**TIBBS Career Blitz Career Profile Questionnaire**

1. Please provide your name and employer:

Michelle Villasmil, FUJIFILM Diosynth Biotechnologies

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

I am the Associate Director of Regulatory Affairs at the FUJIFILM Diosynth Biotechnologies site in Research Triangle Park, NC.

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

I got my PhD in *Cell and Molecular Biology* at Drexel University College of Medicine.

1. Did you do a postdoc?

Yes, at UNC-Chapel Hill!

1. What are your main daily responsibilities?

I am the site SME for Regulatory Affairs and provide regulatory expertise to the site and other FDB sites. I manage regulatory activities for client projects and ensure accuracy and alignment to regulatory filings. I maintain site-related regulatory registrations (such as master files and site GMP licenses/certificates).

1. What are the keys to success in your career field?

Collaboration. Regulatory is a discipline that connects all areas of drug manufacturing (e.g., facilities/utilities, manufacturing, analytical and microbiological testing, quality assurance) and building collaborative relationships with internal stakeholders is a key to success within the organization. For contract organizations, collaboration with Sponsors is an important key to success for everyone involved – if we can successfully work as a team, rather than separate entities, we can expect better outcomes.

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

“Industry” covers a lot of potential careers, especially in this area of North Carolina. After meeting with people in different types of industry during my post-doc, Regulatory Affairs (particularly at a contract organization) was the most appealing area to me. Regulatory Affairs is a dynamic field, with the little “c” in cGxP (current Good Practice) always changing. By working in a contract organization, I’d also have exposure to a wide variety of programs at varying stages of development. I gained a lot of experience in the Clinical and Submission areas of Regulatory while at Cato Research, and I made the transition to FUJIFILM Diosynth Biotechnologies to get first-hand exposure to the Quality (aka Chemistry, Manufacturing, and Controls [CMC]) side of Regulatory.

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

My experience at Cato Research helped me earn my Regulatory Affairs Certification (RAC) through the Regulatory Affairs Professionals Society (RAPS). I spent a lot of time researching companies that I wanted to work at and finding programs that were specifically designed for scientists exiting their PhD/post-doc.

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

Look for training/fellow positions at contract organizations and pharmaceutical companies. Once you’re there, say “yes” to any new project opportunity offered.

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 a major factor in my career choice. After working almost constantly during my graduate studies and post-doc, I needed to move into a field that offered a balance. I have been fortunate to work at companies that prioritize a work/life balance. While there can be projects and problems that require off-hours work to meet a deadline, they are few and far between.