2020-2021 Visiting Scientist Fellowship (VSF) Positions

Regulatory Affairs

US and International Policy and Intelligence

Global Regulatory Affairs (GRA) develops optimal regulatory strategies to deliver innovative medicine approvals for the patients we serve. GRA regulatory policy fosters policy changes that enable the regulatory environment to best accommodate innovative medicines. GRA regulatory policy staff engage with multiple Lilly functions and external regulatory stakeholders (e.g., FDA, EMA, NMPA, PhRMA, EFPIA, and National Health Council) to advocate for constructive regulatory reforms.

The Visiting Scientist Fellow will:

- Assess the potential impact of external global regulatory trends on regulatory strategies and the company's portfolio.
- Lead regulatory intelligence projects to inform regulatory policy positions.
- Develop Lilly positions on key regulatory policy issues and advocate for policy change in the US, Europe, and other countries.
- Cultivate opportunities to engage in external multi-stakeholder coalitions to achieve shared regulatory policy objectives.
- Contribute to briefings and updates for Lilly senior leadership.

US Advertising and Promotion

US Advertising and Promotion is responsible for advising US Marketing, Business Communications, and Medical Affairs on developing accurate, balanced, and substantiated product, and disease information to enable informed decision making by our patient, provider and payer customers. The US Advertising and Promotion team interprets and applies US advertising regulations and communicates the expectations of FDA's Office of Prescription Drug Promotion to cross-functional teams.

The Visiting Scientist Fellow will:

- Understand FDA regulations and guidance, industry codes, and Federal and State laws on prescription drug advertising and promotion.
- Work directly with internal business partners such as marketing, legal, medical affairs and other commercial and corporate representatives to ensure that promotional materials comply with regulations and company policies.
- Monitor the environment for advertising and promotion changes that could affect the pharmaceutical industry.

Global Labeling Department

The Global Labeling Department (GoLD) leads the development and global implementation of drug and combination product labeling to enable informed decisions by health care professionals and patients using Lilly products.

The Visiting Scientist Fellow will:

- Provide regulatory leadership to create and update core US and Canada labeling for registration and throughout a product's life-cycle. Labeling include core company data sheets, package inserts, patient labeling, and packaging.
- Apply competitor knowledge and regulatory precedent to evaluate and set labeling parameters, influence drug development strategy, and propose feasible language for marketed product labeling.
- Work cross-functionally across global affiliates on labeling development and labeling processes.

Commercial

Global Pricing, Reimbursement and Access: New Product Planning

Pricing, Reimbursement and Access New Product Planning (PRA NPP) is responsible for influencing the development of pipeline and business development medicines to reflect critical payer needs identified through payer feedback. They also provide price and access recommendations for forecasts to support key business decisions with the ultimate aim of ensuring patients can access Lilly medicines and deliver strong business results. The focus is on the USA, Japan, and major European markets.

The Visiting Scientist Fellow will:

- Work across therapeutic areas in the pipeline to apply scientific expertise in a commercial role.
- Work with the Global Public Policy fellow to deliver an environmental review of key markets and identify key opportunities/threats pertaining to pricing and market access.
- Participate in market research and advisory boards to understand payers' needs and develop reports that outline key takeaways and implications.
- Work on strategic projects based on business need and support the team in the development of price and access recommendations.

Global Public Policy and Public Affairs

Global Public Policy and Public Affairs function provides strategic analysis, expert insights, and practical recommendations on healthcare policy issues affecting Lilly and key stakeholders. GPP-PA focuses on domestic and global policies affecting healthcare access, affordability, and advancement.

The Visiting Scientist Fellow will:

- Develop well-reasoned positions through research, analysis, and collaboration to help Lilly shape public policy to support improved outcomes and incentives for investment in biopharmaceutical innovation.
- Apply scientific knowledge and work cross functionally to develop new policy solutions.
- Focus on today's important policy issues such as biologics and biosimilars, healthcare reform, health financing, and benefits design and innovation policy through both a U.S. and global lens.

Health Outcomes

Global Patient Outcomes & Real World Evidence Research Scientist

Lilly's Global Patient Outcomes & Real World Evidence (GPORWE) function generates and communicates evidence that helps differentiate Lilly's medicines from other treatments so that payers, patients and doctors understand when and how to use the medicines and the expected patient benefits.

The Visiting Scientist Fellow will:

- Provide scientific methodological and conceptual expertise to assist in the development and/or commercialization of a product and ensure successful fulfillment of health outcomes research plans to help enable access for patients.
- Focus on diseases and/or treatments that Lilly is developing within biomedicines (migraine, pain and autoimmune disorders) and may span the entire life-cycle of product development and commercialization.
- Be responsible for the conduct, quality and integrity of real world evidence studies and scientific disclosures resulting from this research.

Global Health Outcomes – Center of Expertise

Lilly's Health Outcomes Center of Expertise works hands-on with real world data, publicly and commercially available, to generate health outcomes-based evidence in support of all Lilly therapeutic areas. They enable enterprise-wide coordination of the real world data strategy, advancement of methods, processes, and learning and development.

The Visiting Scientist Fellow will:

- Apply in-depth knowledge, understanding, and evaluation of clinical, health economic, and/or patient-reported outcomes to produce quality RWE studies and scientific disclosures.
- Learn real world data processes for data circulation, data load, data verification, and establish strategies to transform datasets.
- Effectively communicate RWE findings and concepts to internal and external business partners and participates in dissemination of research findings to the scientific community.

Project Management

Clinical Trial Commercial Product Operations

The Clinical Trial Commercial Product team advances clinical development by establishing & executing sourcing strategies for all Phase I-III clinical trials – ensuring that medicinal products are supplied in a manner that maximizes time and cost effectiveness of study conduct while assuring regulatory compliance.

The Visiting Scientist Fellow will:

- Lead transformational initiatives across the Clinical Design, Delivery, & Analytics Organization to enhance the timely delivery of products to clinical trial patients, while aligning with the global clinical strategies.
- Provide high quality and timely regulatory insights related to clinical trial materials, to drive solutions that meet needs of Lilly affiliates and the business.
- Utilize excellent self-management, leadership, communication and organizational skills to effectively manage upward and cross-functionally.

Clinical Trial Product Management – Diabetes

The purpose of the Clinical Trial Project Manager (CTPM) role is to lead cross-functional study teams in the development, execution, and close out of clinical trials. The CTPM is expected to deliver high quality trials on time, within scope, and within budget. The CTPM leverages clear, concise communication, advanced problem-solving abilities, and the ability to lead without authority in order to achieve clinical trial deliverables.

The Visiting Scientist Fellow will:

- Collaborate with and understand the roles and responsibilities of cross-functional study team members (e.g. medical, stats, regulatory, data management, labs, medical writing, etc.).
- Understand key milestones and deliverables associated with clinical trials.
- Utilize project management skills, clinical trial process knowledge, and scientific expertise to assist study teams with clinical trial execution and producing key deliverables.

Pharmaceutical Project Management

The Pharmaceutical Project Manager (PPM) provides proactive cross-functional leadership for drug development, translating and executing the strategy for delivering a medicine to patients.

The Visiting Scientist Fellow will:

- Serve as the central hub and integration point of the drug development core team working closely with individuals from clinical, Chemistry, Manufacturing & Control (CMC), toxicology, ADME, regulatory, health outcomes, legal, discovery and marketing.
- Impact the drug development strategy and execution through the project time-line, scope, budget and risk to enable decision-making for senior leadership.
- Develop and utilize necessary project management skills to facilitate delivery of team time-lines throughout drug development on budget and within scope for a project/projects in Lilly's portfolio.

Clinical Development and Research

Clinical Design Hub

The Design Hub drives collaboration and the planning of clinical programs/trials through use of data sources, targeted innovation and expertise in functional trial delivery.

The Visiting Scientist Fellow will:

- Gain exposure to Lilly's therapeutic areas and the study development process by working in partnership with asset teams and the Design Hub's Therapeutic Area Sleeves to improve and optimize study design and feasibility.
- Provide input into key strategic decisions for a clinical program/trial, which may include country and site allocation, financial modeling, patient recruitment and retention, study training and targeted innovation.
- Have the opportunity to connect asset teams with new and innovative capabilities that can enhance trial feasibility, patient and site experience, and overall business processes.

Clinical Systems and Supply Planning

The Clinical Systems and Supply Planning (CSSP) organization sits within the clinical development space focused on bringing clinical research to people around the world. We manage technology solutions and business processes and we create efficiencies through creativity, consolidation and automation. In partnership with IT and clinical functional leadership, CSSP develops strategies for core capabilities that support study design, patients, research sites, study management, data collection and movement, financials and analytics.

The Visiting Scientist will:

- Learn about and ensure technology processes are optimized across clinical design, delivery, and analytics.
- Use their background and knowledge to influence technology or process-related projects that will enhance clinical development and execution.
- Define and measure processes applicable to focus areas and achieve proficiency with technologies.

Medical

Global Medical Information

Global Medical Information (GMI) plays an integral role in driving medical launch strategy through creation of answers to unsolicited requests from customers (consumers, health care professionals, and payers) and through collection and analysis of customer insights.

The Visiting Scientist Fellow will:

- Complete work cross-functionally and globally in the development and execution of medical information responses (medical letters, FAQs, slide kits, literature searches, publications, webpages, etc.) according to appropriate procedures.
- Respond to unsolicited medical information inquiries from HCPs and consumers in a prompt, accurate, and compliant manner.
- Serve as the medical information expert in ongoing comprehensive product/disease area training to affiliate and call center partners.

Global Medical Digital Strategy and Operations

The Global Medical Digital Strategy and Capabilities team partners cross functionally with departments such as global medical information, global medical education, global scientific communications, and field based medical professionals to enhance the Lilly customer experience for healthcare providers through best in class digital services to customers.

The Visiting Scientist Fellow will:

- Be exposed to a variety of emerging medical digital technologies
- Gain insight into customer channel preferences (e.g., chat, social media, phone, etc) and the medical digital landscape
- Innovate delivery of medical information across digital channels through proof of concept and pilot projects

Global Medical Affairs – Oncology

The Oncology Medical Affairs fellow will have dual responsibilities within the field-based medical science liaison team and internal medical affairs team. Fellow responsibilities will mimic those of internal MSLs and Clinical Research Scientists (CRS) and will focus on working with internal business colleagues to interpret and represent medical field insights and deliver relevant medical content/scientific training that address the needs of MSLs and internal teams. The fellow will be integrated into an internal medical affairs team to prepare for launch execution and support. Likewise, the fellow will work closely with the internal medical science liaisons to support the early and late phase portfolio asset strategy with careful consideration of the external environment.

The Visiting Scientist Fellow will:

- Developing customer support materials, disease state educational materials, advisory board content and preparation, scientific conference materials, and other medical knowledge management tools in support of our future and currently marketed products.
- Routinely interfacing with internal partners to understand scientific strategy (data disclosure plans, clinical development plans, etc) and subsequently communicate scientific strategy to the field team to ensure awareness of key external and internal milestones.

"Take what you find here and make it **better and better**"

-Col. Eli Lilly