REENA NADPARA, PharmD

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SUMMARY

Highly motivated and dynamic Global Regulatory Affairs professional with a strong scientific background and ability to execute strategic business decisions for overall complex programs in collaboration with regulatory health authorities, cross-functional teams, and co-development partners

Results-driven leadership among IND/CTA submissions, NDA/MAA filings, and M&A due diligence assessments within the Oncology/Hematology, Neuroscience, and Anti-Infective therapeutic areas

PROFESSIONAL EXPERIENCE

MorphoSys (Remote-based in NJ) Jul 2023 – Present
US Regulatory Strategy Lead / Director, Regulatory Affairs

- Led US NDA filing for pelabresib in myelofibrosis in collaboration with Global Program Team (GPT) and Submission Management Team (SMT) by defining submission content plan and driving innovative strategies
- Executed FDA interactions by drafting briefing package documents, leading meeting preparation activities, and implementing feedback promptly on development program
- Served as FDA contact for pelabresib INDs and managed collaborative relationship with regulators
- Provided US regulatory leadership to global development organization and commercial teams

Gilead Sciences, Inc. (Morris Plains, NJ) Jan 2022 – Apr 2023
Global Regulatory Lead (GRL) / Director, Global Regulatory Affairs, Oncology

- Provided strategic regulatory guidance for TRODELVY® (sacituzumab govitecan) GU/GYN and NSCLC programs in collaboration with Global Development Team (GDT) and Program Strategy Team (PST)
- Led Filing Strategy Team (FST) to define submission content and strategies for major BLA/MAA applications and Health Authority engagement plans, serving as global filing lead
- Led Regulatory Project Team (RPT) to develop global regulatory plans with regional input while cultivating a high-performing regulatory team to execute on business goals
- Developed life-cycle plans for new clinical trials, indication expansions, and novel combination strategies
- Supported development of disease area strategies in collaboration with commercial and competitive intelligence
- Managed 2 direct reports, empowering ownership of assigned tasks and accountability across teams

Novartis Pharmaceuticals Corporation (East Hanover, NJ)
Global Program Regulatory Director (GPRD), Regulatory Affairs, Oncology Apr 2021 – Nov 2021
Senior Global Program Regulatory Manager (Sr. GPRM) / Associate Director Sep 2017 – Mar 2021

- Led original US NDA filing and approval of TABRECTA® (capmatinib) as first-in-class therapy in NSCLC, receiving priority review, breakthrough therapy designation, and orphan drug designation
- Developed global regulatory plans to strengthen and grow marketed breast cancer assets KISQALI® (ribociclib) and PIQRAY® (alpelisib) in collaboration with the Global Program Team (GPT)
- Executed innovative fast-to-market regulatory strategies utilizing expedited review pathways, such as Real Time Oncology Review (RTOR), Project Orbis, Rolling Review, and Accelerated Approval
- Led FDA interactions and team rehearsals while proactively minimizing risks with mitigation strategies
- Conducted due diligence assessments on several M&A opportunities within oncology space

Allergan plc (Jersey City, NJ) June 2014 – Aug 2017
Global Regulatory Lead (GRL) / Senior Manager

- Served as FDA contact for assigned products and led Health Authority interactions (including BARDA)
- Led FDA meeting preparation activities, including briefing book development, directing team rehearsals through defense planning, and coordinating HAQ responses

- Prepared routine regulatory submissions, such as IND/NDA amendments, annual reports, PADERs, DSURs/PSURs, safety alerts, IB updates, PAS, and labeling changes
- Led cross-functional team with IND/CTA filings and managed multiple sNDA submissions

Post-Doctoral Fellow / Manager-Level Role

- Participated in numerous FDA interactions (including face-to-face), encompassing Type A, B, and C meetings, mid/late-cycle reviews, labeling and PMR/PMC negotiations, and FDA-EMA parallel scientific advice
- Managed the cross-functional development of 2 major sNDA filings and served as Module 1 lead
- Strengthened Q&A preparation for Anti-Infective Drugs Advisory Committee (AIDAC) meeting to review NDA for AVYCAZ® (ceftazidime and avibactam) by acting as a scribe in the "war room"

RELEVANT INDUSTRY EXPERIENCE

U.S. Food and Drug Administration – Office of Medical Policy Oct 2013 – Nov 2013

Advanced Clerkship Rotation (Silver Spring, MD) / Preceptor: Jonas Santiago, PharmD, M.S.

- Identified deficiencies and provided clinical recommendations for conversion of older prescribing information to the Physician Labeling Rule (PLR) format
- Presented a comparison-based analysis highlighting Antibacterial Task Force evaluation of public docket comments in finalization of the Acute Bacterial Skin and Skin Structure Infections (ABSSSI) final guidance

Novartis Pharmaceuticals Corporation May 2012 – July 2012

Drug Safety & Epidemiology Intern (East Hanover, NJ)

- Examined epidemiology of acute heart failure for RLX-030 (Serelaxin) Risk Management Plan (RMP)
- Updated seriousness/outcomes tables in the Lucentis RMP v11 for identified and potential risks based on PSURs

Tricore Interactive May 2011 – Nov 2012

Medical Writing Intern (Princeton, NJ)

- Developed interactive e-learning training modules for numerous drug products to assist pharmaceutical clients in educating employees on approved prescribing information, disease state/pathology, and marketing/sales
- Created ancillary items, such as assessment questions, summaries, and glossaries, based off module content

PROFESSIONAL DEVELOPMENT

- M1 Lead the Way training program, 9-month multiphase leadership journey offered at Novartis Pharmaceuticals
- Friends of Cancer Research (FOCR) 2019 Annual Meeting Working Group Member on "Characterizing the Use of External Controls for Augmenting Randomized Control Arms and Confirming Benefit"
- Alpha Zeta Omega Professional Pharmaceutical Fraternity, Rutgers University Alumni / Epsilon Chapter

EDUCATION & TRAINING

Allergan, formerly Forest Research Institute / St. John's University June 2014 – April 2016
Post-Doctoral Pharmaceutical Industry Fellowship, Global Regulatory Strategy

Rutgers University, **Ernest Mario School of Pharmacy** Sept 2008 – May 2014
Degree: Doctor of Pharmacy (PharmD) / Cumulative GPA: 3.658