

A day in the life of a Principal Scientist



Michael Woolley is a Principal Scientist in the Drug Product Development department at Novartis, Austria. In this role, he is part of a team that develops the manufacturing process for protein-based therapeutics (predominantly, antibody therapies). Michael did both his PhD (University of Warwick, UK) and postdoctoral research (University of Birmingham, UK) on the structure and function of the CGRP (Calcitonin gene-related peptide) receptor, a family B GPCR (G protein-coupled receptor). This research focused on understanding the ligand binding and activation mechanisms of this receptor.

Can you tell us more about what you do?

I work in Drug Product Development for Novartis in Austria. Our site is a new production and development centre for protein-based therapeutics and consists of many large, impressive-looking buildings, with stunning mountains in the background.

Our department designs, tests and implements the manufacturing process for new biologic medicines. We are responsible for the final formulation, sterile filtration and filling into primary packaging of protein-based therapeutics (often antibodies). In order to develop robust and stable medicinal products, ensuring consistent high quality, every part of this process is important and needs to be tested. Once we have designed our manufacturing process, we transfer it to a commercial manufacturing site. We work with production facilities all over the world, but most are in Europe. Being in production and seeing a process you helped design in a commercial set-up is exciting!

What's the most interesting project you've worked on?

In the 3 years I've been working with Novartis, I've worked on the same project, which has been a great introduction to working in industry. I was able to start the development process from the beginning and was able to learn all of the different stages it must go through. Now the process is running in the production site, and we are manufacturing our medicine for clinical studies.

My background is in the structure and function of receptor proteins, so that was well suited to understanding the proteins we work with. What I discovered was how many other things there are to learn with this job. This includes biotechnology, material chemistry and engineering, as well as the process required to submit a molecule to one of the registration authorities (e.g., the European Medicines Agency or the Food and Drug Administration). Since I've been working on the project, we've had some really positive data from the clinics, which has added to the feeling that I'm working on an important molecule that will hopefully improve a lot of peoples' lives.

What do most people not realize about your job?

One thing that took me by surprise is the level of detail we go into. In the manufacturing process, everything is important and it all gets tested. This includes how a solution is mixed or what filter you use for sterile filtration. Scientifically, it's very interesting; however, I'd never thought about these steps in that much detail during my academic research.

What inspires you about your job?

What I find most inspiring is being able to see the direct consequence of the work we do in such a positive way. Every experiment or report goes into designing and testing a manufacturing process for medicines that will go to clinical studies and then hopefully a commercial product. The work we do has a big impact, and that is a really satisfying feeling.

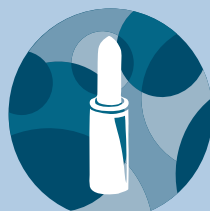
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What is your advice for someone who would like to move from academia to industry?

My experience of industry is that it is very collaborative and structured. We work to clear timelines (both short term and long term) and there is a defined plan and framework to achieve this. I would, therefore, recommend thinking about the non-scientific or 'transferable' skills required to work with many

people across different sites in an aligned and constructive way. Obviously, scientific expertise is important, but is likely to be shared with everyone else coming from academia. Other skills like effective communication, working collaboratively in a team to specific timelines, flexibility, etc. are really important to consider if you are thinking about moving to industry. ■

Job profile

Principal Scientists work as members of a team, designing, planning, performing, documenting and interpreting scientific experiments, while also maintaining and qualifying equipment and infrastructures and managing operational aspects in the lab.

Qualifications and key skills

Qualifications include technical expert studies with a PhD and a minimum of 2 years of relevant industrial experience, or alternatively, a Master of Science with 6 years of relevant experience or a Bachelor of Science or equivalent technical education with 12 years of relevant experience in industry or equivalent. Good oral and written reporting skills, as well as project management experience and a good understanding of regulatory expectations and development activities and processes are additional requirements for this role.

Responsibilities

These include, but are not limited to, overseeing and leading on all activities of assigned teams and projects; actively contributing to budget and resource planning; supervising project-related activities, evaluating and interpreting results and drawing relevant conclusions; writing protocols, scientific reports, lab procedures or process-related standard operating procedure (SOPs), as well as scientific documents intended for external partners (e.g., other line units, authorities, external companies); interacting with authorities; guiding the development and implementation of new technologies; developing, mentoring and coaching other scientific associates; presenting scientific/technical results internally and contributing to publications, presentations and patents.



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