**TIBBS Career Blitz Career Profile Questionnaire**

1. Please provide your name and employer:

Name: Joanna Warren

Employer: GSK (formerly known as GlaxoSmithKline)

1. What is your current title and how long have you worked in your current job?

Job Title: Global Regulatory Affairs Lead (GRL) Delegate, Manager

Time in current role: Started Dec 16th, 2021

1. Where did you get your PhD and what discipline was it in?

PhD in Immunology from UNC-CH (Microbiology & Immunology Department)

My research was focused on studying the adaptive immune response to untreated and treated HIV-infection to inform vaccine design. I also had the opportunity to work on 2 first-in-human HIV vaccine trials.

1. Did you do a postdoc?

Yes, I stayed in my PhD lab for an additional 10 months. Half my time was spent on continuing work from my PhD (HIV-related work). The other half was spent collaborating with another lab where my work focused on identifying immunogens for vaccine design against Chlamydia infection.

1. What are your main daily responsibilities?

Responsibilities shift day to day depending on where in the drug development process the assets are in, whether there are upcoming internal governance meetings or external health authority interactions/ submissions. Overall, I have the following responsibilities –

1. **Writer:** Author, prepare and support global regulatory submissions, which may include preparing for:
   1. Meetings with health authorities: pre-Investigational New Drug (IND) applications (US-FDA), European Medical Agency (EMA) Scientific Advice (SA) Meetings, PMDA (Japan), Health Canada.
   2. IND applications/ CTA initial submissions
   3. IND/CTA Amendments to health authorities
   4. Updating documents (ex. Investigator’s Brochure, Annual Report)
2. **US Agent**: Serve as the primary liaison with the FDA including coordinating meeting activities such as preparing meeting materials, meeting attendance, and documenting interactions with the agency, preparing responses to FDA questions, emailing/ calling FDA.
3. **Regulatory Lead**: oversee day to day activities, communicate project status, risk and mitigation plans and accomplishments, prepare for internal governance meetings, collaborate with other functions, attend internal meetings (ex. safety, clinical team), coordinate/prepare submissions to health authorities.
4. What are the keys to success in your career field?

Attention to detail/ organized, eagerness to learn, team player, communication skills (writing and speaking)!

1. What were the most important factors in choosing your career path and current employer?

Meaningful and impactful work, work-life balance, opportunity to learn and grow.

1. What activities (if any) did you participate in that helped you be successful in obtaining your job?

I participated in several activities during my graduate career, including attending several events hosted by TIBBS.

* 1. Certificate in Business Fundamentals
  2. Drug Development Conference at Biogen (offered by TIBBS)
  3. The Process of Drug Development: Eli Lilly e-course on FDA drug discovery and development (offered by TIBBS)
  4. American Association for the Advancement of Science: e-courses on science communication/writing (offered through TIBBS)
  5. Duke Regulatory Affairs Training Program (ORAQ): e-course on regulation of drugs/devices by the FDA
  6. Design and Interpretation of Clinical Trials: Johns Hopkins e-course on randomized clinical trials (course on Coursera)
  7. Clinical Protocol Development Workshop, UNC-CH: submission of sponsor-investigator INDs (workshop at UNC – Translational and Clinical Sciences Institute
  8. Science Writing and Communications (SWAC) – editor/ writer

Additionally, my exposure to the regulatory world, preparing documents for first-in-human vaccine trials during my PhD, as well as the various courses I took to explore this topic helped me speak about my experience and why I wanted a career in regulatory during job interviews.

Since entering the regulatory field, I stay up to date with current regulations by attending webinars hosted by the FDA and signing up for newsletters from various health authorities and website (ex. <https://www.raps.org/news-and-articles>).

1. What 1 or 2 pieces of advice do you have for people who want to land a job like yours?

Try to gain as much experience as possible – whether through taking courses (in-person or online), reading up on regulatory news, or having hands on experience with preparing documents for the FDA. Also, it is important to keep an open mind, have a willingness to learn and be flexible (regulations and ways of working change all the time!). I enjoyed browsing through the “*Fundamentals of Pharmaceutical and Biologics Regulations*” to better understand the history of regulatory affairs and the FDA (note: this book is detailed).

1. How is the work/life balance in your career field and how much of a factor was that in your career choice?

Work/life balance was extremely important to me when choosing a career.

In both of my roles in regulatory (at GSK and at Parexel, a contract research organization where I was a regulatory consultant) I was not expected to work more than 8 hours a day or on weekends. However, in both jobs, I sometimes find myself working longer hours because I truly enjoy the work (and at Parexel, working with clients can sometimes make you want to work longer hours).