EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Dhruva Teja Thurlapati

Work experience

Sep 2024 – Present **Scientific officer Clinical Assessment | Health Products Regulatory Authority (HPRA), Dublin, Ireland**

Key Deliverables:

- Relevant scientific evaluation of the safety & efficacy of medicinal products, including herbal medicines which are the subject of new applications; analysis of their benefit/risk profiles; reporting and forming conclusions in respect of their assessment carried out as well as consideration of the public health consequences of their use.
- Reviewing the safety and efficacy of authorised medicinal products, including herbal medicines; analysis of their risk/benefit profiles; reporting and forming conclusions in respect of their suitability for use as medicinal products as well as consideration of the public health consequences of their use.
- Assisting in the review and finalisation of documentation relating to new marketing authorisation applications and line extension applications, including herbal medicines and product information review
- Technical liaison with HPRA colleagues, applicants, regulatory authorities and other relevant bodies, healthcare professionals and the community.
- Representing the Authority on national and international bodies, especially European Bodies if required
- Participation at all levels (Authority, national and international) in the formulation and preparation of regulatory policies, guidelines, legislation and opinions

April 2023 – September 2024 **Scientific officer | Health Products Regulatory Authority (HPRA), Dublin, Ireland**

Key Deliverables:

- Scientific evaluation of cumulative and emerging data (Aggregate reports/ Periodic safety reports) on the risks of medicinal products from various post marketing sources including clinical trials, pharmacovigilance databases and scientific literature to facilitate the timely detection and assessment of any safety concerns.
- Working closely with the Pharmacovigilance Surveillance Assessor and other members of the team to ensure timely, effective, and appropriate processing and evaluation of adverse reaction data, including follow up of individual case safety reports (ICSRs) for Clinical trial reports and Case report forms (CRF).
- Working closely with the Pharmacovigilance Surveillance Assessor during pharmacovigilance inspections
- Assisting in the implementation and maintenance of quality management in the PV section, including identifying potential problems and providing solutions in a timely manner.
- Highlighting any company/sponsor compliance concerns with PV obligations and liaising with team colleagues, particularly the Pharmacovigilance Compliance group to ensure follow up to address any issues identified.

- Assisting in monitoring company/sponsor compliance with PV reporting requirements and obligations and ensuring accurate and consistent use of nomenclatures and coding standards/requirements.
- Ensuring appropriate maintenance and management of adverse reaction data (paper and electronic records).
- Participating in audits as required and to the development of corrective and preventative actions, as necessary.
- Contributing to preparation, review, and evaluation of cumulative PV data, as necessary and providing presentations to both internal and external stakeholders, as required.
- Collating data to contribute to responses to requests for information from HPRA, including for the EU network, WHO, Marketing Authorisation Holders (MAHs), healthcare professionals and patients/consumers.
- Monitoring the safety of authorised medicinal products (pharmacovigilance) by reviewing periodic safety update reports (PSURs) and aggregated adverse reactions report data, data from clinical studies and by evaluating the published literature.
- Assisting the Management team to ensure that PV section procedures remain consistent with relevant developments in National, European and International regulations, legislation and guidelines.

December 2021 – April 2023 **Pharmacy Assistant | Cara Allcare Pharmacy, Dublin, Ireland (Part Time)**

Key Deliverables:

- Carrying out a wide array of marketing, sales and customer services.
- B2C targeted product selling by promotions and link selling.
- Comprehensive understanding of the OTC medication and therapies.
- Attention to the customer needs and providing the accurate medical information and services.
- Advising customer or patients on the Government's schemes on the prescriptions like GMS (government medical services), DPS (Drug Payment Scheme) and LTI (Long Term Illness)
- Maintaining inventory in the pharmacy.

March 2019 – October 2021 **Senior Business Process Associate | Tata Consultancy Services, India**

Key Deliverables:

- Carrying out a wide array of ICSR case processing like case data entry, labelling, numbers approval, manual coding, narrative writing, quality review, quality assurance, SAE reconciliation and ancillary activities (prospective and retrospective QC) in line with SOPs (standard operating procedures) and WI (work instructions)
- Accountable for processing various type of drugs with different types of cases including spontaneous, Clinical trials (interventional & non-interventional studies, blinded and unblinded trials) and literature cases
- Worked and supported on clinical data reconciliation between safety database and Rave EDC.
- Develop and maintain SOPs as required to assure consistency and compliance.
- Closely worked with QMS (quality management systems department) and client for SOP’s and workinstruction update and internal trainings to assure consistency and compliance.
- Accountable for data analysis, trend analysis and retrospective data review and quality review.
- Accountable for extensive multifunctional communication between pharmacovigilance, stakeholders, surveillance scientists and project managers.
- Possess experience in resource planning, daily work allocations, clients/ stakeholders’ communication with daily metrics, cross team collaboration, Data review plan/ strategy and Adhoc queries management.
- Pivotal role involvement in all team/ Stakeholder meetings for minimizing

RCA and implementing a new and innovative methodologies for effective outputs in line with SOPs and WI

- Assisted higher leadership on service delivery, team management and change management during high volumes and process change.
- Assisted the line manager for work allocations and conducting daily meetings on workflow metrics and QRTT.
- Actively participating in internal & external GCP audits, client meetings and daily workflow meetings and ensure to maintain minimal process laps.
- Ensured training compliance for the team and conducted refresher trainings more often to make sure efficient streamlining of the project.
- Assisted the line manager on work allocations, resource or staff management and on performance evaluations.
- Participated in automation projects for pharmacovigilance process in argus safety (sandbox project).
- Performing appropriate compliance checks to ensure records are maintained as well as updating data reports as per FDA & GCP compliance.
- Undergone various trainings during the tenure for Continuous Improvement

April 2016 - March 2019 **Operations Specialist 1 | IQVIA, The Human Data Science Company, India**

Key Deliverables:

- Oversaw registry/triage of incoming cases to prioritise daily workflow
- As an SME (subject matter expert) in tirage process, collaborated with internal and external stakeholders to improve the process and resolve queries.
- As an SME in therapeutic area of Immunology, Rheumatology and Haematology, collaborated with pharmacovigilance physicians to resolve case queries.
- Worked cross-functionally between various pharmacovigilance process and therapeutic areas.
- Processed various types of drugs with different types of cases including a clinical trial for interventional & non-interventional studies, literature and legal cases
- Collaborated with the stakeholders for the successful completion of CAPA and new projects.
- Effectively executed SAE reconciliations, process CAPA's and performance improvements
- Promptly completed case processing activities including duplicate search, case data entry, labelling, approval numbers, manual coding, narrative writing and quality review
- Interacted with Local Safety Officer and customers for clarification of unclear or illegible information.
- Collaborated with Pharmacovigilance Physician to discuss source documents, coding conventions (as per latest MedDRA) and ad-hoc queries
- Involved in preparation of deviation memos, completion of protocol request forms, request deletions/case corrections and single case unblinding as required
- Worked closely with the management and clients to innovate new methods or to improve the pharmacovigilance process

Education and training

Sep-2021 to Sep 2022 **MSc. Pharmaceutical Business and Technology | Griffith College Dublin**
Primary module: Regulatory affairs | Clinical Research management | Business strategy | Operational Excellence

Aug-2010 to Apr-2016 **Doctor of Pharmacy | Rajiv Gandhi University of Health Sciences, India**
Primary module: Pharmacotherapeutics | Clinical Research | Epidemiology | Biostatistics

Additional information

Publications

Projects

- Drug Use Evaluation and Therapy Management on Dialysis Dependent Patients
- Customer Brand Selection and Purchasing Behaviour Towards Advertised Over the Counter Pharmaceutical Products in Dublin

Memberships

Other Relevant Information