Anurag Jain

320, MR-4, Mahalaxmi nagar, Near Pioneer College ◆Indore (MP) 452010 ◆**Mob** **+91-99777-39167**
◆anuragjain2706@gmail.com

Objective

Seeking a challenging opportunity in Regulatory Affairs to foster my intellectual ability and provide me with an overall expertise in regulatory issues, strategy and planning.

Professional Experience

SENTISS PHARMA PRIVATE LIMITED – [DRUG REGULATORY AFFAIRS] [DECEMBER 2021 - CONTINUE]

- Compilation of quality submissions for US Market by incorporating the relevant documents for repetitive deficiencies from the regulatory authorities for achieving fast and smooth approvals.
- Preparation of controlled correspondences, Pre-ANDA meeting requests and meeting packages.
- Compilation of quality submissions for ophthalmic, otic, inhalation and nasal dosage form.
- Compilation of PFC (Pre-Facility Correspondence) submissions.
- Review of documents relevant to the submissions in order to ensure compliance with the current regulatory and pharmacopoeial requirements.
- Preparation of submissions for filing review comments, information requests and complete responses.

BAXTER PHARMACEUTICALS INDIA PRIVATE LIMITED – [DRUG REGULATORY AFFAIRS] [SEPTEMBER 2018 – DECEMBER 2021]

- Compilation of quality submissions for Regulated Markets by incorporating the relevant documents for repetitive deficiencies from the regulatory authorities for achieving fast and smooth approvals.
- Preparation of Pre-NDA meeting request and meeting packages.
- Compilation of complex submissions like 505(b)(2) [injectable dosage form] and (a)(3)(f) submissions (submissions for which no DMF for drug substance has been filed with regulatory authority).
- Compilation of submissions for post approval related activities (e.g., Annual Reports, ssCBE, CBE-0, CBE-30, PAS, solicited and unsolicited administrative amendments).
- Review of documents relevant to the submissions in order to ensure compliance with the current regulatory and pharmacopoeial requirements.
- Preparation of submissions for filing review comments, information requests and complete responses.

AMNEAL PHARMACEUTICALS PRIVATE LIMITED – [DRUG REGULATORY AFFAIRS] [APRIL 2016 – AUGUST 2018]

- Compilation of quality submissions for US FDA, Health Canada and EU [injectable dosage form (both lyophilized and liquid injectables)] by incorporating the relevant documents for repetitive deficiencies from the regulatory authorities for achieving fast and smooth approvals.
- Compilation of quality submissions for complex generic injectable dosage form (e.g., suspension, emulsion, liposomes, peptides etc).
- Compilation of complex submissions like 505(b)(2) [injectable and solid oral dosage form] and (a)(3)(f) submissions (submissions for which no DMF for drug substance has been filed with regulatory authority).
- Compilation of quality submissions for ophthalmic and otic dosage form.

- Compilation of PLAIR (Pre-Launch Activities Importation Requests) and PFC (Pre-Facility Correspondence) submissions.
- Compilation of submissions for post approval related activities (e.g., Annual Reports, ssCBE, CBE-0, CBE-30, PAS, solicited and unsolicited administrative amendments).
- Review of documents relevant to the submissions in order ensure compliance with the current regulatory and pharmacopoeial requirements.
- Preparation of submissions for filing review comments, information requests and complete responses.

EMCURE PHARMACEUTICALS LIMITED – [DRUG REGULATORY AFFAIRS] [OCTOBER 2014 – APRIL 2016]

- Review of documents and verify for completeness and correctness, ensure that the products comply with the regulation of US FDA and Health Canada. Compilation of submissions (solid oral and parenteral) for US FDA and Health Canada.
- Knowledge of current guidelines and regulations.
- Review of documents for products under development like of bill of material, scheme and scope, formula clearance, batch size justification, trade dress proposal, new product proposal, stability plan etc.
- Preparation of ANDA, amendments, supplements, annual reports and adverse drug experience reports.
- Preparation of structured product labelling (SPL), other labelling related activity and drug listing of products.
- Review of stability protocols, comparative dissolution study protocols and reports, dose dumping study protocols and reports, breakability study protocols and reports, leachability study protocols and reports.
- Preparation of regulatory approval and commitment packages for the approved ANDAs and supplements and review of APQRs.
- Preparation of submissions for filing review comments, easily correctable deficiencies and assisting in complete response submissions.
- Review of analytical method validation protocols and reports.

GOVERNMENT ORGANIZATION - CIVIL HOSPITAL, SENDHWA: PHARMACIST (OCTOBER 2013 - CONTINUE)

- Working and supervising with the healthcare team to ensure the selection of the best medication at the correct dose for an appropriate duration.
- Monitoring and preventing or minimizing drug interactions.
- Providing medication counseling to patients, checking prescriptions to ensure that there are no errors and that they are appropriate and safe for the individual patients.
- Dispensing medications for patients in ward, the emergency department and those attending outpatient clinics.
- Ensuring medicines are stored appropriately and securely, maintain stock records and inventory, temperature records of cool chain management and expiry.

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RANBAXY LABORATORIES PVT LTD: APPRENTICE [QA (QC REVIEW) (MAY 2011 – DEC 2011)]

- Archival and distribution of controlled documents to QC Laboratory, Packaging Material Laboratory, Exhibit Stability Laboratory, Commercial Stability Laboratory, Microbiology Laboratory.

- Prepare Stability Study Protocols for validation batches, revisions to established marketed product, annual addition batches, batches charged on stability as a result of process deviation and any other batch deemed necessary to be charged on stability by QA.

- Review and approve Stability Protocols generated by PDR/PDL/Stability Department to determine:
  - Whether the approved protocol is made available before collection of stability samples.
  - Whether specifications are available for all the test mentioned.
  - Whether correct test procedure is referred to in the stability protocol.
  - Whether the stability conditions mentioned in the protocol are as per the requirements mentioned in the SOP.
  - Whether the testing intervals included support the shelf life of the product.

- Review and approve stability results and reports comprising of intermediate and finished product analytical results to determine:
  - Whether the test results conform to the specifications.
  - The data supports proposed expiry and testing was carried out within the specified timelines and that there are no deviations from the applicable SOPs during the entire stability program including sample management, testing, documentation and destruction.

- Review and approve method transfer documents.

Education

- **Master of Pharmacy (Drug Regulatory Affairs)**
  From: NRI Institute of Pharmaceutical Sciences, Bhopal. Affiliated by **Rajiv Gandhi Prodyogiki Vishwavidyalaya,** Bhopal (6.92 SGPA in First sem., 8.2 SGPA in Second sem., 7.20 SGPA in Third sem.,7.0 SGPA in Fourth sem., (CGPA 7.36). 2011 – 2013

- **GPAT: All India Rank- 558**

- **Bachelor of Pharmacy**
  From: Swami Vivekanand College of Pharmacy, Indore. Affiliated by **Rajiv Gandhi Prodyogiki Vishwavidyalaya,** Bhopal with 72.2% in June 2011.

Training

- **Waters Global Training:** Liquid Chromatography, September 2011.

- **Ranbaxy laboratories limited, Dewas.** July 2010.

- **U S FDA E-Learning Courses from Center for Drug Evaluation and Research (CDER)**
  Certificate of Completion on the following modules -

  - Office of Compliance Overview, Manufacturing and Product Quality, Scientific Investigation, Bioequivalence and Good Laboratory Practice Inspection Programs, Enforcement Responsibilities, Risk Management and Drug Surveillance, Generic Drug Overview, Abbreviated New Drug Review Process, Role of Office of New Drug, The Drug Review Process, Biologic Review, Pediatric.
  - Regulation, Overview of Drug Safety (Activities and Responsibilities of CDER's Office of Surveillance and Epidemiology), Introdution to FDA human drug review and approval basics, Bringing an Over The Counter (OTC) Drug to Market.
  - Certificate of attendance for various RAPS pre-approved **CDER Small Business and Industry Assistance** (SBIA) webinars.

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- **Medscape Education**
  - The Past, Present and Future of FDA Human Drug Regulation
  - Risk Evaluation and Mitigation Strategies

- **BioPharm Institute**
  - **GMP:** Documentation and Record Keeping
  - **GCP:** Introduction to Clinical Trials and Drug Development

- **World Intellectual Property Organization**
  - **DL 101**: General Courses on Intellectual Property

Project

- **In Master of Pharmacy**

  Major - "Regulatory Requirements and Market Analysis for Over The Counter Drug Products in Perspective of USA"

  Minor - "A Comparison between Europe and USA Guidelines, Basic Requirements for Aseptic Manufacturing of Sterile Medicinal Products"

- **In Bachelor of Pharmacy**

  Major - "Transdermal Drug Delivery System for Non-Steroidal Anti-inflammatory Drugs".

  Minor - "Novel Sunscreen Agents".

Computer Proficiency

- Competent using software including: Dossier management software (eCTD Express, PharmaReady, Educe, eCTD Viewer, Lorenz eCTD Validator), Documentum Compliance Manager, TrackWise, ISI toolbox, ISI writer, Adobe Acrobat, Windows Office, TcU, Baxedge etc.
- I have well experience in handling of Internet and collection of scientific literature.

Area of Interest

- Regulatory Affairs
- Quality Assurance
- Intellectual Property Rights

Personnel Profile

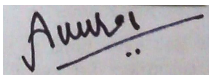
Father's Name	Mr. Rajendra Kumar Jain
Mother's Name	Mrs. Sunita Jain
Date of Birth	June 27, 1990.
Nationality	Indian
Marital Status	Single

Anurag Jain

Declaration

I vouch the authenticity of the above-mentioned information.

DATE – AUGUST 27, 2022



PLACE – GURGAON

ANURAG JAIN