**DR. VIJAYALAKSHMI** **GUDAPARTHI**

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**CAREER OVERVIEW**

* A Pharmaceutical professional offering 20 years of proven skill-sets in driving various submissions to regulated, semi-regulated markets, achieving approvals, expanding exports & improving organizational profitability
* In-depth understanding of Regulatory Guidelines like ICH - Q & M guidelines for Quality and Stability requirements, WHO-Stability requirements for III & IV Zone countries.
* Received training for eCTD dossier submissions and also knows about CTD & ACTD formats.
* Sound knowledge of Submissions to US-FDA, EU- Centralized & Decentralized procedures.
* Currently working as a Professor and HOD of Pharm. Chemistry and QA & RA department in L J college of Pharmacy, Ahmedabad**.**
* Attended several National and international conferences
* Having several national and International publications in my credit

**WORK EXPERIENCE**

**1st Aug 2011- Till Date In a reputed Pharmaceutical Institution, Ahmedabad as HOD & Professor- QA & RA and Pharmaceutical Chemistry department**

**5th May’ 2005 – 20th June 2011 PharmaZell R&D (India) Private Limited (A division of PharmaZell GmbH, Germany) as Asst. General Manager- Quality Assurance and Regulatory affairs**

* Handled domestic as well as international regulatory affairs in both regulated and ROW experience in regulatory submissions and registration of Generic drug substance as well as Drug Product. Exposure to Branded Generics
* Implementing the Quality systems and Practices, Documentation, qualification, validation and regulatory filings.
* Training , framing the documentation for all the departments (sops/protocols and various other cGMP records)
* Have been responsible for setting up and managing teams in past and current assignments.
* Preparation, review, and assembling of regulatory submissions (ANDAs) and amendments
* To review the DMF and Technical Package received from the Vendor.
* Provide regulatory support for the review and approval of labeling, advertising and promotional materials.
* Review and evaluation of supporting documentation for accuracy and conformance with the applicable ICH and FDA regulations and guidance
* To publish the submissions using various eCTD submission software and maintain the product life cycle
* Excellent Communication, Inter Personal ,Team management and Project management skills woven with a strong technical and functional background is my asset
* Am a key member to provide regulatory guidance for post-approval changes from RA perspective and have contributed significantly to cost reduction and strategic improvements in product quality through its life cycle
* Key element of my responsibility includes imparting training and design regulatory strategies and approaches
* I work closely with the top management, besides interfacing with the cross functional teams, and successfully managed regulatory audits by giving strategic inputs and guiding them with regulatory requirements

**Mar 2000 to Mar 2005 Orchid Chemicals and Pharmaceuticals Limited , Chennai as Manager- QA & RA .**

* Ensure compliance of submissions with all applicable regulations, guidance and regulatory operations document specifications.
* Monitoring and ensuring that GMP is followed in the Plant
* Planning and implementation of self-inspection programme
* Responsible for Review and Approval of Master batch manufacturing record and batch packing records (Including ANDA submission batches)
* Review, preparation and submission of Amendments and Supplements (Prior Approval supplements, CBE-30 and CBE-0) to NDAs and ANDAs.
* Communicate and closely work with the FDA regarding the regulatory issues and follow up on product deficiencies and approval timelines.
* Handle queries received from Drug authorities and answer them well within the stipulated time.
* Checking of Product Artworks as per the Registration Packaging / Labeling guidelines of the country for product registration & export consignment.
* To co-ordinate for outsourcing analytical functions such as BA/BE studies, Analytical Method Validations etc.

**Jan 1997 to Feb 2000 in Teaching at Sri Venkateswara college of Pharmacy Madhapur, Hyderabad**

**Sep 1994 to Dec 1997 TTK Pharma Limited. , Hyderabad as Executive Q.C & Q.A**

* Worked on ISO 9002 and US FDA documentation and analysis of API’S and formulations.
* Evaluation and investigation of product /system deviations & change controls
* Evaluation and investigation of Product failures
* Evaluation and investigation of market complaints
* Review of stability specifications and stability data.
* Review of batch records and batch releasing
* Preparation of internal SOPs
* Preparation of Annual product Review documents.
* Awarded Best performance award by corporate management

**SCHOLASTICS**

**Ph.D. (Pharmaceutical Chemistry) from Sri Padmavathi Mahila University in 2012.**

**M. Pharm (Pharmaceutical Chemistry) from university in 1993 - First class with distinction**

**B. Pharm from Bangalore University in 1991- First class**

**D. Pharm from Board of Technical Education, A.P- First class with distinction**

**ACHIEVEMENTS**

* **Awarded Prof. S.Rangaswamy Gold medal for securing highest marks in M.Pharm from the University**

**IT SKILLS**

* Familiar with MS office, Literature search through net

**PERSONAL DOSSIER**

Date of Birth: 29th Dec, 1969 Languages Known: Telugu, Hindi, Tamil, Kannada & English

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**Member ships**: Life member IPA, APTI **Dr Vijayalakshmi Gudaparthi**