Research Internship Report

Daiichi Sankyo Co., Ltd.

Graduate School of Engineering
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2024 (D1), Okamoto Lab
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1. Overview of the Internship

Host Organization: Daiichi Sankyo Co., Ltd.
Host Contact Person: Koji Wakui
Internship Period: From February 1 to March 31, 2024
Research Topic: Analysis and Evaluation of the Physicochemical Stability of Lipid Nanoparticles
Background Leading to the Internship:
After joining my lab, I became interested in the differences between basic research in academia and applied research in industry. I felt that it was important to understand these differences to shape my future career. I sought opportunities to gain insight into research that is closer to practical applications in the industry, and I participated in one-day factory tours through the Graduate Program for Excellence. However, my desire to learn more about real-world industry practices and specific tasks increased. Through the GMSI Job-Type Internship Program, I discovered this internship opportunity and decided to apply. I chose to apply to Daiichi Sankyo Co., Ltd. for my internship because I felt that my background in nucleic acid and mid-sized molecule drug research would be useful. The selection process involved document review and a web interview. After being selected, I was introduced to a research topic that aligned with my expertise. This internship was also part of the domestic internship component of MERIT Practical Learning.

2. Tasks and Achievements

Background:
In recent years, lipid nanoparticle-based drug development has made remarkable progress, especially due to the explosive spread of COVID-19. However, there are still many challenges to be addressed in their development. Unlike conventional small-molecule drugs, lipid nanoparticle drugs are more complex, and many uncertainties remain regarding their long-term stability. The specific parameters that contribute to

stability are not fully understood. Therefore, during this internship, I focused on investigating these issues from the perspective of quality and stability evaluation in lipid nanoparticle drug development.

Overall Plan:
I created various degradation samples of lipid nanoparticles and collected data on various physicochemical properties. Based on comprehensive analysis of the obtained data, I evaluated the factors that influence stability.

Tasks:
Evaluation of stability-related parameters:
For various lipid nanoparticle samples, I obtained data on physicochemical parameters such as average particle size, zeta potential, etc. I followed the quality evaluation standards of the host organization's research institute, compiling the data and optimizing testing methods to ensure stable data acquisition. Afterward, I conducted a comprehensive analysis of the data, combining the data that I obtained with pre-existing data from the company. I extracted and ranked the parameters that strongly contributed to stability and used the collected data and analysis results to create a model to predict lipid nanoparticle stability. Additionally, during the data collection process, I identified unassigned peaks and examined the degradation forms of lipid nanoparticles. The results were reported in team meetings held every two weeks and at a final presentation organized by the research institute, where I received valuable feedback.

3. Reflections

Before participating in the internship, I was mainly interested in upstream drug discovery research, and I had little knowledge of CMC research related to drug manufacturing and analysis. However, working on analysis and evaluation tasks allowed me to experience the practical side of industry research, which is quite different from academic research, and it was highly stimulating. Particularly, encountering the ultimate value standard of "Would I administer this drug to someone whom I care about?" and learning about the passion of those working at the forefront of drug development for obtaining drug approval were a major takeaway. In academic research, we often focus on proving the effectiveness of our hypotheses or molecules, while in CMC research, I strongly felt the responsibility of ensuring the quality of drugs, which involves strict data evaluation and quantitative analysis. I was also impressed by the

research approach that actively incorporates advanced measurement methods without sticking to traditional techniques.

4. Message to Prospective Interns

Although you might be busy with your own thesis research, I understand that long-term internships can seem like a high hurdle. However, conducting research in an environment different from your own can offer perspectives that you don't normally encounter, which can also be beneficial to your own research. I believe that the University of Tokyo offers many such opportunities, so I encourage you to explore them.

5. Acknowledgments

I would like to express my sincere gratitude to everyone at Daiichi Sankyo Co., Ltd. for accepting me for this two-month-long internship. In particular, I would like to thank Mr. Koji Wakui, my host contact person; Mr. Saito, Mr. Nakamura, and Mr. Onishi for their guidance with research consultations despite their busy schedules; and the team members who assisted me with data collection and provided valuable advice. I also deeply appreciate the support from the GMSI office for their help with the internship application and procedures. Lastly, I would like to express my gratitude to my supervisor, Professor Akimitsu Okamoto, my co-advisor, Professor Takanabe, and the MERIT office for their approval and support in my participation in this internship.