

# 2023 TAKEDA Summer Internships for BSCP



Takeda is committed to lifelong learning. Takeda's summer internship program blends real world experience with an extensive overview of the pharmaceutical industry. Knowledgeable mentors will provide guidance as you gain professional hands-on experience to start your career or further develop in your expertise.

The summer internship program is a full-time commitment of 12 weeks in length and offers a unique perspective into a world-class pharmaceutical company. Our internship program also provides you the opportunity to network with people at Takeda through various planned events and activities. As part of your internship engagement, you will be expected to contribute meaningfully towards on-going initiatives and projects.

## Requirements / Qualifications:

As stated above, Takeda is committed to lifelong learning opportunities. To that end, our internship program is open to currently enrolled students seeking early experiences and non-traditional candidates interested in making a career change and gaining new experience.

The requirements for these two groups of candidates are specified below:

### Candidates currently enrolled at an accredited university:

- Must be authorized to work in the US without sponsorship (i.e., Takeda will not sponsor interns)
- Must be available to work full-time (40 hours/week), within core business hours (8 AM-5 PM), for a minimum of 12 weeks during the summer months
- Minimum GPA 3.0/4.0
- Undergraduate, Graduate, PhD, MD student with at least one year of university studies before internship
- Return to university for at least one semester post-internship
- Takeda does not provide student housing or housing stipends

### Non-traditional candidates not currently enrolled at university:

- Must be authorized to work in the US without sponsorship (i.e., Takeda will not sponsor interns)
- Must be available to work full-time (40 hours/week), within core business hours (8 AM-5 PM), for a minimum of 12 weeks during the summer months
- Must provide a cover letter explaining why you are seeking this internship, relevant experience that makes you a good candidate, and what you hope to achieve through the experience
- Strong preference for non-traditional candidates with some experience relevant to the desired intern role



## POSITIONS

### **Global Drug Metabolism & Pharmacokinetics (DMPK) - R0084370**

*This position will be hybrid and based in Cambridge, MA.*

Non-viral gene therapy (NV-GT) is a class of gene and cell therapy approaches which seeks to utilize exciting new technologies in order to improve drug delivery, targeting, and overall therapeutic outcomes. Among these, lipid nanoparticles (LNPs) are one category of delivery vehicles which can deliver nucleic acids to cells of interest. However, much work needs to be carried out in understanding how LNP formulation, concentration, and cargo affect drug delivery.

The project will be evaluating the differential ability of primary liver cells to respond to transgene uptake and expression via non-viral gene therapy approaches.

- 1) Evaluating the differential uptake kinetics and biodistribution of the transgene in mono-, co-, and multi-culture systems. The biodistribution of the transgene will be evaluated at the subcellular, cellular, and cell-population level utilizing a variety of biomolecular and analytical approaches.
- 2) Investigating the efficiency of transgene delivery to differential cellular compartments utilizing the most promising candidates identified in (1) by assessing the ability of the transgene to produce a functional protein at different time points.

#### **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Develop assays for understanding LNP delivery to different cellular and subcellular compartments

### **Product Stewardship, Process Development Biologics - R0083636**

*This position can be remote.*

Creates Tech writing templates for development reports and regulatory documents. Creates templates to support M1 ancillary documents across projects to support regulatory submissions. This will be done by working within teams across regulatory submission function, functional area subject matter experts, Quality, and external organizations (CDMOs & CMOs).

# 2023 TAKEDA Summer Internships for BSCP



The candidate is preferred to have experience in pharma/biotech documentation, contributed to regulatory submissions, building databases, have good interpersonal skills, be highly organized and detail-oriented.

## **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Documentation, IT, build templates, Computer. Education in Pharmaceutical Sciences, Regulatory, Pharmaceutical Quality Control, or Scientific Disciplines

## **Digital Health Science/Digital Strategy - R0083505**

*This position will be hybrid and based in Cambridge, MA.*

The digital health science team is developing a digital endpoint for the GIPr franchise to monitor the number of vomiting and retching events in patient population. This project will start off with understanding of feasibility of novel endpoint development using digital wearable device. We have the perfect opportunity for a motivated intern to learn digital endpoint development process, and work with vendors to evaluate feasibility to develop algorithm and conduct verification and validation studies.

This project will benefit the organization along 3 lines:

- (1) Build institutional knowledge of feasibility of novel endpoint development for certain patient populations
- (2) Test drive some vendors along the way to make sure we understand the technical capabilities they provide to the organization, and
- (3) Inform novel endpoint development next steps

The expectations for the selected intern would be that by the end of the summer, they would learn how to work with cross-functional team, oversee vendors, and have a clear understanding of how to develop novel endpoint for clinical trials. A driven individual would build on their engineering / data science / life science background with a set of complementary skills that would allow them to pursue a career within biotech / pharma.

## **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills

# 2023 TAKEDA Summer Internships for BSCP



- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Past experience in wearable devices, collection, handling of data preferred

## **Bioanalytical Science-Biologics, Clinical Biomarker Innovation and Development - R0084037**

*This position can be remote.*

The objective of the project work is to understand the various approaches of gene therapy to treat rare diseases and understand the basic immunity problems involved in these potential treatments and knowledge on mitigation strategies for the immunogenicity problems. The intern should have basic knowledge and skills acquired in their educational programs on various AAV vectors and their immune responses in pre-clinical and clinical studies. The intern project work will provide awareness on the challenges on real world problems in solving the immunogenicity issues is a plus. Also will provide opportunity to promote interaction with and learning from peers and leaders across the team.

### **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Gene therapy vectors. Immune responses, Immune modulation strategies

## **BioAnalytics - R0083640**

*This position will be onsite (4+ days) and based in Lexington, MA.*

The bioanalytical group in Analytical Development -Biological Department at Takeda Pharmaceuticals is looking for a highly motivated intern to help develop the Digital PCR (dPCR) method for quantification of residual host cell DNA (hcDNA). This internship provides an opportunity to develop a “direct dPCR method” for the high-throughput testing of hcDNA in early clinical phase in-process samples. The intern will use a streamlined approach that includes molecular biology, biochemical, and other approaches and collaborate with molecular biology scientists to develop and optimize the dPCR method. Takeda discovers and makes many

# 2023 TAKEDA Summer Internships for BSCP



therapeutic proteins for treating gastrointestinal disorders and other therapeutic areas such as cancer, rare diseases, and immunological disorders.

## **Duties & Responsibilities:**

The intern will perform analytical activities, including but not limited to DNA extraction/quantification, dPCR/qPCR-based hcDNA assay development, and optimization for the quantification and size analysis of in-process samples. The intern will get the opportunity to design experiments and drive scientific conclusions based on the results. A supervised research project will be performed during this internship term, and the intern will give a presentation to the AD-Bio department at the end.

## **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Interest in novel assay development for protein products, knowledge of various molecular biology techniques, and hands-on experience with qPCR and DNA extraction/quantification are highly desirable.
- They should have excellent troubleshooting skills and be able to seek guidance when necessary. The position requires a willingness to perform hands-on wet-lab activities, receive constructive feedback effectively, good organizational and communication skills, attention to detail, and function as a team member and independently.

## **Global Drug Metabolism & Pharmacokinetics (DMPK) - R0084033**

*This position will be hybrid and based in Cambridge, MA.*

To study the pharmacokinetic of the gene therapeutics, the bioanalytical team aim to provide cutting-edge and up-to-date genomic assay platform for gene therapy program in Takeda. Due to variety of transgene targets and design concepts, the genomic assay teams require constant evolve and integrate novel knowledge to fulfill the unmet needs from different research teams. Our team currently support the rare disease branch to quantify the biodistribution of gene therapeutics. Majority method development are based on the PCR method. This internship program will intend to facilitate a ddPCR-based method for detecting disease specific biomarkers that will include the sample and reagent preparations, and machine operation. The candidates should have background knowledge of molecular biology and biochemistry. In the end of training, the intern will be familiar with the process of ddPCR, mindset of experiment design for genomic assays, and present the workflow and result for the method development in the department meeting.

# 2023 TAKEDA Summer Internships for BSCP



## **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Ability to identify problem, seek solution, and innovate idea through online research tools
- Proficiency with MS Office Software such as Word, Excel, and Powerpoint
- Ability to perform Quantitative-PCR and RT-PCR
- Ability to well-organized experiment records

## **Medical Writing - R0083649**

*This position will be hybrid and based in Cambridge, MA.*

The Rare Genetics and Hematology Medical Writing Intern will help support a regulatory filing for a Takeda product. The intern will learn about the phases of clinical research, clinical study conduct and data analysis, and development of the complex clinical deliverables comprising a submission to a regulatory agency. Specifically, the intern will work closely with a Takeda medical writer and understand how writers draft, review, and finalize the content of clinical submission documents strategically and in collaboration with cross-functional teams composed of MDs, biostatisticians, regulatory affairs leads, clinical operations managers, clinical pharmacologists, and others. The intern can expect to gain experience with key aspects of document development, including standard operating procedures, style guide, planning and project management approaches, use of an electronic document management system, and document review and finalization software tools. By the end of the summer, the intern will have a deeper understanding of clinical regulatory writing and the connection between this content and a new product label.

## **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Proficiency with MS Word, Projects, Teams, Outlook, Excel; excellent written and verbal communication; demonstrated writing ability a plus



## Drug Metabolism & Pharmacokinetics (DMPK) - R0084001

*This position will be hybrid and based in Cambridge, MA.*

Goal: To address if the AAVR abundance in liver and skeletal muscles, internalization rate and receptor turnover impacts the AAV9 transduction efficiency in human, NHP and rodent model

Background: recombinant Adeno-associated virus (rAAV) continues to be a promising viral vector for delivery of therapeutic genes in human gene therapy. Among the pathways required for entry and infection on the target cells, engagement of AAV to universal AAV receptor is critical for the infection of multiple AAV serotypes. In addition, it is intriguing that variable transduction efficiencies are observed in different tissues for AAV serotypes, namely AAV9. There are various potential stages involved leading to the transduction stage, namely the rate of endocytic uptake, endosomal trafficking, endosomal release, nuclear localization, uncoating, possibly contributing to the variability in transduction efficiency with different tissues and different species. In this current study, we would like to understand the correlation of these contributing mechanisms to transduction efficiency, in context to AAV9.

### **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Previous experience in cell culture and aseptic techniques.
- Previous experience in flow assays and ddPCR is highly desirable.

## Global Regulatory Affairs CMC & Devices - R0083654

*This position will be hybrid and based in Cambridge, MA.*

GRA CMC & Devices Strategist - Site Transfer Regulatory Knowledge Tool for combination products (Drug/Device)

GRA CMC have developed a new tool to drive site transfer projects, the focus on the Intern would be learning key regulatory requirements, interacting with various leaders and developing/recommending a strategic plan on how to implement for combination products (Drug/Device). In addition the project will explore how to synergize with existing databases with regulatory intelligence information.

The objective of the tool is to provide visibility to the status of the site transfer for each country & to be used to make a recommendation on best regulatory strategy for prioritization in registration of the transfer (and multiple changes) at a global level involving cross-function teams in GRA, LOC and GMSGQ.



# 2023 TAKEDA Summer Internships for BSCP



This project will allow for the intern to be mentored by regulatory individuals, to attend key cross functional meetings, and to have visibility in making recommendations impacting project success and process improvement.

## **How you will contribute:**

- Deadline-driven with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Creative thinking – able to develop innovative solutions and think creatively
- Computer literacy
- Data management
- Project planning/Task management

## **Research & Development - IT R0083853**

*This position will be hybrid and based in Cambridge, MA.*

Alta Petens/Future Fit is a program at Takeda that aims to accelerate execution of our clinical trials portfolio to help bring medicines to our patients faster, cheaper and in a more efficient manner. From a technology/IT perspective, this would include analyzing and building roadmaps/models/frameworks around Alta Petens/Future Fit in context of existing solutions and the end-user needs.

## **How you will contribute:**

- Hunger to learn and grow, self-driven and accountable with a high level of organizational and planning skills
- Strong analytical, problem-solving, and oral and written communication skills
- Ability to work well in teams, effectively manage projects, and present ideas clearly and concisely.
- Global mindset to grow in a diverse work environment
- Excellent communication and leadership skills
- Technology and some domain familiarity