TRANSITIONING FROM ACADEMIC RESEARCH TO PHARMACEUTICAL INDUSTRY DRUG FORMULATION AND ANALYTICAL DEVELOPMENT

By Bobby Walker, M.S., Singota Solutions

Singota® Solutions is a CDMO located in Bloomington, Indiana, USA that specializes in Parenteral, Early Phase Drug Development and Aseptic Filling projects.

Fresh college graduates and/or academic research associates may find it difficult to make the transition from academic research and studies to industry research, which demands from them additional skills, sets different objectives, and defines "success" differently.

Whether they work for a pharmaceutical/biopharmaceutical sponsor or an organization supporting the industry, individuals with a better understanding of these differences have several advantages. They may be more attractive candidates for industry research positions. They can be champions for increased collaboration between CDMOs and academic researchers, or institutions collaborating with CDMO clients. Most important, these individuals can optimize the impact of their work by considering how findings might contribute both to academic knowledge and practical applications in industry.

Consider how the following elements differ between academic research and industry research:

Focus of Experiments

In industry, the focus of experiments is to safely and quickly complete and, when possible, innovate a given process. The goal is to provide clients with results based on agreed upon deadlines. Those results come with hard deadlines — to the day, and often, to the hour — versus the more forgiving deadlines common to academia.

Additionally, in academia, the focus of experiments is more theoretical. For example, an experiment's previous execution, detailed in an academic paper, could be approached from a fresh angle based on new research findings or a desire to produce similar results under different conditions. In industry, meanwhile, most test findings are expected to fall within a particular specification range, guided by specification documents dictating the exact range of values each experiment should yield.

Metrics to Gauge Experiment "Success"

Academic research often is assessed based on contributions to the field, theoretical significance, and methodological rigor. These aims often are accompanied by longer timelines to complete projects (e.g., around five years for a dissertation defense). Industry research, meanwhile, is often assessed based on practical impact to a client, cost-effectiveness, and the ability to address specific industry challenges.

These differing goals, theoretical versus practical, are inherently tied to cost and return on investment (ROI). In an academic lab, the professor/post-doctoral researcher/principal investigator (PI) pursues grants and other types of funding. A generous grant can fund a research initiative for years, giving that program a budget to experiment with new equipment and to develop more complicated experiments. Industry projects are only pursued if the ROI is projected to be profitable, all while keeping costs low to maximize this outcome.

Additionally, in academic research, it is not uncommon to follow a previous protocol, or for a researcher to create their own protocol with minimal oversight. While those still may be based off previous protocols, researchers can have leeway to implement new/different steps (following approval by the lab's principal investigator). As noted above, within industry, each experiment or test is conducted within the guardrails of client-specific or in-house standard operating procedures (SOPs).

Not only are the tester's results reviewed by the organization's quality control (QC) development department, they also are reviewed by quality assurance (QA) to ensure everything is within spec. Clients also weigh in, as they must determine whether the results are acceptable or they want re-testing. Academic research reporting typically goes through the professor/PI/postdoctoral researcher, comprising an informal discussion of results, analysis of what happened, interpretation of the findings, and a plan for next steps. The more risk-averse nature of industry versus academia heightens scrutiny on results and makes pre-planning for experiments more crucial. In fact, one of the most significant shifts transitioning from academic research to industry research is the necessity to budget a lot more time before conducting the experiment.

Additionally, in industry research, the same exact experiment, performed for two different clients, may be guided by different SOPs for each client. Typically, in academia, regardless of the project, the same test would call for the same protocol. Similarly, industry experiment reports must be all-encompassing. Researchers must consider all the internal departments viewing their work, parties downstream who will depend on the results, and, ultimately, end users. This consideration is narrower in academia, where researchers typically report only to one or two individuals.

Speaking Two Different Languages

Regulatory guidelines and tightly guarded confidentiality lead to industry language that is not used in academia. Academic researchers collaborating with other universities and researchers typically do not encounter many situations where confidentiality is a dire concern. Academic collaborations with industry introduce that element, and full immersion in industry skyrockets it to a top priority.

Consider that some of an organization's clients may be competing against other clients that vendor serves. Accordingly, Singota researchers refer to our clients by numbers versus actual company names, and this extends beyond paperwork. CDMO employees cannot be loose-lipped with client names due to the numerous clients who regularly pass through the lab to observe or audit.

Also, anyone in the life sciences must familiarize themselves with countless acronyms and industry-specific terminology often not used in academic settings. For example, if an experiment at Singota deviates from expected results, it is considered "out-of-specification," which prompts a lab investigation. In academia, a similar occurrence is more likely to be reported in the lab notebook and discussed informally with the professor/PI. In industry, rather than talking out the issue and re-testing, an out-of-specification. means providing all relevant materials to QA, which determines whether the error rose to the level of a deviation (i.e., requiring corrective and preventative action, or CAPA).

Pace of Work and Sources of Stress

A stark difference between academic and industry settings is the presence of clients and potential clients in the latter, touring the facility or performing an audit. While everyone is expected to adhere to GMP/GLP at all times anyway, it can be difficult not to feel increased pressure when a client passes through. The last thing a company wants is for a client audit report to note lab personnel not wearing gloves while performing an aseptic technique, or that a substance was obviously mislabeled.

Regulatory Scrutiny

Academic research tends to adhere to institutional and ethical guidelines, with less direct involvement by regulatory bodies. Procedures for how to perform experiments are made informally, without a standard approval process. In industry, researchers must comply with specific regulations covering processes, instrumentation quality (e.g., day-of-use checks on equipment), sample inventory tracking, and SOP training.

The level of attention to detail required in certain aspects of experimentation also is a marked shift between academia and industry. In academic settings, the serial numbers on vials, pipettes, or other supplies may not be tracked; when supplies run low or a certain item is needed to conduct an experiment, a lab manager usually takes care of it. Meanwhile, industry research demands meticulous tracking of all supplies or other resources (e.g., the reference number for a timer used to track a portion of the experiment) within the electronic lab notebook.

The stakes are higher than in an academic setting, because a potentially large sum of money is on the table, depending on the company's ability to secure a client. This makes academia an inherently lower-stress environment, because it's not as strictly regulated and there are not vast sums of money on the line. In academia, budget is determined more by the professor/PI's quality and quantity of published work — specifically, a combination of publication and citation counts known as an H-index.

A more tangible source of stress in industry versus academia is allocation and use of resources. Many sponsors are small biotechs with precious little active pharmaceutical ingredient (API) on hand. The number of samples a sponsor provides is carefully calculated and, every few months, researchers also must carefully calculate the number of samples needed for clinical trials, testing, and other activities.

If a client's samples are inappropriately used and researchers need to request more, a formal process typically must be followed, reaching out to their project managers (PMs) to inquire about the client's willingness to dispense more API to complete testing. Even if the client is willing, factors like the drug's viability may limit accessibility.

How Singota Eases the Transition

Singota and its employees strive not only to acknowledge the significant differences between working in an academic research environment and working in a business research environment, but also to ease the transition for employees and partners. This is necessary because, as Singota grows, we continue to hire expertise from multiple sources. Individuals coming out of academia often bring with them new perspectives on solving problems — a trait we value highly.

This can comprise of formal training, one-on-one guidance from peers in the lab, introduction to more complicated experiments, and peer/supervisor notes on ways to manage documentation before, during, and after an experiment. We also emphasize taking the time to perform tasks properly. It can be easy to feel rushed — and then rush through a task — because of the industry's continuous timeline demands.

Thus, new hires have to be made comfortable slowing down a bit to ensure they are following appropriate SOPs for a given experiment adhering carefully to each prescribed step. We also ensure reference materials are available and accessible so newer or transitioning industry researchers can look at those documents directly to confirm their actions are correct, or contact the scientists who conducted those experiments for insights.

Improved Understanding Leads to Improved Collaboration

Individuals at organizations around the world have made the transition from undergraduate or graduate research experience in an academic setting to industry research. Their connections with colleagues often remain strong and serve as the impetus for many academic/industry collaborations. Greater mutual understanding of what both academia and industry are trying to achieve with their projects is conducive to finding a middle ground, increasing the frequency and effectiveness of such collaborations.

An appreciation for differing priorities between both sectors has fostered — and will continue to drive — successful academic and industry collaborations. The experiences transitioning researchers are able to bring to industry, supervisors engaged in new hires' continuing education and transition, and encouragement to rethink laboratory practices based on the academic experience, all contribute to that goal. To learn more, visit us at https://singota.com/ and on LinkedIn.

About The Author
Mr. Walker is an Associate Pharmaceutical Scientist at Singota Solutions. He received his bachelor's and master's degrees in biotechnology from Indiana University-Bloomington, Indiana. While in college, he conducted ovarian cancer research and interned for two summers in Eli Lilly's Medicines Innovations Hub. In his free time, he enjoys watching NFL football, biking on trails, and traveling the world.