



UCB Global Regulatory Affairs (GRA) PharmD Fellowship Program

Program Guide and Application Information 2021-2023



Message from **Executive Sponsor**

At UCB, everything we do starts with a simple question: “How will this create value for people living with severe diseases?” Our ambition is to transform the lives of people living with severe diseases. We focus on neurology, immunology, and rare diseases – putting patients at the center of our world. We are Inspired by Patients. Driven by Science. These are not only words, but are the cornerstone of our patient value culture at UCB. With a diverse portfolio of marketed products and a deep pipeline of new assets in discovery and early clinical stages, UCB measures success by the value we can deliver with our solutions.

As we continue to build on previous successes, we are committed to scientific innovation and organizational agility to keep pace with the evolving healthcare landscape. To succeed in this commitment, talent is key. We focus on developing talent with the competencies, skills, and capabilities needed to successfully deliver patient value in this complex environment.

The UCB Global Regulatory Affairs Fellowship is designed to provide PharmD graduates with the opportunity to learn and experience all aspects of Regulatory Affairs under the mentorship of experienced preceptors. As importantly, Fellows will also develop the necessary competencies to succeed as a regulatory professional. As a mid-size pharmaceutical company, Fellows will have significant opportunity to interact with senior leaders at UCB, thereby enhancing their learning experience.

If you have the desire to work in a biopharmaceutical company with a focus on patient value, innovation and agility, and commitment to staff development, I encourage you to apply for a UCB Regulatory Fellowship.

- *Deborah Hogerman*

Head of Global Regulatory Affairs

UCB, founded in 1928 by Emmanuel Janssen, is a global biopharmaceutical company focused on severe diseases that have significant unmet needs. With a team of approximately 7,500 employees and operations in nearly 40 countries, UCB is investing more than a quarter of its revenue in cutting-edge scientific research to meet unmet patient needs. Global headquarters are in Brussels, Belgium, with U.S. headquarters in Atlanta, Georgia. Additional U.S. UCB sites are located across Massachusetts, North Carolina, Washington, and Washington, D.C.

By putting **patients at the heart of everything we do**, we enable people to **live their best lives**, delivering impactful solutions **patients value**.

Our Areas of Focus



Neurology



Immunology



Bone

Our People

~40
countries

7.9K
employees



3.5M patients use our medicines
around the world

Everything we
do starts with
one question:

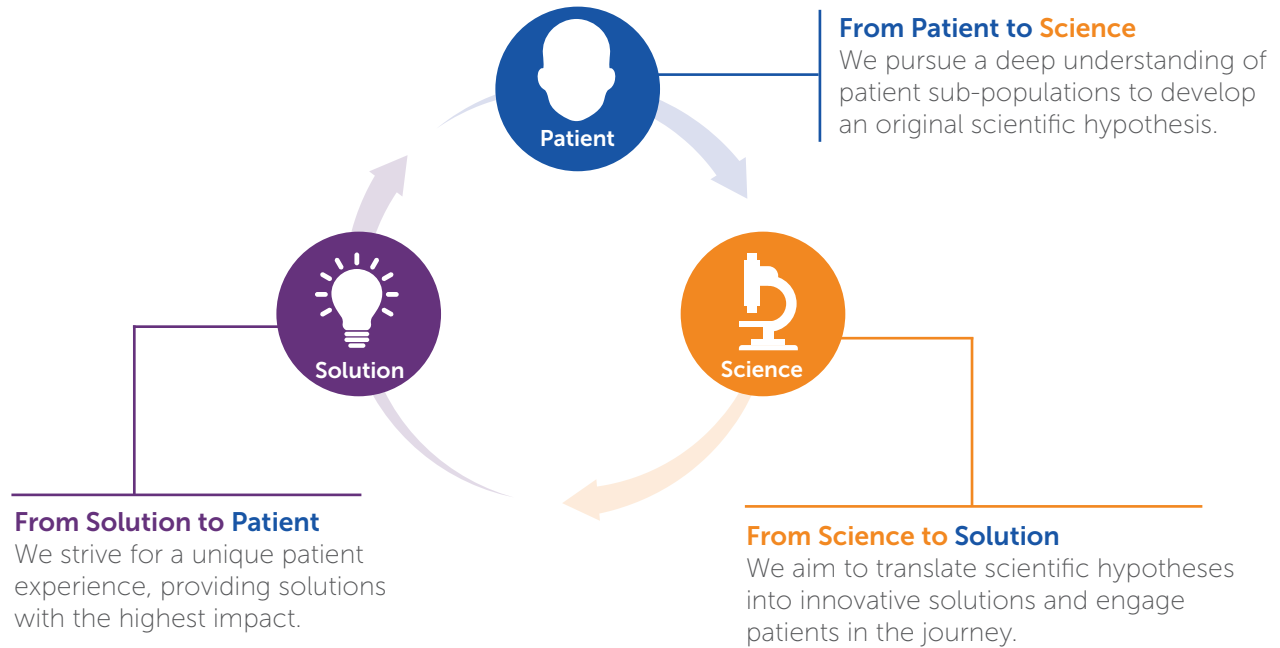
“How will
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Innovation

At UCB, we want to help people live their best lives, whatever that means for them. We're focused on severe, chronic neurological and immunological conditions. And we're blazing a path integrating new technologies, like machine learning and data analytics, into how we work today to unlock a healthier tomorrow.

Our approach to innovation keeps patients at the center. We use patient insights to inform our science to build solutions to deliver to patients. Innovation is ongoing as we continue to search for solutions to meet the unmet needs of patients.

We put patients at the heart of everything we do



	Indications	Phase 1	Phase 2	Phase 3	Filed
bimekizumab (IL17AF)	psoriasis				
	psoriatic arthritis				
	axial spondyloarthritis				
	hidradenitis suppurativa				
rozanolixizumab (FcRn)	myasthenia gravis				
	immune thrombocytopenia				
	chronic inflammatory demyelinating polyneuropathy (CIDP)				
zilucoplan (C5)	myasthenia gravis				
	immune-mediated necrotizing myopathy (IMNM)				
	amyotrophic lateral sclerosis ¹				
	COVID-associated acute respiratory distress syndrome (ARDS) ²				
Staccato® alprazolam	active epileptic seizure				
dapirolizumab pegol (CD40L)	systemic lupus erythematosus ³				
UCB0107 (Tau)	progressive supranuclear palsy (PSP)				
1 Project					
1 Project					

UCB is connecting science in new ways to illuminate the biological pathways involved in severe diseases. Our researchers are developing a range of novel chemical entities (NCEs) and novel biological entities (NBEs) to improve people's lives.

The UCB pipeline delivers:

- A promising portfolio targeting severe diseases and addressing unmet medical needs
- Focus on neurological and immunological diseases
- More convenient and effective treatments for patients and specialists

¹ In partnership with HEALEY ALS Platform Trial

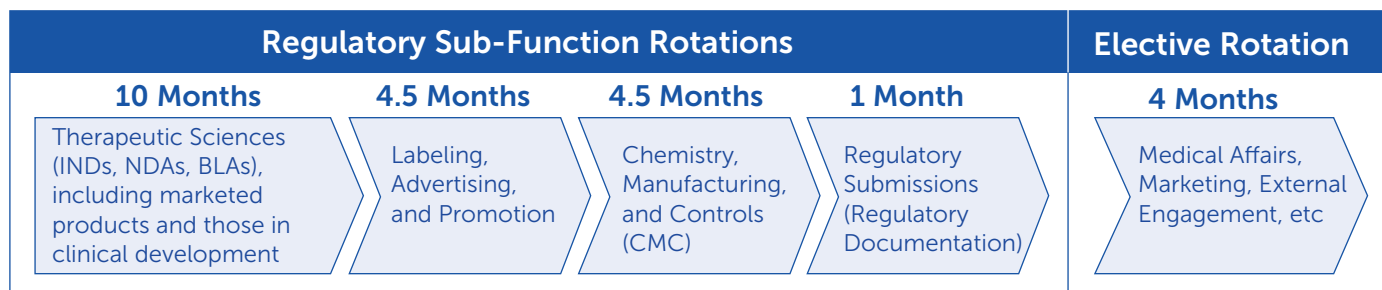
² In partnership with University of Ghent (Belgium) & Medical Research Council (U.K.)

³ In partnership with Biogen

UCB GRA PharmD Fellowship Program

The Global Regulatory Affairs was established in 2017 with a vision to grow top regulatory talent for the future. The fellowship, a collaboration with the Industry Pharmacists Organization (IPhO), is a 2-year rotational program located at UCB's Atlanta campus, which is in the suburb of Smyrna. The rotations through the various sub-functions of Regulatory Affairs aim to provide the Fellows with the depth and breadth of experience with all aspects of Regulatory Affairs. The Fellows will also have an opportunity for a four-month elective rotation in an area outside of Regulatory to gain additional insights from the outside in.

During the rotations in Regulatory Affairs, the Fellows will be assigned to work with the Regulatory Science Lead for one or more compounds, including pipeline and marketed products, ensuring that the chosen project will provide the greatest learning opportunity and exposure to FDA and other global regulatory health authorities.



Essential Functions & Responsibilities

- Support regulatory scientists/global regulatory leads in preparation and delivery of regulatory submissions, in collaboration with other support functions in GRA
- Support CMC associates to develop CMC-specific regulatory strategy and learn how to define content for CMC submissions
- Support advertising and promotion/labeling associates to understand regulatory requirements related to advertising and promotion as well as pharmaceutical company policies to ensure compliance with the regulations
- Acquire in-depth knowledge of fundamentals of regulatory affairs, regulatory intelligence, and development of regulatory strategy
- Provide regulatory operational support for pipeline and/or marketed product(s)
- Deliver project assignments supporting the business
- Develop proficiency in use of GRA systems



1st Year Fellow

The UCB fellowship program offers one of the best environments to grow as a fellow. The rotational aspect to the fellowship allows the fellow to gain expertise in all areas pertaining to regulatory affairs as they simultaneously build the crucial understanding of regulatory strategy on a global level. In my short time at UCB, I have already appreciated the company's integration of me into their family, and I am extremely satisfied knowing this is the ideal program to grow into a seasoned industry professional.

- Nicolas James



2nd Year Fellow

In the past year the UCB Global Regulatory Affairs Fellowship has offered me a well-rounded experience across various disciplines within Regulatory Affairs. I work hand in hand with passionate industry leaders to push innovation, science and medicine forward while putting patient value at the center of all we do. The UCB fellowship has and will continue to foster a challenging and encouraging environment that has allowed me to grow my regulatory expertise and develop professionally.

- Howraa Alasker



I have been a Regulatory Therapeutic Sciences Preceptor with the fellowship program since its inception in 2017 with the goal of providing opportunities for fellows to showcase their own leadership and critical thinking skills. We have been able to offer significant regulatory growth experiences - from IND submissions to late stage approvals. The fellows we've had at UCB are highly motivated and not only do they contribute to regulatory strategy with our teams, they have all contributed to my own professional growth and development in some way.

- *Jennifer King*
Regulatory Science Lead



The fellowship is an excellent springboard for a career in regulatory affairs because it provides a great opportunity for hands-on experience on the crucial role regulatory affairs plays across a product lifecycle from development through post-marketing. Each fellow gains valuable foundational expertise during the rotations in the different sub-functions, and is thereafter able to make an informed decision on a career path to pursue.

- *Wanja Muthoga*
GRA CMC Scientist

What's unique about the UCB-IPhO Fellowship?

The Regulatory Affairs Fellowship at UCB offers a unique opportunity to work in an environment that is patient focused, creative, flexible, and agile, with an exciting and promising pipeline.

The support of fellowship leadership and preceptors, coupled with the unique combination of rotations and experiences, will help to ensure the success of the Fellows, developing them to become best-in-class regulatory professionals ready for a career in a variety of settings. Following two years, the Fellow will have the experience to move into a strategic/operational (manager/senior manager) role, such as Regulatory Scientist, Regulatory Program Manager, or Regulatory Liaison, within the pharmaceutical industry, CROs, or the FDA.

In addition, this fellowship is offered in collaboration with IPhO. Through IPhO, the Fellow can gain exposure to broader networking and leadership opportunities for pharmacists in industry.

Benefits of the IPhO partnership include:

- **Organizational Leadership:** Fellow will be a member of the IPhO National Fellows Council (NFC), with opportunities to develop and practice cross-functional leadership skills in the following committees: Fellows Development, Student Development, & Professional Programming.
- **Professional Development:** As a part of the IPhO NFC, the fellow will have access to fellow-targeted career development programming, such as webinars and live events.
- **Publication Opportunities:** Fellow can publish a poster/paper/article in conjunction with an IPhO leadership team member
- **Networking Opportunities:** As a part of the IPhO NFC, the fellow will have the opportunity to network with over 70 fellows across the country in various functional areas, along with exclusive access to a Fellows Directory of over 350 current fellows.
- **Teaching Experience:** Fellow will have an opportunity to be an instructor for IPhO Institute for Pharmaceutical Industry Learning (webinars), as well as provide guidance to hundreds of student pharmacists at nearly 90 IPhO chapters.
- **Mentorship:** Fellow will receive mentorship from IPhO leadership, including priority access to IPhO's network of advisors through Mentor Match, a system containing nearly 2,000 established industry pharmacists ready to assist with fellow career development.



Fellowship Preceptors (L to R): Oana Pop, Iram Hasan, Alexis Harper, Wanja Muthoga, Jennifer King, and Tanyja Porcha

Application Process

The Fellow will be selected on a nationally competitive basis, and candidates must have a Doctor of Pharmacy degree from an ACPE-accredited college of pharmacy by June 30, 2021. The fellowship offers a competitive salary and benefits package.

Requirements

- Doctor of Pharmacy degree (Pharm D)
- Graduate of an accredited and nationally recognized pharmacy school
- U.S. citizen or permanent resident

Qualifications

- Ability to work independently
- Ability to work in a collaborative team environment and build effective partnerships
- Flexible and adaptable, and ability to work under pressure
- Excellent written and verbal communication skills – knows when and how to communicate, using strong interpersonal skills and written communications when appropriate
- Analytical – logically breaking situations or issues down into their essential elements: carrying out diagnosis and developing solutions
- Strong organizational and project management skills with a high level of attention to detail and time management skills
- Overriding commitment to integrity and high standards in self and others

How to apply

This fellowship position may only be applied for through the IPhO FellowMatch service:

https://www.industrypharmacist.org/fm_landing.php

A letter of intent and CV should be submitted through the FellowMatch portal. Two letters of recommendation are to be emailed directly to Iram Hasan (iram.hasan@ucb.com).

The application deadline is **November 6, 2020**.

Applications will be reviewed on a rolling basis, and applicants are encouraged to submit their materials on FellowMatch accordingly.

Contact Information

Address your cover letter and letters of recommendation to Iram Hasan

Iram Hasan, PharmD

Regulatory Scientist

UCB Fellowship Program Director

For questions regarding the Fellowship program, contact Iram Hasan at iram.hasan@ucb.com

The UCB GRA Fellowship has been built to provide fellows with a unique global regulatory experience – one that establishes a strong foundation in regulatory knowledge coupled with the autonomy to tailor the program to the fellows' interests. With the support and mentorship of executive leadership and seasoned regulatory professionals across UCB and IPhO, the program positions fellows on the path to a successful career in global regulatory affairs.

- Iram Hasan

Regulatory Scientist, UCB Fellowship Program Director





UCB Atlanta Campus

The UCB Atlanta campus stands as a symbol of our longterm commitment to the Atlanta business community. Since opening our doors in 1994, this beautiful campus has grown from a handful of people to approximately 400 employees today. UCB is the largest biopharmaceutical company with a U.S. headquarters in the Atlanta area. We are conveniently located just a short drive from the heart of downtown Atlanta. Considered the capital of southern business, metro Atlanta is a thriving corporate hub which continues to attract top companies to the area, boosting the local economy and growing the population, which now exceeds 6 million people. Our proximity and easy access to Hartsfield-Jackson International Airport, one of the largest airports in the world, is key for UCB's global reach.