (MFDS)  
Scientific Reviewer

### **BACKGROUND**

The Korean Ministry of Food and Drug Safety (MFDS), the Korean equivalent of the U.S. FDA, has a number of international cooperation programs designed to help key staff better understand global medical product development practices. Through one such program, Na Ry Woo, an MFDS Scientific Reviewer, is spending a year in the United States increasing her knowledge of medical product development practices of a U.S. Contract Research Organization (CRO) and of U.S. FDA regulations.

Na Ry's host organization is Amarex Clinical Research, LLC, an NSF International company, a CRO located in Germantown, Maryland. Amarex helps biotech, pharmaceutical, medical device, diagnostic and vaccine companies obtain U.S. FDA and international marketing approval of their new medical products.

Arriving in the U.S. in November 2019, Na Ry and her family started their American adventure in temporary quarters in Germantown.

**Patrick:** Na Ry can you describe the Korean MFDS and the training program in which you are participating?

**Na Ry:** The MFDS is a governmental regulatory agency responsible for market authorization of drug products, biological products and medical devices in Korea. I am working as a scientific reviewer of drugs within the cardiovascular and neurology product divisions at MFDS. The Korean and U.S. medical product regulatory systems are similar, and continued collaborations with the most developed foreign agencies, especially the U.S. FDA, helps the MFDS to maintain and grow its regulatory system.

**Patrick:** How did you come to be at Amarex?

**Na Ry:** I was very excited when I learned that I was accepted into this training program. It was difficult finding an appropriate training organization. From the outset I planned to get my training at a CRO as it's the most appropriate organization for learning U.S. FDA policies and procedures. I later learned that Dr. Heemin Rhee, a former U.S. FDA pharmacologist, current consultant and U.S.-Korea liaison within the biotech and pharma industry, recommended me to my sponsor organization, Amarex. Dr. Rhee's relationship with Amarex developed several years ago because Amarex has done a lot of U.S.-Korea biotechnology collaborating for global drug development. Dr. Rhee made the suggestion and they immediately began preparing for this working relationship and started the visa process so that I could move to the United States.

**Patrick:** Where do you live now, how did you find your new home, and who came with you from Korea?

**Na Ry:** I came with my immediate family, which includes my husband and two daughters. We live in an apartment in Rockville, Maryland. A senior colleague, who had completed a two-year training program at the U.S. FDA, recommended the location. The experience so far has been very special to me and my family.



**Patrick: How are you and the family adjusting?**

**Na Ry:** My children are in the local elementary school and they enjoy the experience. It makes me very happy that they have such a unique opportunity. They are very fast at learning English too because their classmates are so kind and happy to help my girls. My husband is their primary caregiver while I work, and he enjoys spending time learning English also. We go sightseeing at every free moment, trying to soak up the American experience. My friends at Amarex say that I go out and enjoy the U.S. life much more than they do!

**Patrick: Now that you have been working at Amarex for several months, what are the highlights of your experience, both at work and outside of work?**

**Na Ry:** I work in the Regulatory Affairs department. My work consists primarily of preparing documents for submission to the FDA and this has given me a better understanding of the FDA submission process. I also participate in regular departmental meetings to learn about all ongoing regulatory activities that Amarex handles. It is a great place to work. Many of the employees are international and I enjoy the social activities that I participate in with my colleagues. We have many celebrations here, such as a monthly office 'social hour' and traditional U.S. holidays. Outside of work, I spend more time with my family now than I did when we were in Korea. In Korea our schedules are so different that we don't often have dinner together. We are getting to know each other so much more in this experience.

**Patrick: What, if anything, has been difficult for you?**

**Na Ry:** English is my greatest difficulty. It is a barrier for me, it is hard to understand what people are saying in conversations. I expect that after one year of training here, I will be fluent in English and I will be able to speak and understand the language freely.

**Patrick: Have you met other Korean speakers here in Maryland?**

**Na Ry:** Yes, in my second week I attended a meeting arranged by the Korean Trade Investment Promotion Agency (KOTRA) with the Maryland state Department of Commerce and I met several representatives from five visiting Korean biotech companies. The following day I attended a conference hosted by the Korean American Professional Association of Life Scientists (KAPAL), where I met many Korean scientists and a few other MFDS trainees. A friend and colleague, Dr. Haeyoung Ahn, has also kindly offered ongoing advice and encouragement during my stay in Maryland. Dr. Ahn is a former FDA Deputy Director of the Division of Pharmacology-3. She now works as a consultant to Korean biotech and pharmaceutical companies.

**Patrick: I understand many Korean names have a particular and special meaning. Does your name have a particular meaning?**

**Na Ry:** Yes, Korean names usually do have a particular and very special meaning, but my parents just wanted my name to be easy to pronounce so it does not have a special meaning. I notice that my American colleagues do not have difficulty pronouncing my name, so that is a success. There is a flower called Nary in Korean though, so you could say it is a type of flower.

**Patrick: Thank you Na Ry. We look forward to another interview with you near the end of your training to learn about your complete experience.**

For more information, contact [healthsciences@nsf.org](mailto:healthsciences@nsf.org) or visit [www.nsfhealthsciences.org](http://www.nsfhealthsciences.org)

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Cite as: NSF International. September 2020. Korean MFDS Staffer Working at U.S. CRO Shares Her Experience. NSF: York, UK.

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