TIEW SHU XIAN

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Malaysia.

Date of Birth: 2nd March 1990
Race : Chinese
Religion: Buddhism

SUMMARY

Enthusiastic and motivated to contribute knowledge and experience in multidisciplinary fields (chemistry, analytical, formulation, manufacturing and regulation) to the growth and development of the company in parallel to the global business challenges and devote in the effort of business activities.

ACADEMIC QUALIFICATION

2014-2018	Ph.D. in Physical Chemistry *University of Malaya (UM), Malaysia*
2009-2012	Bachelor of Science (Hons) in Chemistry [Distinction]: CGPA 3.75 *The National University of Malaysia (UKM)*

RESEARCH EXPERIENCE

- Pharmaceutical products: tablets, capsules, syrup, injection, cream.
- Hydrophobically modified polymer for drug delivery.
- Nanolipid carrier for sustained release.
- Extraction of plants essential oil for bioassay activity.

KNOWLEDGE & SKILLS

- **Regulation:** Good understanding and application in
  - Product registration and regulatory management for USFDA
  - Assist in establishment and streamline of documentation system in start-up company for R&D department and manufacturing Plant to meet regulatory compliance of regulated market
  - Provide regulatory guidance and support for product development and planning throughout the product lifecycle
  - Labeling and PIL review

- **Technical Documentations**
  Acquire knowledge and experience in formulation, analytical chemistry and manufacturing process to write/compile, analyse, interpret, evaluate, review technical documents in R&D and manufacturing Plant, research articles/journals, literature review, etc, to meet regulatory requirement as per authority guidances/policies and for regulatory documentation database management.

- **Product Development**: Acquire knowledge and experience in formulation and technology of
  - Tablets
  - Capsules
  - Sterile Products
  - Syrup
  - Colloidal science
  - Polymer modification
  - Drug release

- **Chemical Analysis:** Posses knowledge and experience on instrumental analysis and hands-on:
  - High Performance Liquid Chromatography (HPLC)
  - Fourier transform infrared (FTIR)
  - Ultra-Visible (UV-Vis)
  - Malvern Nano ZS Zetasizer
  - Thermal analysis (Differential Scanning Calorimetry (DSC), Thermogravimetry Analysis (TGA)
  - Franz diffusion cells
  - Microscopy observation (TEM, FE-SEM), optical polarizing microscope)

- **Languages**: English, Mandarin, Bahasa Malaysia, Hokkien, Cantonese, Japanese (Level 1)

- **Computer**: Microsoft Office, Adobe Acrobat, ChemDraw, GraphPad, OriginPro

WORKING EXPERIENCE

Assistant Manager, Regulatory Affairs (January 2023 - Present) **–**
Senior Executive, Regulatory Affairs (July 2021 - December 2022)
Novugen Oncology Sdn. Bhd., Malaysia

• Responsible to author, review and publish ANDA sections for US market
• Identify, review, and approve the required documents received towards dossier compilation including R& D documents and plant documents
• Clearances to the regulatory requirements received from CFTs at each phase of product development
• Responsible to get the required documents for submission on liaison all the internal and external sources for its completeness
• Responsible to work on eCTD and labelling activities and ensure their compliance for US market
• Compilation and review of labelling documents PIL, medication guide and review of artworks in accordance with PLR labelling requirements
• Responsible to adhere to the regulatory framework of organisation, and time to time amendments and encourage to propose new improvements in the system within and outside of scope of regulatory affairs
• Responsible to read and interpret the regulatory guidance and learn to apply them efficiently and accurately on each assigned project to deliver them on time
• Thorough understanding on USP requirements while reviewing the specification and keep updating the team with the current requirements
• Review/evaluate the change controls and deviations related to RA decision tree
• To liaise with various contract organisation, and other outside stakeholders on current Agency's regulatory requirements and align them with product goals
• Ensuring regulatory compliances of DMF's in connection with marketing applications

Senior Research Officer (April 2020 - June 2021) – **Research Officer** (April 2019 - March 2020) –
Research Scientist (April 2018 - March 2019)
R&D Department, Y.S.P. Industries (M) Sdn. Bhd., Malaysia

- Literature and patent searching to design and strategize product development plan to be in compliance with the regulations of the authorities.
- Participate in dossier preparation and review for regulatory submission and correspondence with the challenges of regulatory agencies.
- Assist management in coordinating project development with multi-functional teams, technical brainstorming and support on the challenges of on-going projects.
- Develop new pharmaceutical products and improve the formulation of the existing products of different dosage forms by executing and analyzing trial batches for formulation, process/technology optimization and stability studies, which also includes evaluation and compatibility of raw materials and packaging materials.
- Technology transfer from bench top to manufacturing scale-up until commercialization by providing technical support during execution of scale up and process validation following cGMP practises.
- Establish process validation protocols and prepare reports, summary and documents for technical reports.
- Conduct training and guide juniors.
- Sourcing and liaise with suppliers for supply and maintenance of laboratory equipments and consumables.

Research Assistant (December 2012-March 2018); *Department of Chemistry, University of Malaya*

- Conduct literature survey, design, develop and conduct the analyses of the research project, followed by data collection and interpretation and report writing.
- Responsible for the management, inventory and maintenance record of the laboratory and instruments.
- Prepare laboratory and project documentation, including purchasing, grant applications and progress reports.
- Work on the consultation cases with government and private parties.
- Tutor and guide undergraduates for the practical classes, master and internship students on research projects.
- Train new staffs and students on lab documentation and technical matters.
- Plan and organize events and workshops.

Chemist Trainee (internship) (July-September 2012); *Department of Chemistry Malaysia, Petaling Jaya*

- Prepared sample and conducted the analyses of palm oils, fats, petroleum, alcohol and tobacco products.

ACHIEVEMENTS

A) Regulatory Affairs

- Project owner of the first FDA approved ANDA for pharmaceutical product of the organisation (No CMC query from USFDA).
- Assist in establishment and streamline documentation system of start-up manufacturing Plant for USFDA regulatory compliance and to succeed in USFDA inspection.
- Review and support R&D documentation for product development and strategy.
- Working on review and ANDA compilation of manufacturing section for every projects involved.
- Assist cross-functional teams with technical and regulatory knowledge and experience to reduce agency's possible queries

B) Research & Development

- Supported regulatory affairs section on the challenges and queries arisen from the authorities for products registration.
- Introduced new analytical technology or concept for better analytical result and to correspond with the inquiries of the authorities.
- Investigated the root cause of the product complaints of one of the star products and troubleshoot it.
- Developed new procedure and system on documentation management to save time and ease communication of intra-department and inter-departments.
- Brought in new equipment to facilitate product development study.

C) Intellectual Patent (IP)

- Method to produce slow release delivery carrier lipid nanoparticles of different Log P value (US Patent US 14/952.291, 02 June 2016)
- Lidocaine loaded lipid nanoparticles with prolong release property (MY-195829-A, granted on 23 February 2023)
- A mixed fatty acids formulation for enhancing mangostin anticancer effect (MY-180829-A, granted on 10 December 2022)
- Salicyclic acid loaded lipid nanoparticles with prolong release property (MY-191600-A, granted on 01 July 2022)

D) Publications

- Tiew, S. X., Misran, M. (2019). J. Chem. Soc. Pak., 41 (2), 207-218.
- Tiew, S. X., Misran, M. (2018). Int. J. Polym. Mat. 67 (10), 619-628. DOI: 10.1080/00914037.2017.1362637
- Tiew, S.X., Misran, M. (2017). J. Appl. Polym. Sci., 45273, 11 pages. DOI: 10.1002/app.45273
- Voon, S.H., Tiew, S.X., Kue, C.S., Lee, H.B., Kiew, L.V., Misran, M., Kamkaew, A., Burgess K., & Chung. L.Y. (2016). J. Biomed. Nanotech., 12, 1431-1452.
- Tiew, S. X., Woo, J. O., Misran, M., & Ali, H. M. (2016). Mat. Today: Proceedings, 3, 635-639.

E) Awards

- Alchemy of R&D – by Novugen Oncology Sdn. Bhd. (2023)
- Scholarship of MyBrainSc 2016- by Ministry of Higher Education Malaysia (MoHE) (2016)
- Scholarship Scheme University of Malays (SBUM) – by UM (2015)
- Distinction in Bachelor Degree of Science with Honours (Chemistry) – by UKM (2012)
- UKM Tun Sri Lanang Library Knowledge Founder Award 2010 – by UKM (2010)

F) Self-improvement

- Global Pharma Regulatory Affairs (2021)
- Drug Product Development Managament Course (Drug Discovery, Drug Development, Drug Commercialisation) (2021)

MEMBERSHIP/ VOLUNTEERING

- Institute of Chemistry Malaysia: Certified Member