Vivian Midori Maruyama
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Bachelor's Degree in Pharmaceutical Sciences by the State University of Campinas (Unicamp) in Sao Paulo, Brazil. Experienced in the main area of regulatory toxicology, including performing toxicological assessments, human health risk assessments, determination of health-based exposure limits (HBELs) and evaluation of toxicological studies.

Education

2021 – ONGOING SPECIALIZATION DEGREE (LATO SENSU) – TOXICOLOGICAL SCIENCES, OSWALDO CRUZ FACULTIES (FOC), BRAZIL

2018 BACHELOR OF SCIENCE (BSC) – PHARMACEUTICAL SCIENCES, STATE UNIVERSITIY OF CAMPINAS (UNICAMP), BRAZIL

Professional Experience

NOVEMBER 2021 – ONGOING | ASSOCIATE TOXICOLOGIST | AFFYGILITY SOLUTIONS

- Perform health-based exposure limits (ADE/OEL) reports for active pharmaceutical ingredients and other substances

MAY 2020 – NOVEMBER 2021| TOXICOLOGIST | EMS PHARMA

- Perform health-based exposure limits (PDE/ADE) reports for active pharmaceutical ingredients in order to support Anvisa's good manufacturing practice (GMP) framework
- Provide support to meet regulatory requirements such as qualification of impurities as per International Council for Harmonization (ICH) and Anvisa's guidelines, working along with drug master file (DMF) and project support officer (PSO) teams
- Responsible for approving Change Control (CC) and keeping track of actions
- Follow up of Cleaning Validation actions after implementing PDE/ADE values
- Provide toxicological expertise to support Quality Risk Management
- Support corporate standard operating procedures (SOPs)' implementing by writing SOPs and providing training to employees within Quality Assurance context
- Responsible for welcoming new employees to the team

MARCH 2018 – MAY 2020 | TOXICOLOGY CONSULTANT | PLANITOX

- Provide toxicological and regulatory expertise to clients of pharmaceutical, agrochemical and chemical industries to meet regulatory requirements
- Perform occupational and dietary risk assessments of pesticides for submission to Anvisa
- Technical analysis of the company (PATE) form filling for registration of pesticides
- Review studies according to Organization for Economic Co-operation and Development (OECD) Section 4 Guidelines
- Perform full toxicity reports of active ingredients
- Perform tests with adults and children according to ISO 8317 in order to assure child-resistant packages for clients

FEBRUARY 2017 – FEBRUARY 2018 | TOXICOLOGY AND HEALTH SCIENCE INTERN | SYNGENTA CROP PROTECTION

- Elaborate and review medical information for labeling of products
- Monitor acute toxicity studies within contract research organizations (CROs) for submission to Anvisa
- Write waiving and bridging documents to support registration of products by Anvisa and other LatAm regulatory agencies
- Perform toxicity assessments of components
- Perform classification of products and Acute Toxicity Estimate (ATE) calculations according to global harmonized system (GHS)

2013 – 2018 | EXPERIENCE RELATED TO GRADUATION

- Undergraduate research supported by FAPESP entitled “The role of fatty acid-binding proteins in the macrophage infection by Leishmania: a potential target for new drugs against leishmaniasis”, including performing *in vitro L. amazonensis* and *L. braziliensis* infections, incubation of cell plates, MTT cytotoxicity assays and evaluation of results.
- Internship at CAISM University Hospital (Unicamp) supporting all pharmaceutical-related activities, including manipulating chemotherapeutic drugs, providing pharmaceutical attention to intensive care and oncology patients, and supporting pharmacy inventory management.

SKILLS

- English: advanced
- Spanish: intermediate
- Portuguese: native
- MS Software