

Karishma Arun Bodupali

REGULATORY PROJECT MANAGER SPECIALIZING IN GLOBAL REGULATORY SUBMISSIONS AND AI-DRIVEN SOLUTIONS

WORK EXPERIENCE

NOVO NORDISK | REGULATORY PROFESSIONAL AND PROJECT MANAGER

REGULATORY PROFESSIONAL, SEMAGLUTIDE (Sept 2022 – Present | Copenhagen, Denmark)

- Led the rollout plan for new drug product submissions in top 10 markets, reducing preparation time by **30%** through cross-functional collaboration.
- Managed regulatory submissions for Australia, Switzerland, and LATAM, ensuring adherence to international standards and timelines.
- Acted as the lead regulatory representative on cross-functional teams to ensure compliance for new product launches.

PROJECT MANAGER, RQ&C EXECUTIVE OFFICE (Apr 2021 – Sept 2022 | Copenhagen, Denmark)

- Directed the global rollout of an AI-driven translation project across 4 regions, coordinating over 10 stakeholders, resulting in streamlined processes and regional compliance.
- Developed a strategy based on historical translation error rates, enhancing translation efficiency by **25%**.
- Optimized regional processes through end-user feedback, reducing rollout time by **15%**.

REGULATORY AFFAIRS PROFESSIONAL (Sept 2020 – Apr 2021 | Gatwick, UK)

- Managed life-cycle regulatory activities for diabetes and obesity products, ensuring MHRA compliance within deadlines.
- Developed the UK's first SaaS-based AI chatbot in collaboration with medical and IT teams, cutting response times by **40%** and expanding patient access by **35%**.
- Updated internal SOPs to meet audit requirements, achieving **100%** compliance within two months.

CARTHERICS PTY LTD. | STUDENT CONSULTANT (Apr 2021 – Nov 2021 | Melbourne, Australia)

- Identified 44 competitors using key data sources, leading to a strategic shortlist of the top 10 presented to executive leadership.
- Developed a predictive model analysing competitors' clinical trials and manufacturing methods, guiding sales strategy.
- Recommended an expanded sales strategy based on model insights, adopted by senior executives to target additional indications.

RAKUTEN MOBILE INC. | PROJECT MANAGEMENT INTERN Oct 2019 – Jan 2020 | Tokyo, Japan

- Collaborated with senior managers to translate technical details into actionable project goals and timelines.
- Led the deployment and testing of devices for 600+ users, identifying 4% of network issues pre-4G launch in Japan.
- Created and delivered training for 300+ graduates for a network testing event, enhancing project readiness and data collection.

EDUCATION

- **UNIVERSITY OF MELBOURNE** | MSc IN BIOTECHNOLOGY (FIRST CLASS HONORS)
Mar 2020 – Dec 2021 | Melbourne, Australia
- **UNIVERSITY OF TSUKUBA** | BSc IN BIOLOGICAL SCIENCES
Sept 2015 – Aug 2019 | Tsukuba, Japan
– Thesis: "Molecular Analysis of the KLHL7 Protein"

TECHNICAL SKILLS & LANGUAGES

TECHNICAL SKILLS

MS Office • IBM SPSS • MS Project • Azure DevOps • Confluence • SharePoint • Power BI • Vault RIM

LANGUAGES

English (Fluent) • Hindi (Fluent) • Gujarati (Fluent)
• Japanese (Intermediate)