PROFESSIONAL SUMMARY

Experienced Regulatory Affairs Professional with more than 7 years of experience in the pharmaceutical clinical research industry. Excellent reputation for resolving problems and improving client satisfaction.

Proficient in current pharmaceutical clinical research regulations, standards and best practices. Analytical and detail-oriented professional focused on making sure regulatory applications and products meet all relevant domestic and international regulatory requirements. Methodical and objective with good judgment and sound critical thinking and problem-solving abilities.

Skilled at preparing and submitting regulatory documentation, including reviewing materials, technical data and accuracy of filings. Articulate and personable with exceptional data analysis, report writing and recordkeeping abilities.

CONTACT

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NICK CHIN, LL.M.

WORK EXPERIENCE

Associate Manager, Regulatory Affairs (Consultant)
Parexel International (Malaysia) Sdn Bhd
Jan 2020 – PRESENT

Senior Regulatory Affairs Associate
Parexel International (Malaysia) Sdn Bhd
Oct 2018 – Dec 2019

- Global Regulatory Lead coordinating clinical trial applications in APAC countries, EU, US and Canada.
- Project Lead for regulatory consultation service assignments covering countries in APAC, North America, Middle Eastern, LATAM and EU regions.
- Develop and implement regulatory strategy to accelerate clinical trial application submissions timelines.
- Compile and coordinate the preparation of post-approval core regulatory document dossiers in accordance with agreed timelines.
- Participate in inter-departmental meetings discussing clinical trial project issues and priorities to develop clear and concise plans with milestones to reach desired outcomes.
- Efficiently manage budgets and resources for global clinical trial projects as well as consultation-based projects.
- Drive regulatory policy shaping initiatives with local regulatory agency and other external stakeholders.
- Support pharmaceutical company clients as consultant in pre-Clinical Trial Application (CTA) submission meetings with Malaysia Health Authority.
- Perform gap analysis reviews and provide dossier improvement recommendations as technical SME on ICH and ASEAN CTD packages (pharmaceutical products) for marketing authorization application submissions.
- Provide inputs and considerations as Regulatory SME in the development of clinical study protocol documents.
- Perform country level labels review and adaptation for Singapore and Malaysia.

KEY SKILLS

- Global Project Management
- Client Communication
- Presentation
- Strategic Planning
- Technical Documentation
- Regulatory Submission
- Good Clinical Practice
- Regulatory Operations
- Team Player
- Legal Research
- VeevaVault

- Prepare, compile and submit regulatory file applications (CTA & MAA) to Malaysia NPRA and Singapore HSA.
- Interpret regulatory rules or regulation updates and communicate with others through corporate policies and procedures.
- Write or update standard operating procedures, work instructions or policies.
- Develop and customize project specific regulatory submission plans for multinational clinical trials.
- Provide trainings on Clinical Trial Application (CTA) and Marketing Authorization Application (MAA) regulatory requirements for Malaysia and Singapore.
- SME for business proposal review during pre-award stage.
- Serve as Local Regulatory Contact (Malaysia and Singapore) in assigned studies across various therapeutic areas for Regulatory Team Lead, Clinical Operations and Project Management.
- Provide pre-, ongoing, and post-inspection follow-up assistance to governmental inspectors.
- Serve as the assigned company licensed pharmacist responsible in maintenance of Poison Type A license of the organization.

Regulatory & Start-Up Specialist
Quintiles Malaysia Sdn Bhd
(presently known as IQVIA RDS Malaysia Sdn Bhd)
Apr 2017 – Sep 2018

- Performed tasks at country level (Malaysia and Singapore) associated with Regulatory, Start-up (RSU) and Maintenance activities of clinical trials in accordance with applicable local and international regulations, standard operating procedures (SOPs), project requirements and contractual/budgetary guidelines.
- Contributed to the collection, interpretation, analysis and dissemination of accurate regulatory intelligence to support assigned studies and wider company.
- Prepared and delivered country-specific RA/EC trainings to clinical operation team.
- Provided pre-, ongoing, and post-inspection follow-up assistance to governmental inspectors.
- Served as Single Point of Contact (SPOC) in assigned studies across various therapeutic areas for investigative sites, RSU Team Lead, Clinical Operations, Feasibility, Site Identification and Project Management.

Community Pharmacist Cum Store Manager
DF Pharmacy Sdn Bhd
Apr 2015 – Mar 2017

- Displayed patient-oriented and comprehensive clinical pharmacy services and pharmaceutical care.
- Achieved and maintained top customer satisfaction and retention by cultivating productive relationships with patients.
- Provided advice on health issues, symptoms and medications.
- Provided patient counseling and advice on prescriptions as well as alternatives and over-the-counter medications.

- Effectively prioritized tasks and organized workflow to increase efficiency.
- Managed drug and supply inventories.
- Maintained effective level of medicines and supplies to meet expected demand.
- Monitored ordering of pharmacy medication stock to maintain streamlined inventory and low overhead.
- Supervised and coached team of pharmacy technicians, trainees and interns.

EDUCATION

Taylor's University
Nov 2018 – Dec 2020
Master of Laws (LL.M.) in Medical and Healthcare Law

- Awarded Master of Laws (LL.M.) with Distinction
- Received Taylor's High Achievers Scholarship

Monash University Malaysia
Feb 2011 – Apr 2015
Bachelor of Pharmacy (Hons)

- Awarded with First Class Honours
- Received Best All-Round Award (Young Leaders Scholarship)

CERTIFICATION

- Certified and trained in Good Clinical Practice (GCP) endorsed by National Committee for Clinical Research (NCCR) Malaysia

PROFESSIONAL AFFILIATIONS

- Registered pharmacist with Pharmacy Board of Malaysia
- Accredited member of Golden Key International Honour Society

PUBLICATIONS

- Chin, W.K. et al, 2021. **A proposal for a legally enforceable no-fault compensation framework for clinical trial-related injury in Malaysia,** Accountability in Research, pp.1-46

- Chin, W.K. et al, 2018. **A systematic review on the off-label use of montelukast in atopic dermatitis treatment**, International Journal of Clinical Pharmacy, 40(5), pp.963-969

- Chin, W.K. et al, 2018. **Leukotriene receptor antagonism may not be effective in atopic dermatitis treatment after all**, Journal of Clinical Pharmacy and Therapeutics, 43(1), pp.159-162

- Chin, W.K. et al, 2017. **The impact of sleep amount and sleep quality on glycemic control in type 2 diabetes: a systematic review and meta-analysis**, Sleep Medicine Reviews, 31, pp.91-101