CURRICULUM VITAE

Gowthami V.

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CAREER OBJECTIVE

- To work with a progressive organization in a highly motivating and challenging environment that provides the best opportunities to grow and utilize my potential to achieve the organization goal while improving my career skills and achieving my personal goals.
- To work in projects that will challenge me to perform best of my knowledge and adding value to organization.

ACADEMIC CREDENTIALS

Course	Institute	Aggregate	Board/University	Year of Passing
Master of Pharmacy (Chemistry)	T-JohnCollege of Pharmacy,Bannerghatta Bangalore.	78%	Rajiv Gandhi University of Health Sciences	June-2015
Bachelor of Pharmacy	Vivekananda College of Pharmacy, Rajajinagar, Bangalore.	69%	Rajiv Gandhi University of Health Sciences	July-2013
P.U.C (PCMB)	Vijaya PU college, R.V.Road,Basavanagdi, Bangalore.	46%	Department of Pre-University Education	May-2009
S. S. L. C	Nirmala Girls High School,Shanthinagar, Bangalore.	68%	KarnatakaSecondary Education Board	April-2007

SUMMARY OF EXPERIENCE

Presently worked at Forus Healthcare Pvt Ltd banglore as ***Technical writer and Dossier preparation***, in which supporting to all the departments of Quality and Regulatiry affairs, R and D in medical device.

Previously workedin Paraxel InternationalPVT Ltd– Bangalore as ***Associate in Regulatory Affairs***, having one year experience in the areas of preparation, Review of documents and Compilation of Clinical Trails Applications.

Previously worked in Apotex Research Private Limited – Bangalore, as Assistant analyst having ***One year six months*** experience in the areas of Quality control with respect to regulatory affairs.Creating

submission plan and uploading of documents under the variousmodules 1-5 in the eCTD software, Maintenance of submission in eCTD as per life cycle of the product and also responsible for reviewing of analytical data of in-process analysis, finished product analysis and Stability data for submission batches in whichco-ordinating on regular basis with Regulatory Department.

RELAVENT WORK EXPERIENCE

Forus Healthcare Pvt Ltd (17-Sep-2018 to till 13-Jun-2019)

- At Forus, I have worked on design controls, verification, validation and review of ophthalmic medical devices- 3nethra classic, Classic-HD, DHPand 3nethra neo.
- 3nethra neo, Classic, DHP and Classic HD:

  > Supporting the design team of 3nethra neo and Classic in adhering to all the requirements of FDA. In particular, I have led efforts for the following:

  * Design inputs development (product, interface, hardware and system requirements)
  * Risk Management and Usability engineering files
  * User manuals
  * Coordinating with 3rd party labs for compliance testing of neo (60601 testing for medical device safety & EMI/EMC, light safety testing as per 15004-2, and biocompatibility testing as per 10993)
  * Verifying the availability of all requirements for design transfer to production (Device Master Record)
- Preparing the manual according to the new requirements as per the ISO-13485 and upload to SVN portal by checkout.
- Review of documents like software requirement specification with respect to system software requiremrnt specifications in which applying the condition for the taceability.
- Preparing the DHR and upload to Jtrak for the baselining ad release of document.
- Capturing the images manually according to the manual requiremtnts by using the device.
- Preparing the review forms and the technical dossier file according to the country requirements.

Paraxel International (17-Apr-2017 to 16-Mar-2018).

- Preparation of Documents/ Dossiers for Clinical trail applications and INDs.
- Dossier compilation for Eu markets and submission to authority.
- Basically working for the client to fulfill their regulatory submission acrocss the global and archival into their documentation system.
- Adhering to the Standard operating proceduresand proper training during regular review and compilation and Supports the full procedural document lifecycle of the product or drugs, Corporate

SOPs, Work Instructions (WIs) and Forms by serving as a SOP Writer for Clinical Operations and eTMF.

- Ensuring all the source of documents are correct and complete in coordination with all the team members of clinical pharmacology, clinincal operations, pharmacovigilance, Clinical investigator, project manager, sub-investigators, Research associates, Research [pharmacist, Sponsors , Country specific organization or country orgainisation team (CPO) , SPOCs , Global tream (DRA,s), and clinical pharmacology .
- Preparation of submission package or dossier for U.K and E.U countries (Germany, Austria) according to the country specific requirements.
- Preparation of Initial clinical trial application, Amendment applications,Annual reports, Import and export licence application and regarding regulatory authority deficiencies.
- Responsible for the pre registration and post registration amendments as per the guidelines.
- Provide timely compilation of DMF for the regulatory authorities like USFDA, EU and ROW markets
- Communicate with the clients and regulatory agencies on the regulatory follow-up of submisisons under review. Works with functional area SMEs to develop cross-functional process models.
- Responsible for activities which lead to and maintain domestic and international regulatory approval of pharmaceutical products.
- Regualar communication with the client , including, but not limited to , face-to-face meetings, presentations, telephones, email, and conference call interaction.
- Query response regarding the deficiencies and submission of response package according to the health authority requirements
- Designs, develops and implements corporate and departmental procedures, work instructions, guidelines and process maps to ensure compliance with regulatory requirements and policies
- Tools used: eTMF, Liquent (for updating the systems), REDI RR (to upload the package , AOR), REDI AA (only QC form and cover letter) , DRAWA (Working area for dossier preparation), CES portal (for UK Submission), Irelease (for checking cover letter and Aor) , Pulse (For tracking the uploads) and CTMS medidata.

Apotex Research Private Limited (25-Oct-2015 to 28-Feb-2017)

- Previously worked as assistant analyst having ***one year six months*** experience in the areas of Quality control with respect to regulatory affairs .Responsible for reviewing of analytical data of in-process analysis, finished product analysis and stability data, supporting related teams from Quality Assurance and Regulatory departments.
- Responsible for compilation and review of dossier for a product(Solid, Liquids and semisolid dosage forms) of regulated markets and customers.

- Responsible for Review of documents that are required for the submission such as PDR,MFR,MPR, BMR and BPR, analytical method validations, process validations, stability protocols, specifications and test methods (RM, FM and PM, IP) etc.
- Synchronize with the various departments (F R&D and QC , QA , packaging , Purchase , Production , medical for collection of technical and medical data and Clinical trail related documents from clinical teams ,) for the compilation of dossiers as per the guidelines.
- Compile CMC-Sections, DMF, API, pharmaceutical intermediates for finished dosages, pharmaceutical formulation in CTD format to FDA
- Having experience in LIMS and knowledge on SOP,s and training systems.
- Coordinate and perform the lifecycle management processes with regard to pharmaceutical quality documentation(change control procedures, prepare and submit variations, site transfers etc. with regard to strategy and content)
- Expert in planning, management and delivery of projects where stake is high and time is crucial.
- Expert in e-CTD submission, validation with submission via gateway like CESP and portal submisisons (MHRA)
- Conduct the issue resolution, communicating with the client and their functional areas to ensure that all the issues are resolved in a compliant manner.
- Preparation of dossier according to the Module 1 and Module 2 (Quality) and Module 3 as in eCTD requirements or country specific requirements.
- Submisison of drug product registration application in eCTD in European continent. Have through knowledge of filling procedures and have submitted drug product application via DCP , MRP and national filling procedurs in Europe.
- Prepare the gap analysis for the quality related documents and dossiers
- Circulate query checklist for dossier requirements and compile of query response.

Lake Chemicals Private Limited (12-Oct-2014 to 10-Mar-2015)

- Worked as a project trainee in Analytical and Synthetic R&D department.
- Involved in supporting of all analysis job for a dedicated product “Cloxazolam” a Benzodiazepine derivative which is anticonvulsant, sedative and skeletal muscle relaxant.

TECHNICAL SKILLS

- Sound knowledge on handling and processing of quality control jobs on Pharmaceutical lab instruments.
- Knowledge on clinical GCP, cGMP, GLP, ISO 14155 , LIMS and good at documentation.
- Good computer knowledge how to prepare PPT’s, Excel sheet data, Word documents (MS Office).
- Confident and dedicated at work, having strong review knowledge.

- Deep understanding in problem solving and time conscious.
- Good team player having strong communication skills.

PROFESSIONAL ACHIEVEMENTS

- Presented a Seminar on Fluconazole gels in CES college of Pharmacy during International conference at Hyderabad.
- Attended National seminar (AICTE) on Nano medicines in Manipal college of Pharmacy.

INTERESTED AREAS OF WORK

- Quality Assurance
- Regulatory Affairs
- Clinical operations
- Clinical data management

PERSONAL PROFILE

Name	: Gowthami V.
Fathers Name	: Vishwanatha N.
Marital status	: Single
Language Proficiency	: English, Hindi and Kannada
Residential address	: 18^{h} Cross, 8th Main, SampangiramNagara, Bangalore – 560027.

DECLARATION

I hereby declare that all the information furnished above is true to best of my knowledge. Hoping my proposal evokes encouraging response.

Yours Faithfully

Gowthami V.