Dr. Reddy’s Laboratories

PHARMACEUTICAL INDUSTRY FELLOWSHIP PROGRAM
2017-2019
Since 1984, Dr. Reddy’s has succeeded in its purpose of providing affordable and innovative medicines for healthier lives.

Globally headquartered in Hyderabad, India, Dr. Reddy’s was founded in 1984, established a US presence in 1992 and won its first patent challenge in the US in 2001.

As a fully integrated pharmaceutical company that is driven by the belief that Good Health Can’t Wait, our purpose is to accelerate access to affordable and innovative medicines through our core businesses:

- Active Pharmaceutical Ingredients
- Custom Pharmaceutical Services
- Global Generics
- OTC products
- Differentiated Formulations
- Biologics

Our products are marketed globally, and our strong portfolio of businesses, geographies and products allows us to provide affordable medication to people across the world, regardless of geographic and socio-economic barriers.

**OUR BELIEF**

Our belief lies at the core of our work and serves as an overarching conviction for all 20,000 of us. This is what makes up our DNA at Dr. Reddy’s Laboratories.

It’s a belief rooted in our empathy with our patients and partners. A belief which stems from our deep understanding of patient needs, and our determination to meet those needs by resolving challenges that only a few can. A belief that rests on our dynamism in serving those unmet and under-met needs with speed and agility.

We are driven by the fundamental belief that **Good Health Can’t Wait**.

**Good Health** is always the goal. We are in the business of good health, and we don’t see medicines as just molecules, but as tools that will help people get back their health and promote wellness among them.

**Can’t Wait** captures our commitment to act with speed, along with our partners to find innovative solutions that address the needs of patients, and accelerate the much needed medicines to a large number of people around the world.
Our principles serve to provide both guidance for our current behavior and inspiration for our future actions. To help us guide in living up to our brand belief at every touch point we have identified two principles:

**Empathy**
We understand the needs of our patients and partners better than others.

**Dynamism**
We solve challenges that only a few can, and do this with agility.

Our purpose is about why we do what we do. It stems from our Belief and Principles.

We accelerate **access** to **affordable** and **innovative** medicines because

**Good Health Can’t Wait.**
If our purpose is about why we do what we do, then our promises must make clear what we do. It’s about what we offer, about what commitments we make to our customers. It will always be the reason why our customers choose us over the others.

The 5 promises that we must make and keep at all times are:

I) Bringing expensive medicine within reach
II) Address unmet patient needs
III) Help patients manage diseases better
IV) Enable and help our partners to ensure availability of drugs
V) Work with our partners and help them be successful

Each of us at Dr. Reddy’s is driven by the urgency and belief that Good Health Can’t Wait. Our patients trust our medicines and we believe that this trust must be earned every single day. We continually remind ourselves that the interests of our patients must always come first. In pursuit of this, we believe in creating an environment of innovation and learning, as we push ourselves to reach higher levels of excellence.

To aid that, here are a set of values that we must adhere to at all times:

**Integrity and Transparency**
Uphold the highest standards of integrity and transparency in all our conversations.

**Safety**
Remain committed to providing safe working environments through continuous improvements of our infrastructure, work practices and behaviors.

**Quality**
Be dedicated to designing quality into our products and processes to delight our stakeholders.

**Productivity**
Strive to achieve more with less through a culture of innovation, continuous improvements and sustained focus on elimination of waste.

**Respect for the Individual**
Stay committed to creating a work environment that encourages diverse perspectives and upholds the dignity of work and of individuals.

**Collaboration and Teamwork**
Leverage expertise and resources from across our global network to create greater value for our stakeholders.

**Sustainability**
Create value for all our stakeholders in a manner that respects our natural environment and serves the best interests of the communities in which we live and work.
Our brand is not just what we say. It is what we do. It is what our customers experience from us.

Our behavior must be consistent in order for us to deliver on our promises and live our brand belief across all touchpoints. The more focused and inspired our behavior is, the stronger the bond, the richer the relationship with our customers.

To help us be consistent, we have identified a set of 5 behaviors. These are:

**Reach out to understand**
Be empathetic to the needs of our people, partners and patients. Engage meaningfully, going beyond the stated and the obvious to develop a holistic view of their needs.

**Be the first to respond and the fastest to act**
Have a sense of urgency in the way we think, act and communicate. Create simple plans and processes and take ownership for their timely execution.

**Do things differently**
Innovate in ways which are meaningful. Spot opportunities, experiment, take risks, empower our teams and find a way to tackle the toughest challenges.

**Simplify**
Question and eliminate what is not essential within our systems, processes, roles and communications to become ever more dynamic and human.

**Create shared success**
Create a culture that values teamwork while acknowledging individual excellence. Collaborate across our businesses and with our partners to create shared value.
• Prescription products: 60+ products are marketed under the Dr. Reddy’s label in 280+ dosing presentations.
• Over-The-Counter products: 5 products are marketed in 150+ store-brand packaging presentations (private label).
• Robust pipeline in various stages of development: 76 ANDAs are pending, of which 50 are Para IV certifications and 18 FTFs.
• Dosage forms: Oral solids, injectables, liquids, topicals, patches and other forms are available.
• 33 of our prescription products are ranked among the top 3 in market share.
• Dr. Reddy’s is ranked among the top 10 corporations in Total Prescriptions dispensed*

*IMS Health, National Prescription Audit September 2015
The Dr. Reddy’s Laboratories Post-Doctoral Pharmaceutical Industry Fellowship is intended to provide a comprehensive multi-disciplinary experience for PharmD graduates who desire to focus and accelerate their career in the Pharmaceutical Industry.

Fellows will have the opportunity to gain first-hand knowledge in multiple functional areas. The focus will be Pharmacovigilance/Medical Affairs with exposure to other disciplines based on the individual preference of each new fellow.

The fellow will be a fully integrated part of Dr. Reddy’s Laboratories reporting to the Global Head - Pharmacovigilance and the Head of Medical Affairs North American Generics and Canada. Responsibilities will be focused in the US and Canada. The fellow will develop a thorough understanding of the operations in Pharmacovigilance and in Medical Affairs in the US and how it differs from our other geographies. Medical Affairs is significantly different in India. The fellow may spend 3 to 6 months at our site in Hyderabad learning Global Medical Affairs.

Within Medical Affairs for North America, the fellows may learn the daily responsibilities of Medical Information and Promotional Review for prescription and over-the-counter products, train Nurse Educators/Medical Science Liaisons, support labeling updates with Regulatory Affairs, and engage with Quality Assurance and Supply Chain for product complaints. The fellow will gain real life experience while learning the necessities to successfully manage Medical Affairs activities for a global generics company.

As defined by the World Health Organization, ‘Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem.’ Within Dr. Reddy’s Pharmacovigilance, the fellow will be trained in the skills necessary for compliance with global post-marketing and clinical trial adverse event report regulations, the creation of aggregate safety reports such as PADERs/PSURs/PBRERs, and learn the complexities of signal management for generic and branded prescription and over-the-counter drugs, biosimilars and devices in a global environment. Additionally, fellows will also get the opportunity to have ‘hands on’ learning experiences across a variety of safety initiatives such as patient registry & support programs, medication take-back programs and complex multi-sponsor REMS programs. Training on vendor management, validation, understanding compliance, management of safety database(s) and electronic submission to Regulatory Authorities will also be required. If desired, the fellow could also be exposed to Clinical Operations activities involving protocol development, study start up investigation meeting requirements, risk-based study monitoring and preparation of final study report. Throughout the fellowship, the fellow will collaborate with various cross-functional teams. In essence, the fellow will gain working knowledge in all areas of global clinical and post-marketing Pharmacovigilance and Drug Safety.
“What an amazing experience! I was continually challenged and encouraged by my mentors and colleagues, all of which provided immeasurable benefits for my professional development. I was able to work on several key projects from Day 1. The multi-disciplinary aspects of the fellowship gave me a unique opportunity to gain insights into the operations of different functional areas I’ve never even dreamed of. And I built valuable relationships, both professional and personal. I am very fortunate to have been blessed with this opportunity.”

Min Gong, RPh, PharmD
Dr. Reddy’s Fellow, 2015-2016

While Pharmacovigilance and Medical Affairs will be the primary focus in the first year, the fellow will be able to rotate through various North American departments including Clinical Development (differentiated formulations or generic focus), Quality Assurance, Regulatory Affairs, or Sales and Marketing during the second year based on the career aspirations of the individual fellow. Dr. Reddy’s also has facilities in Bristol, Tennessee, Middleburgh, New York and Shreveport, Louisiana. At these locations, the fellow will learn Supply Chain Management for both prescription and OTC products.

As our organization is a lean organization and undergoing rapid growth, there are many opportunities for interactions with other internal stakeholders. The fellow will become a key stakeholder in many areas and activities. Other functional areas/activities may include:

- Warehousing
- Sales and Marketing (both internal and external facing interactions)
- Preparations activities for interacting with Regulatory Authorities such as the FDA and HealthCanada
- Regulatory submission
- Internal and/or External Auditing

YEAR ONE

- 6 Months Medical Affairs
- 6 Months Pharmacovigilance
YEAR TWO

(Choice of at least 4) [Minimum 2 Months; Maximum 6 Months]

- Sales & Marketing
- Regulatory Affairs
- Quality Assurance
  - Clinical
- Quality Assurance
  - Post Approval
- Supply Chain
- Clinical Development
  - Generics
- Clinical Development
  - Differentiated Formulations
- Biosimilars

During the second year, additional opportunities in Pharmacovigilance, Medical Affairs and Clinical Development at the Corporate Office in Hyderabad, India will be available, if the fellow would like to attain working knowledge of the rules and regulations for India.

“I have learned so much in such a short time since beginning The Dr. Reddy’s Fellowship Program. These past few months at Dr. Reddy’s have been great. I have learned a lot about Pharmacovigilance, and I am so excited to work with other departments over the next 2 years. In addition to learning about the Pharmaceutical Industry I have received career development training that I will utilize during my entire professional life. I am confident that choosing this fellowship will prepare me for a career within the Pharmaceutical Industry. I look forward to working with our new fellows in 2017!”

Urvi Patel, PharmD

“Choosing The Dr. Reddy’s Fellowship was the best decision. I have been given so many opportunities and have been included in many projects while in Medical Affairs. I have grown exponentially since joining. Being exposed to so many cross functional teams has helped me build skills and friendships that will last forever. I am very excited to explore all the areas within the Pharmaceutical Industry this fellowship offers.”

Shalon Jones MPH, PharmD
Potential Activities

MEDICAL INFORMATION
- Call center inquiry processing – work alongside a Medical Information Associate (MIA) to intake Medical Inquiries (MI), Adverse Events (AE) and Product Complaints (PC)
- AE case processing using a validated safety database
- PC retrieval kit processing
- Writing standard response documents

POST-MARKETING PV
- AE Reporting
- PADER creation
- REMS participation and monitoring
- Signal Detection

CLINICAL PV
- Protocol review
- Trial cite evaluation and monitoring visit

MEDICAL AFFAIRS
- Promotional Review Committee
- Safe Disposal Committee
- Labeling Committee
- Field experience
Goals and Objectives

**PHARMACOVIGILANCE**
- Develop working knowledge and practice of global drug, biosimilar and device safety rules and regulations during clinical trials
- Develop working knowledge and practice of global drug, biosimilar and device safety rules and regulations for approved products
- Develop working knowledge and practice of various validated technologies and database tools used to support Pharmacovigilance
- Become proficient at Signal Management
- Liaise with internal colleagues to interpret safety data to perform benefit: risk assessments
- Write, review and analyze individual case safety reports and aggregate safety reports
- Review study protocols and clinical trial data for Adverse Events
- Actively participate in patient registry, support programs and multi-sponsor REMS programs
- Assist in the training of adverse event reporting for new hires

**MEDICAL AFFAIRS**
- Respond to medical inquiries from Health Care Provider (HCP) and patients
- Develop scientifically accurate medical responses to unsolicited medical information inquiries
- Create standard responses to FAQs to respond to unsolicited medical inquiries from patients and consumers
- Assist in developing claims for OTC products, including Rx-to-OTC switches
- Assist in the development, review and approval of labeling activities
- Train Medical Information call center staff
- Participate in the medical review of promotional and non-promotional materials
- Participate in medical slide content development and review
- Serve as a subject matter expert on the selected disease state
**Program Directors and Advising Faculty**

**Karin Greenberg, BS Pharm, RPh, PharmD, BCPS**
Global Head Pharmacovigilance  
Ernest Mario School of Pharmacy Graduate

Dr. Karin A. Greenberg is a graduate of Rutgers University, Ernest Mario School of Pharmacy (BS Pharmacy; 1993 and Doctorate of Pharmacy; 1995) who is a licensed pharmacist in 2 states (NJ and NY). Karin completed her Post-Doctoral Residency (Drug Safety & Medical Affairs) with Janssen Pharmaceuticals in 1996. She also has her Board Certification in Pharmacotherapy Specialties (BCPS) since 1999.

**Joy Kainer, BS Pharm, RPh, PharmD**
Head Medical Affairs North American Generics and Canada  
Ernest Mario School of Pharmacy Graduate

Dr. Joy Kainer is a graduate of Rutgers University, Ernest Mario School of Pharmacy (BS Pharmacy; 1989) and received her Doctorate of Pharmacy from Shenandoah University, Bernard J. Dunn School of Pharmacy in 2008 and is a registered pharmacist in New Jersey since 1989.

With more than 25 years of experience beginning as a retail pharmacist, Joy has more than 20 years of pharmaceutical industry experience focused on Medical Affairs, in particular Medical Communications and Medical Information, Investigator Initiated Grants and Continuing Education Grants, Publication Strategy and Promotional Review Committee, and Sales Training.
Two fellows will be selected for the 2-Year Multi-disciplinary program. Fellows will begin their employment at Dr. Reddy’s in July 2017.
Knowledge of product development with strong clinical background (clinical trials, Pharmacovigilance, Medical Affairs, vendor management, budgeting, auditing)

Knowledge of appropriate worldwide assessment of benefit risk management, medical evaluation of Individual Case Safety Reports, signal detection strategies, evaluation of safety signals and formulation of responses to regulatory inquiries on product safety issues.

Strong decision making and problem solving abilities as well as excellent time management, data research and situation analysis proficiencies.

Upon completion of the fellowship, you will have a working knowledge of the following:

- Medical Affairs/Product Development
- Excellent Presentation Skills
- Clinical Outcomes Experience
- Medical Evaluation
- Medical Safety Analysis & Reporting
- US and EU pharmacovigilance regulatory requirements
- Healthcare Management & Administration
- Counseling & Training for Medical Information and Pharmacovigilance
- Drug Safety & Adverse Event Reporting
- Single Case Reviews
- Experience with ARGUS, ARISg, AdEERS, Clintrace.
- Good knowledge of ICH GCP compliance
- Vendor Management/Vendor Training

The selected fellows will be offered a highly competitive salary and benefits.
To be considered for the Dr. Reddy’s Fellowship Program, you must meet the following criteria:

- Be a graduate of an accredited Doctor of Pharmacy Program prior to the start date of the fellowship term
- Have a strong interest in pursuing a career in the pharmaceutical industry
- Be a U.S. citizen or lawful permanent resident

Complete on-line application at

Curriculum Vitae (Resume) November 27, 2016

Initial Interviews (at ASHP Clinical Mid-Year Conference) December 4-7, 2016

Letter of Intent December 18, 2016

Secondary Interviews January 9-27, 2017

Official College Transcript January 9, 2017

Three Letters of Recommendation January 9, 2017

Applications should be sent to DRL Medical Affairs North America at drlma@drreddys.com.