

## The RAC General Scope Exam or: How I Learned to Stop Worrying and Love GHTF Guidelines

By Karen Long, RAC

Like many of my colleagues, I came to regulatory by happenstance. My company was preparing its first new drug application (NDA) and it was all hands on deck to get the big submission out the door. I enjoyed the excitement of assembling a submission that was essential to my company's success. Lab work had never been this exciting! (Except maybe the time I spilled the glacial acetic acid and the Hazmat team arrived, but that was exciting in the wrong way.) Regulatory work was important!

In the window between the big submission and the inevitable questions from the health authorities, my manager suggested that I take the US Regulatory Affairs Certification (RAC) exam to broaden my knowledge. Over the next three months, I read through the RAPS *Fundamentals of US Regulatory Affairs* book and the US Food and Drug Administration (FDA) website and took the practice exam whenever I was feeling cocky. It was a good year; our NDA was approved and I got a spiffy RAC lapel pin.

Years later, I was working at a different company that decided to “change focus” shortly after I arrived. I lost my manager, half of my department and the project I had been hired to complete. It seemed a good time to upgrade my skills, so I signed up for the EU RAC exam. Again, I worked through the *Fundamentals* book and the practice exam and met with a long-suffering group of colleagues from my local RAPS chapter until the intricacies of EU regulatory became clearer. The EU exam was definitely harder for me than the US exam. At that time, the EU was composed of 25 nation states and its regulatory framework was rapidly evolving to accommodate more. The regulations were written to appease two dozen health authorities, not to win any literary awards. It was a tough slog, but I got another RAC pin.

The following year, I signed up for the Canadian RAC exam. Why not??? At least, I was getting familiar with the exam format, and the Canadian regulatory framework for drugs and devices is similar to both the US and EU systems. And as a Canadian, I had home country advantage. The language of the Canadian regulations was so familiar and comfortable compared to the

bureaucratic eloquence of the EU regulations. And it was a tremendous relief to only have to consider a single country (albeit in French and English!).

When RAPS announced the General Scope exam, a friend from my local RAPS chapter threw down the challenge to take one more exam, more or less as a joke. My friend Ron had all three RAC credentials too—but he took his exams in the midst of an NDA, rather than an economic downturn, so I think his are more deserved. We both registered for the exam thinking that a *Fundamentals* book and a practice exam would be available before the testing date. But since this was the first running of the General Scope exam, these useful study aids had not yet been created. We were on our own.

We had accepted the challenge in August and planned to take the exam in November, so we had roughly three months to prepare. We drew up a study schedule to cover all of the major areas identified by RAPS: the International Conference on Harmonisation (ICH) guidance for drugs, the Global Harmonization Task Force (GHTF) for devices and the relevant guidelines from the International Standards Organization (ISO) and the World Health Organization (WHO).

Drawing up the schedule was the easy part. We assigned a major subject to each week (ICH E or GHTF Study Group 5 or ISO 14971, for example). Then we planned to meet for lunch every Thursday and talk each other through various potential questions. In reality, that happened maybe three times. Working at a young company means that priorities shift rapidly and deadlines are unforgiving. Studying for the RAC exam got bumped down the priority list many times. By the last month, we were trying to cover a binder of regulations each week. Fortunately, we had covered the ICH guidelines through work and in previous exams. The ISO guidelines are the bread and butter of the drug industry, so those were familiar. Just the WHO and GHTF guidances were new.

Being a thrifty sort, I had no intention of purchasing the publicly available study bundles for guidance documents (e.g., ICH and GHTF). But I made an exception for the WHO guidelines. WHO can be charitably described as a “mature





bureaucracy,” meaning its website is a labyrinth! It was far easier to order the pamphlets from RAPS. I was impressed by the WHO guidance document, *Medical Device Regulation: Global Overview & Guiding Principles*. I will definitely be using it as a training tool for people unfamiliar with global regulatory systems.

The other great revelation was the GHTF guidelines. I had heard of them, of course, but since they were not enforceable, I had mentally

put them in the “nice-to-know” category. As part of our exam preparation, they shifted to the “need-to-know” category. They are REALLY good! They have all kinds of useful ideas in them! Who knew?? I particularly enjoyed the two on clinical evaluations. My company was preparing to implement the revised *Medical Devices Directive (MDD)* and was looking for a template for our clinical evaluation reports. It was all there! We also had the good fortune to have Dr. Larry Kessler, author of many of the GHTF guidelines, come to speak at our RAPS chapter. He was so passionate about harmonization of device regulations; it was incredibly inspirational.

In the end, the exam went well. I have another dandy pin. I wish they gave RAC points instead. Reading regulations in your spare time for three months should be worth something a little bigger. Maybe I should suggest a badge or a jaunty hat for multiple RACs?

I almost wish I could go back and take the US exam again. So much has changed since 1999, and I’m clearly the sort of person who works best under a deadline. But not yet...I’m going to hold out for that hat.

**Author**

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