



Name: Nick Themeles

Background:

- **Educational Background:**
 - University of Massachusetts – B.S., Biology
 - Northeastern University – M.S., Regulatory Affairs
 - George Washington University – Master of Business Administration
- **Your first job after college:**
 - Manufacturing Development Associate, Genzyme Corporation
- **How did you land your first job after college?**
 - Inadvertent networking in an undergrad class spring of senior year. A classmate had been connected to an HR recruiter at Genzyme Corporation, upon his job acceptance my classmate was handed a stack of business cards from the HR recruiter who requested to share with potential candidates he felt were a good fit for the open roles. In short, when mentioning what industry and location I was aiming for he shared the information with me, interviewed and ultimately accepted the offer.

Current Position:

- **What is your current title and name of the company you work for?**
 - Global Regulatory Affairs, Director – Amylyx Pharmaceuticals, Inc.
- **How did you land this job?** (*networking, interning, traditional job application, etc.*)
 - A former colleague I had worked closely with is in the process of establishing a Global Regulatory Department. Due to our work history, collaboration and experience I was asked to explore an opportunity that would offer professional growth, mentorship and an environment where I could have more influence and leadership opportunity.
- **3-5 job skills required for your role:**
 1. Experience with US and ex-US clinical trial and marketing application submissions.

2. Regulatory guidance on projects including regulatory strategy, requirements for clinical studies and marketing approval in domestic and international markets, strategic development plans (early and late-stage developments), and Health Authority interactions.
 3. Strong knowledge of drug development and regulatory policy, including product approval and launch.
 4. Proficiency in pharmaceutical technical writing such as reports, and regulatory submissions and reviewing technical documentation and reports.
 5. Ability to successfully communicate verbally and in writing to convey complex information or obtain data across multiple disciplines and externally with partners including the FDA, international regulatory authorities, CROs, CMOs, etc.
- **What does a typical day/week at work look like for you?**
 - Depending on the program (or how many programs are being supported) there can be a lot of meetings: project related meetings, team meetings and management meetings. Hands-on work on projects and product documentation as well as processes, preparing and holding presentations. It is also essential to stay current on changes in the regulatory space and work on areas that are important in the longer term.
 - Communicating. Regulatory Affairs stand at the midpoint between a variety of departments, SMEs and regulatory agencies and information is flowing between all these groups. Communication lies at the center and do a lot of it in the form of emails, presentations and documents.
 - Providing regulatory advice. Amid the changing global regulatory landscape and internal corporate strategy, Regulatory Affairs is part of that change evaluation process determining how the overall regulatory strategy can support the desired outcome and how much regulatory stress to expect/is involved with a given change. For example, is a change in overall product strategy worthwhile when the regulatory hurdles demand large quantities (sometimes years' worth) of clinical or manufacturing data and the development costs needed to collect to support said change? Regulatory advice will be essential to plan these changes.
 - **How are you still applying your undergraduate STEM degree to your current role?**
 - Having earned what, I would call a degree in a broad subject with many facets (biology) I'm not applying direct knowledge to my current role. Occasionally, leveraging physiology and cellular biology concepts at a very high level however the analytical and critical thinking skills ascertained throughout is what I can leverage and apply.
 - **What's next for your career?**

- Further developing my skills and experience within my field, it never ends with the changing global landscape in regulations that influence healthcare. From a managerial perspective to train and develop others who are new to Regulatory Affairs or in junior roles looking to advance. The technical skills are one part but developing others in a way that was not available to me is important both professionally and personally, therefore focusing on different aspects of people management. Broader insight and experience with business development, commercialization, brand strategy and corporate strategy is also a big interest.

Perspective:

- **What was your big career break?**
 - It could very well end up being my current role! But given my experience to date, I would say being hired in 2008 at Biogen. My manager hired me based of skill set, personality/group fit but also the ability to apply the previous gained knowledge to a drug modality I had no prior experience with. So, I would say that was my biggest break because he did not look at me from a “black and white” skill set only viewpoint but potential moving forward. For that, I’m grateful and was able to receive some rare but much needed experience in the field I likely would not have gotten otherwise.
- **Best Career Advice you ever received:**
 1. Don’t let significantly more experienced or seasoned individuals discourage you from your development goals and getting to where you want to go/be professionally if they are difficult, undermining, politically motivated or even hostile in the work environment. No individual’s skill set, or experience is identical, everyone got to where they are via different paths. During a college internship my manager shared that with me, it was the first piece of professionally advice I received.
 2. On a roughly monthly basis during one-on-one meetings with your manager ask if they are satisfied with your output, quality of work, performance etc. and what can be improved. It shows you’re not just executing a “to do” list but demonstrates you are invested in your growth and improvement. I read in a “Money Magazine” article and absurdly enough it stuck with me decades later.
- **What was your Biggest Career Failure/ Regret? How did it help guide your career path? What did you learn from them?**
 - Not saying “no” or declining, in a professional manner, programs and projects that would create a stagnancy or dead end in my growth, development and ultimately career. Being raised with the mindset and a respect for the workplace and/or management to take on what was asked of me because one, you have a job and must do it and two, “don’t make waves” get it done and get it done well. This demonstrates willingness and

teamwork. However, when these large volumes of requests to take on “X” project/program become solely to the advantage of the company and leadership teams’ “to do” list, you simply become a means to an end, a commodity, moved from program to program or project to project as needed. I failed myself by allowing to become one of these commodities.

- This helped guided my career path in a couple ways. First, when I decided to start communicating that most of these requests were not in line with my desired career path and make the decision that is best for me it gave me more control over my development. It also simultaneously communicates where your interests lie. This is not to say one should decline everything that is not completely aligned or beneficial to one’s career trajectory – there will always be the inevitable undesirable projects and programs. Second, it opened up other opportunities that were more in line with my development, may be this was good timing, whatever the case, had I agreed to everything prior the better opportunity would never have had a chance.
 - The learnings from all this are that there will be a time in your career and development, more likely mid stage where you have to be critical and aware of what is being asked of you professionally. Is this benefiting all involved or just management and the company.
- **How do you decide when it’s time to move on from a position or which new direction to take?**

This could be any number of red flags, personally I find its one or more of the following:

1. When performance and the ability to align your career development within your organization are not recognized in the form of additional opportunities adding to your skill set or allowing you to achieve broader visibility.
2. When there is miscommunication or significantly different messaging coming from levels of management in terms of opportunity and employee growth – this can and will stall (or derail) your career.
3. When your direct manager and/or leadership either has no interest in professionally developing you (or others) or there is no clear upward mobility pathway (providing that is one part of your longer-term goals).

It’s important to qualify the above that the decision to move on or change direction should not be made on an isolated experience of an n=1, but on a consistent longer-term pattern.

- **What advice do you have for recent STEM graduates?**

1. Networking is great, but don't network to do death and force connections. I think those that happen naturally or with some level of proactiveness are best. Don't connect just to gain one more connection.
2. Be open to the many aspects of STEM positions. For those just starting out, I would recommend trying most any opportunity as there is so many, you'll likely come across an area or function that you didn't know existed.
3. I can't take credit for this one and recently realized how invaluable it is with my most recent job change. Have a "council" of trusted individuals in the form of a limited group consisting of colleagues, friends or combination thereof. Like anything it will change over time, with individuals coming in or out. Having a "council" for advice and feedback on everything from role specifics/functional responsibilities to questions for the interviewers, to salary and compensation negotiating, to how to handle giving your notice and exit interview in the current position, was the most beneficial piece in my decision to move on from my last role. My council consisted of none other than the Career Lab Formula creator and author, a longtime colleague in my field who I've been through it all with and a very good friend who built his own successful global business from the ground up. Each had their own perspective on the whole picture but also their unique input and constructive insight on specifics pieces. In other words, they helped me set expectations for myself and what I should (or should not) expect from the process. Of course, having these confidants as the foundation of these relationships was key and hope to support each of them in whatever manner they request in the future.