UCB Global Regulatory Affairs (GRA) PharmD Fellowship Program

Program Guide and Application Information 2020-2022

Inspired by **patients.**
Driven by **science.**

In partnership with

IPhO
Industry Pharmacists Organization

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 bone disorders – 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.

UCB is celebrating 90 years, and 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.

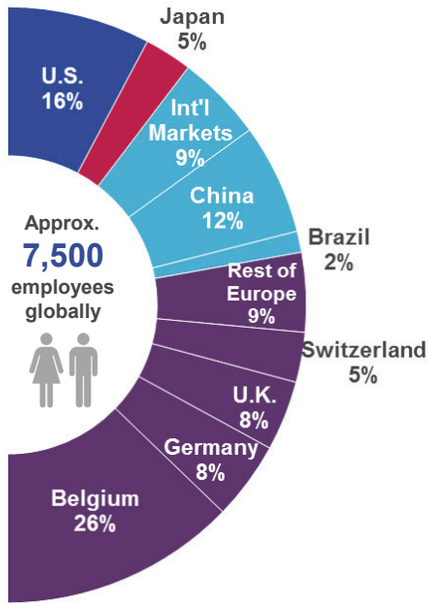
- Deborah Hogerman

Head of Regulatory Therapeutic Sciences

UCB, founded in 1928 by Emmanuel Janssen, is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases. With a team of approximately 7,500 employees and operations in more than 40 countries, we are a global biopharmaceutical company investing more than a quarter of our 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 include global clinical development at our Research Triangle Park, North Carolina campus (UCB Biosciences, Inc.), and research supporting UCB's pipeline in Cambridge, Massachusetts..

UCB is focused on the **discovery and development** of **innovative medicines** and solutions to **transform the lives** of people with severe diseases.

Presence in 38 countries completed by a robust network of partners



2 RESEARCH CENTERS
- Braine-l'Alleud (Belgium)
- Slough (U.K.)

3 DEVELOPMENT HUBS
- Monheim (Germany)
- RTP North Carolina (U.S.)
- Tokyo (Japan)

4 MANUFACTURING FACILITIES
- Braine-l'Alleud (Belgium)
- Zuhai (China)
- Saitama (Japan)
- Bulle (Switzerland)

Innovation

Our innovation leverages patient insights to drive our science and find solutions that we can ultimately deliver to patients, bringing them what they value. We have a passionate, long-term commitment to discovering and developing innovative medicines that transform the lives of people living with severe diseases. We do that by connecting with patients and their families around the world living with the physical and social burdens of severe disease. Those connections offer new perspectives, drive innovation, and offer the hope of a new generation of therapies that are helping to transform lives.

Small molecule drug / NCE
Antibody-based drug / NBE

Neurology	Indications	Phase 1	Phase 2	Phase 3	Filed
padsevonil / UCB0942 (PPSI)	epilepsy – highly drug resistant				
UCB0599	Parkinson's disease				
UCB0107	Progressive Supranuclear Palsy (PSP)				
Immunology	**Indications**	**Phase 1**	**Phase 2**	**Phase 3**	**Filed**
bimekizumab (IL17AF)	psoriasis				
	psoriatic arthritis				
	axial spondyloarthritis				
dapirolizumab pegol**	systemic lupus erythematosus				
rozanolixizumab / UCB7665	myasthenia gravis				
	immune thrombocytopenia				
	chronic inflammatory demyelinating polyneuropathy (CIDP)				
UCB7858 / UCB0159	auto-inflammatory diseases				
Bone Health	**Indications**	**Phase 1**	**Phase 2**	**Phase 3**	**Filed**
Evenity™ (romosozumab)*	osteoporosis in patients at high risk of fracture (Europe)				

* In collaboration with Amgen - Launched in Japan / USA
** In collaboration with Biogen

The UCB pipeline delivers:

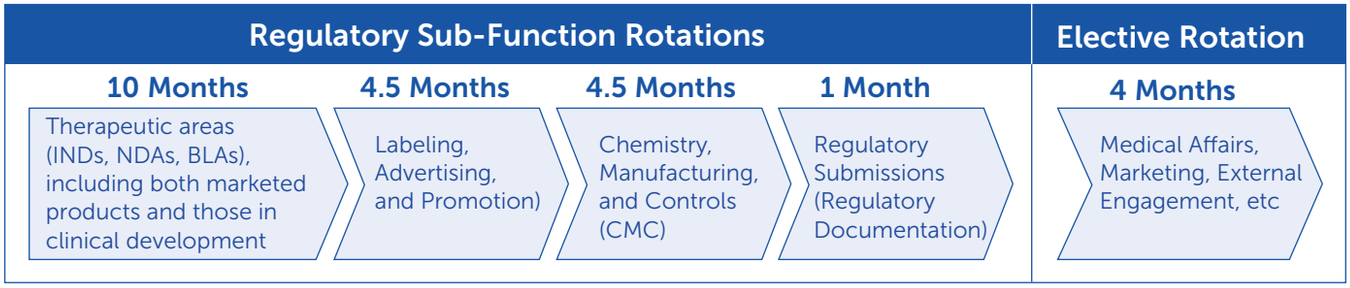
- A promising portfolio targeting severe diseases and addressing unmet medical needs
- Focus on neurological and immunological diseases
- More convenient and effective treatments for patients and specialists

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.

UCB GRA PharmD Fellowship Program

The Global Regulatory Affairs (GRA) 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. The rotations through the various sub-functions of Regulatory Affairs aim to provide the Fellows with exposure to and experience with all aspects of Regulatory Affairs, as well as, internal, global, and U.S. Food and Drug Administration (FDA) exposure. 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 internal, global, as well as FDA exposure.



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

Professional organization components include:

- IPhO Professional Development Projects
- Organizational Leadership - Fellow will be a member of the IPhO National Fellows Council
- Teaching Experience as Instructor, IPhO Institute for Pharmaceutical Industry Learning (webinars)
- Committee Leadership – the National Fellows Council has several committees that the Fellow can help lead, including scholarly publications, professional programming, student development, marketing communications, and social media
- Publication Opportunities (poster/paper/article), preferably but not necessarily in conjunction with an IPhO leadership team member
- Mentorship from IPhO leadership

1st Year Fellow

The UCB Global Regulatory Affairs Fellowship offers a well-rounded experience across multiple functions within Regulatory Affairs. Providing both a challenging and encouraging environment that fosters the professional growth of the fellow through guidance from highly experienced industry professionals. I am grateful to have this excellent opportunity to work closely with like-minded passionate colleagues. Through this fellowship I am confident that the experiences I gain will allow me to excel in the biopharmaceutical industry.

- Howraa Alasker, PharmD

2nd Year Fellow

My experiences in UCB's Fellowship this past year have been profound in a variety of disciplines. I have been given the opportunity to evolve my expertise in Regulatory Affairs with projects where my insights are valued, have gained an understanding of the holistic mission of bringing value to patients through innovation and dedication to science, and the role Regulatory Affairs plays in bringing this vision to a reality with Health Authorities and patient populations across the globe.

- Tanya Chaudhri, PharmD, RPh

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.

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

Fellowship Preceptors (L to R):
Wanja Muthoga and Kristen Piatak

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, 2020. 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
- Flexibility and adaptability, 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
- Integrity – 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: **www.industrypharmacist.org/fmlanding.php.**

A letter of intent, CV, and 2 letters of recommendation are required.

The application deadline is **November 1, 2019.**

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

UCB's fellowship program ensures the depth and breadth of experience that will position the Fellow to be set up for success. As an alumnus of an industry-based PharmD fellowship program, I can appreciate the importance of a unique and varied program, and that is what we have aimed to build for our Fellows at UCB.

- Iram Hasan

Regulatory Scientist, UCB Fellowship Program Director

UCB Smyrna Campus

The UCB Smyrna 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. UCB also has a Solution Accelerator Office on the Georgia Tech campus. We are conveniently located just a short drive from the heart of downtown Atlanta. Considered the capital of southern business, 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 5.5 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.

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