Prava Venkata Raj Kumar

MANAGER PRODUCT PROJECT, 50 000 ГРН.

15 марта 2021 Город: Киев

Готов к командировкам: Березань

Возраст: 45 лет

Режим работы: полный рабочий день, свободный график работы, удаленная работа

Категории: HR, управление персоналом, Медицина, фармацевтика, Наука, образование, переводы

✔ Готов к командировкам

Описание

TheRXPharmacist

Dr.P.V.RAJ KUMAR

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Senior Quality Assurance Manager and Clinical Pharmacology Research, Pharmacist Professional: Over all 16 Years expertise in Pharmaceutical Wing:

ÄPharmacist & Clinical Research Coordinator, Formulation Operations/ManufacturingÄ Quality Assurance (Aurobindo Pharma Ltd. India.)

Proficient in developing & streamlining systems with proven ability to enhance operational effectiveness and meet operational goals within the cost, time & quality parameters. Experience in conceptualizing profitable production operations encompassing procurement, quality and industrial relations. Well versed with the operations of equipment according to health, safety & equipment manuals. Have developed different validated methods for different dosage forms for semi regulated and highly regulated markets. Worked under most quality conscious environment abiding regulatory requirements and standard operating procedures. Possesees sound communication skills in English & very fluent in English, professional skills, multi task accepting skills, possesses human values, ethics and humainity in work place environment.

An experience well qualified professional, known for creative and facilitating high-quality R&D solution by using innovative technologies for a consistent record of delivering superior bottom line results. Solution –focused, multifaceted, exceptional experience guiding and managing all pharmaceutical development challenges encountered by fast-placed, aggressive, highly competitive and driven in exceeding organizational growth and profit objectives. Accomplished and recognized scientist with progressively responsible and diversified leadership experience in competitive pharmaceutical environments. Possesses successful record of accomplishment in building research and development alliances.

Sound practical knowledge regarding capacity of planning and handing international audits-like US FDA, UK MHRA, TGA AUSTRALIA, FRENCH, and WHO etc... Adept in enhancing production process operations, optimizing resource utilization, escalating productivity and operational efficiencies. Actively involved in managing the final product submissions, negotiating with Regulatory Authorities to obtain timely product approvals. Adroit in participating in Product Teams with regard to implementation of regulatory requirements.

Strong background in providing responses to Regulatory Agencies regarding product information or issues; keen communicator with honed problem solving and analytical abilities.

EMPLOYMENT RECITAL

Aurobindo Pharma Ltd., R&D (Formulation Generics) Research Scientist, Clinical Pharmacology Research Co-ordinator, Quality Assurance Auditor

Duration: From April 2007 to December 2010

Gained Long Standing Service Award from the **Aurobindo Pharma Ltd.** by successfully completing **10 Years+ of Rock-Solid service experience (2007-2017)** and valuable recognition certificates from the management for the contributed outstanding performances in the professional career.

Accountabilities:

Strategic Planning:

w Accountable for Auditing of Method Development, Method Validation& Various Regulatory submission studies.

w Facilitating the interpretation of data and completing the required reports and documentation.

w Providing strategic guidance to the teams which are responsible for the R&D permits, dossier preparation / submissions, product approvals & registrations, compliance with policies and norms.

w Enhancing initiatives & input to sustain the strategies and support product approvals / registrations.

w Handling the raw data of given/specified tasks & ensuring compliance with company standards.

Research Functions:

w Managing development of analytical methods for pharmaceuticals preparations.

w Validating analytical methods on basis of specificity, linearity, accuracy, precision, range, detection & quantization limit, and robustness as per FDA/ICH guidelines.

w Introducing the analytical method validations to ensure the ongoing stability, re-qualification etc.

w Managing the resources to prepare development proposals, execute development protocols, and generate technical reports and regulatory submission documents.

w Carrying out formulation and process development studies including Sustained Release/Immediate Release/Delayed Release/Orally Dispersible formulations, optimization of formulation to increase bioavailability, formulation stability and pilot batch documentation.

w Managing and directing the research and development programs to meet organizational needs and to capitalize on potential new products.

w Developing & implementing research and development procedures and techniques and play dual design function role as Quality Control (QC).

w Ensuring all developing projects, initiatives, and processes are in conformance with organization's established policies and objectives.

Core Competences:

w Providing leadership and building strong succession plans for the team & organization.

w Responsible for the direct management of complex R&D projects viz. Neurological disorders, involving a team of scientific staff.

w Developing strategies to enhance team effectiveness to obtain approvals from US-FDA, UK MHRA, TGA Australia & other countries and meet the business goals.

w Ability to work autonomously and have self-managing capacity during crucial decision making situations.

Significant Highlights:

w Effectively carried out the duties of bio-equivalence center’s SOPs and in a consistent manner with current Regulatory (US-FDA, UK-MHRA, TGA, ICH, WHO etc.) guidelines / established practices / expectations.

w Successfully addressed queries from various Regulatory Authorities related to various submission studies.

w Actively involved in conducting bio-analytical method development and validation for the quantification of drugs and metabolites of various Pharmaceutical Formulations-like Tablets (SR, IR, DR & OD), Capsules, Oral Suspensions pertaining to Anti-anxiolytics, Anti-depressants Neurological disorders etc.

w Instrumental in driving various critical bio-equivalence studies like Risedronate Sodium & Ibandronic Acid etc... were successfully done by using Derivatizing Techniques.

w Steered efforts for operating general lab equipment and instrumentation systems-like LC-MS Applied Bio-systems API 3200, API 4000 & Quattro Micro Mass.

w Possesses the ability of managing and utilizing Automated Data Collection/Reporting Systems.

w Gained hands-on experience in Whatson LIMS, Software, Analyst 1.4.1, Nugenesis-SDMS Software & Randomization Schedule for clinical studies.

w Involved in receiving the plasma samples from the clinic and ensuring their proper storage until further assay.

w Played a pivotal role in applying assay for the Routine Batch Sample Analysis (RBSA) of drugs and metabolites in biological fluids involving simple to complex analytical techniques including Solid-Phase Extraction (SPE), Liquid-liquid Extraction (LLE) & Precipitation (PPT) Techniques.

Responsibilities as Quality Assurance Auditor in Clinical Research Pharmacology pertaining to Bio-Availability & Bio-Equivalence Studies, Dosing, Case Study Reports(CSR) of Volunteers, Time point withdrawals(Blood), Storage of sampled time points, Auditing of Bio study data for Pivotal & Pilot submission studies…….etc.

Duration: From January 2011 to December 2015

w Visiting & auditing the various CROs and ensuring that they are suitable for giving the Pivotal & Pilot submission studies from Aurobindo Pharma Ltd.

w Ensure that the dosing was done as per the CFR & protocols to the human volunteers for anti-depressants, Anti-Cancer, Anti-anxiolytics, Anti-biotics, Anti-bacterials, Drugs for curing Gastric disorders viz. Proton pump inhibitors, anti-allergics, Non-steroidal Anti-inflammatory drugs etc.

w Recording & verification of Time deviation blood samples during sampling schedule.

w Complete verification volunteer health records viz. X-Ray, Complete Blood Picture, Previous disease conditions, Contraindications etc.

w Ensure that the volunteers are withdrawn from the bio-study upon observed ADR(Adverse Drug Reactions) as per the 21CFR and defined study protocol.

w Auditing of entire Pivotal study data starting from Method Development, Method Validation to Subject sample analysis and Repeat analysis (In case of any deviations in the Bio-profile).

w Collating the data pertaining to US-FDA, UK-MHRA, TGA-Australia, CANADA & ROW countries and submitting to respective Regulatory Authorities by coordinating with Regulatory Affairs Dept.

w Ensuring that the various Regulatory queries were answered & reciprocated properly according to their requirements within the stipulated time to get the approvals.

w Receiving the Regulatory auditors (FDA,UK,Canada,Brazil,South Africa, Europe etc.) during their audit and executing the documents in a well manner for their review and assisting them till the completion of audit, closing meeting participations, MOM etc.

w Ensure that Lab compliance activities & Quality standards are upto the current regulatory requirements.

w Maintaing health records of Bio-lab, QA employees as per the regulatory requirements.

w Giving training to subordinates of intra & inter Departments viz. QC, Regulatory on QA SOPs.

w Interrelations with PV (Pharmaco Vigilance) Dept. to get updates, trainings on ADR, ADE etc.

Current Designation : Manager in Quality Assurance Department, Aurobindo Pharma Limited, Formulation Unit-Regulatory Market

Duration: From January 2016 to till

Job Responsibilities as Quality Manager

- Write, review, and/or approve internal SOP’s and other GLP, cGMP, GXP related documentation, Micro biology Dept.
- Providing quality and compliance support for the "release of materials including Raw, Finished & stability materials/products.
- Experience in handling Quality Control Lab, Micro biology lab & Chemical lab activities etc.
- Ensure that all lab activities are meeting according to quality standards & conformances/compliances as well as adhering to 21CFR.
- Manage all required activities to support submission of documentation, resolution of investigations and assessment of change controls.
- Notify management of potential quality and regulatory issues.
- Ability to build strong collaborative relationships with SMEs.
- Handling of Quality Risk Management.
- Assessing and approving Good Laboratory Practices (GLP) and regulatory relevant documents related to quality

systems.
- Conducting of Audits for external analytical laboratories, lead in internal and external audits and involve in Data Quality Review.
- Act as Reviewer to ensure all tests are carried out as per respective specification of raw materials, packaging materials and finished products & stability analysis and responsible to ensure the accuracy of the review performed by Reviewer.
- Review the 'System Audit Trial' in Empower Software with respect to Project deletion beyond the scope of data Backup SOP as well as responsible to review Audit Trails of other standalone systems in QC laboratory.
- Ensure Process Non Conformances are investigated, reviewed and approved on timely basis.
- Review of PNC, OOL and OOT trends and effectiveness of the corrective actions pertaining to Microbiology, Chemical analysis & responsible to review and approval of stability protocols pertaining to Tablets, Capsules, Suspensions & PFOS etc.
- Responsible to upload the specification in ERP & responsible to documents submit to Regulatory Affairs Dept.
- Responsible to prepare/review the Quality Risk Assessments pertaining to laboratory activities.
- Ensuring implementation and effectiveness of CAPA related to laboratory.
- Participate and represent the department in Quality Review team meetings (QRM).
- Approval of analytical data related to Raw Materials (RM), In-Process (IP), Finished (FP) and Stability samples.
- Sound knowledge & exposure to SOPs, Qualification and Validation protocols pertaining to Microbiology wing, CGMP, GDP, GLP, European & ROW guidelines.
- Monitoring of the stock reference cultures and ensuring the correct usage of biological indicators, Media and Culture plates for the Microbiology experiments including Hold Time Study, Process Validation & Cleaning Validation studies.
- Had adequate exposure in the Area Qualification, Monitoring & review of Purified Water Trends including OOT, OOL etc.
- QA experience in facing USFDA, UK-MHRA, European, ANVISA-Brazil, TGA-Australia and other various regulatory audits & possesses sound knowledge in their respective guidelines
- Maintaining Technical agreements with Vendors.
- Resolving customer complaints pertaining to marketed products.
- Submission of data to Regulatory agencies including ROW (Rest of the World).
- Participating in the activities pertaining to EHS training, safety, first aid and firefighting etc. organized by the company for the benefits of staff and company.

- Experience in working in multi-disciplinary/cross-functional teams & strong interpersonal and influencing skills.
- Proven ability to lead task forces and drive projects through completion.
- Excellent verbal and written communication skills
- Ability to manage multiple tasks with competing priorities.
- Visiting & inspecting CRO's for Data auditing of various Pivotal/submission studies.
- In process Quality checks during the Method Validation & Routine Batch Sample analysis as well as the different phases of regulatory studies.
- Daily lab inspection as well instrument Calibration data verification.
- Review & approving Cleaning Validation, Hold time Study, Process Validation reports.
- Conducts Facility audits in CRO's and in-house system audits.
- Lead internal auditor with strong working knowledge of quality systems.
- Comply and work towards meeting the company's quality policy, health safety and environment (EHS) objectives and policies.
- Strong leadership skills with proven ability to facilitate cross-functional teams.
- Change Control, SOP review, Revision and issue of controlled copies.

PRECEDING TASKS

► **Ranbaxy Research Laboratories Ltd., R&D (Generics) 2004 –2006**

Research Associate - Clinical Pharmacology & Pharmacokinetics Dept. (CPP)

► **Apotex Research Pvt. Ltd. (Inc. Toranto - Canada) (Generics) 2006 –2007**

Bio-analytical Scientist & Clinical Research Supervisor.

Projects Undertaken

► US-FDA Projects: By using LC-MS (Applied Bio-systems API 3200,API 4000) & Quattro Micro Mass various FDA Projects (Bio-Equivalent studies like Cardiovascular, Anti-anxiolytics, Anti-depressants Neurological disorders, Anti-Cancer drugs, Anti-Ulcers and Anti-biotics, Anti-allergics, Steroids, CNS Stimulants & Anti-epileptics) were successfully completed. Successfully faced US-FDA, UK-MHRA, French, ANVISA-Brazil, Canada & other Regulatory Audits without any observations.

► Pilot Projects like Anti-Ulcer, Tetracyclines and Cephalosporins – by using HPLC.

► Successfully completed Industrial Training at Dr.Reddy's Laboratories [Generics] and exposed to Production, Quality control, Quality Assurance and Research & Development Departments and gained knowledge regarding the standard operating procedures (SOPs) in all the departments, Quality work culture, compliance standards.

Charitable Additional Tasks & Services to the Nation as a State Registered Pharmacist

► Gratifying additional Responsibilities to the society as a Pharmacist & Clinical Pharmacology Research Professional in collaboration with Premier Pharmacy(Qualified Chemists & Druggists-Visakhapatnam, India)

- Develops hospital staff's Pharmacological knowledge by participating in workshops, conferences pertaining to Clinical programs & projects, continuous training of Pharmacy staff, students, interns, externs and health care professionals.
- Coordinate with the PV Operations Manager and Post-Marketing PV Manager to develop a training program.
- Work with the PV Operations Manager to develop guidelines and metrics to assure quality and compliant deliverables.
- Maintain a strong working knowledge of SOPs as well as ICH, GCP, local regulations and guidelines.
- Collaborate on research projects related to nursing and medical care and multidisciplinary services in city as well as in remote places.
- Providing direct patient care and counselling for giving awareness pertaining to usage of medicaments especially for Anti-anxiolytics, Anti-depressants, Neurological disorders etc.
- Set up and co-ordinate nursing services in conjunction with other health services.
- Completes pharmacy operational requirements by organizing and directing technicians' work flow; verifying their preparation and labeling of pharmaceuticals; verifying order entries, charges and inspections.
- Controls medications by monitoring drug therapies, advising interventions.
- Protects patients and technicians by adhering to the infection-control protocols.
- Prepares medications by reviewing and interpreting physician orders, detecting therapeutic incompatibilities.
- Dispenses medications by compounding, packaging, and labeling pharmaceuticals.
- Provides pharmacological information by answering questions and requests of health care professionals, counseling patients on drug therapies.
- Protects patients and technicians by adhering to infection-control protocols.
- Complies with state and federal drug laws as regulated by the state board of pharmacy, the drug enforcement administration and the Food and Drug Administration(FDA) by monitoring nursing unit inspections; maintaining records for controlled substances; removing outdated and damaged drugs from the pharmacy inventory; supervising the work results of support personnel; maintaining/sustaining current registration; studying existing and new legislation; anticipating legislation; advising management on needed actions.
- Maintains pharmacological knowledge by attending educational workshops, reviewing professional publications, establishing personal networks, participating in professional societies.
- Maintains safe and clean working environment by complying with procedures rules and regulations.
- Contributes to team effort by accomplishing related results as needed.
- Assist in the establishment of unit policies and procedures.
- Assist in the selection, evaluation & professional development of nursing personnel.
- Supervise registered nurses, licensed practical nurses and other nursing personnel.
- Evaluate patients' needs and ensure that required nursing care is delivered.
- Set up and co-ordinate nursing services in conjunction with other health services.
- Ensure quality nursing care is provided and appropriate administrative procedures are followed & adhered.
- Administer nursing unit budget and ensure that supplies and equipment are available.

ACADEMICS

► Awarded with Ph.D. Doctorate Degree in Pharmaceutical Sciences from the world reputed Andhra University, Visakhapatnam, India.

► M.Pharmacy Degree from Andhra University, 2002-2004 (Scored marks with 74% i.e. Distinction).

International & National Publications achieved as a part of Thesis work with Good Impact Factor:-

1) **European Journal of Chemistry:** Volume: 5(3), Jul-Dec (2014), 469-474.**Venkata Raj kumar Prava** and Ganapaty Seru. Development and Validation of a new RP-HPLC method for the determination of process related impurities in Pioglitazone hydrochloride.

2) **International Journal of Research in Pharmacy and Chemistry:**Volume 4(4), Oct-Dec 2014, 1104-1111.**Venkata Raj Kumar Prava and Ganapaty Seru**. Development and Validation of RP-HPLC method for simultaneous determination of Phenylephrine and Ketorolac in Pharmaceutical Dosage Forms.

3) **Pharmaceutical Methods:** Volume 5(2), Jul-Dec 2014, 56-60.**Venkata Raj Kumar Prava and Ganapaty Seru.** RP-HPLC Method Development and Validation for the simultaneous determination of Clindamycin and Miconazole in Pharmaceutical Dosage Forms.

4) **International Journal of Chemical Sciences:** Volume 13(4), Oct-Dec 2015, 1818-1828.**Venkata Raj Kumar Prava and Ganapaty Seru**. Validated RP-HPLC Method for simultaneous estimation of Atenolol and Alprazolam in Combined Dosage Forms.

5) **Indo American Journal of Pharmaceutical Sciences(IAJPS):**2016, 3 (12), 1521-1533**. Raj Kumar Prava, Ganapaty Seru,**Jayapal reddy Sama,Arun Satyadev Sidhhanadham. Chiral Liquid Chromatographic Method Development and Validation for separation of Pheniramine Enantiomers.

6) **Asian Journal of Chemistry:** Vol.20, No.6 (2008), 4493-4497.**Venkata Raj kumar Prava, Ganapaty Seru.**

Iridoid compounds and Antimicrobial activity of the roots of Tecoma stans

7) **World Journal of Pharmaceutical and Life Sciences (WJPLS):**2017, Volume 3, Issue 1, 110-130.**Rajkumar Prava, Ganapathy Seru, Jayapal Reddy Sama,**
Arun Satyadev Sidhhanadham. Separation and Determination of Process-Related impurities of Clopidogrel bislphate by RP-HPLC.

8) **World Journal of Pharmaceutical and Medical Research (WJPMR):**2016, 2(6), 108-117. **Sidhhanadham Arun Satyadev, Venkata Raj Kumar Prava,** Aparna Koduru, Karishma. Zika Virus:An alarming terror of present day.

9) **International Journal of Development Research:** Volume 7(1), 11020-11031, January 2017. **Venkata Raj Kumar Prava**, Ganapati Seru, Siva Kumar Gubbala and Arun Sathyadev Siddhanadham. RP-HPLC Method Development and Validation for the Simultaneous determination of Bromhexine and Sulbactam in Pharmaceutical dosage forms.

10) **International Journal of Pharmacognosy and Phytochemical Research(IJPPR):** 2017; 9(3); 395-399. Arun Sathyadev Siddhanadham, Rajendra Prasad Yejella, **Raj kumar Prava, Jayapal Reddy Sama,** Aparna Koduru. Isolation, Characterization and Biological Evaluation of Two New Lignans from Methanolic Extract of Bark of Zanthoxylum armatum.

11) **World Journal of Pharmacy and Pharmaceutical Sciences (WJPPS):** 2017, Volume 6, Issue 4, 1829-1851. **Rajkumar Prava, Ganapathy Seru, Sabbella Radha Krishna, Surendra Babu Lagu.** Design, Characterization and impurity profiling of Celecoxib by RP-HPLC.

12) **World Journal of Pharmaceutical Sciences (WJPPS):**2017, Volume 5, Issue 5, 168-181.**Rajkumar Prava**, Ganapathy Seru, Vamsi Krishna Pujala and Surendra Babu Lagu RP-HPLC Method Development and Validation for the Simultaneous determination of Lamivudine, Abacavir and Dolutegravir in Pharmaceutical dosage forms.

13) **World Journal of Pharmaceutical Research(WJPR):** March 2017, Volume 6, Issue 4, 908-918.**Jayapal Reddy Sama**, Manjunadh setty, Arun Sathyadev Siddhanadham,

Rajkumar Prava, Aparna Koduru. Pharmacognostical and Pytochemical screening of Root extracts of Clerodendron serratum(Linn.)

14) **World Journal of Pharmaceutical Sciences (Online):** ISSN (Print):2321-3310; ISSN

(Online): 2321-3086

Arun Sathyadev Siddhanadham, **Rajkumar Prava,** Buddha Buvana Alekya,

Vamsi Krishna pujala, Sowmya Mantha. **Anti-inflammatory and analgesic activity of**

methanolic bark extracts of Zanthoxylum armatum.

15) **International Journal of Pharmaceutical Sciences and Research :**E-ISSN 0975-8232; P-ISSN:2320-5148, Volume 12, Issue 1,1000-11

Siddhanadham Arun Sathyadev, **Rajkumar Prava,** Sowmya Mantha, Aparna Koduru and Thimmysetty Gowtami. Synthesis, Characterization and Biological Evaluation of some Novel Benzothiazole Analogs as Potential AntiTubercular Agents.

► Research work was done on Separation & Characterization of Process related impurities on Anti-diabetics, Non-Steroidal Anti Inflammatory drugs & Anti-Platelet drugs by using RP-HPLC, IR, NMR & Mass Spectroscopy techniques.

► Developed & Validated various cost effective analytical methods for the estimation of Double & Triple combinations of various Pharmaceutical formulations(Injections, Tablets) by using RP-HPLC(Anti-biotics, Anti-bacterials, Mydriatics, Anti-tussives & Anti Virals etc.)

Work shops Participations, conferences & Oral presentations in National Seminars:

► Participated in Pre-congress Workshop on “Health Economics and Outcomes Research (HEOR) in Low Resource Settings” held at Andhra University College of Pharmaceutical Sciences during 68th Indian Pharmaceutical Congress-2016.

► Participated & presented an oral presentation in the National Seminar on “Recent Trends in Chemical Speciation, Kinetics and Nanomaterials (RTCSKN-2017)” for the Topic “Constituents of Phytochemical, Medicinal and Aromatic plants for the treatment of Inflammation and Cancer” held at Andhra University on 3rd & 4th March 2017 pertaining to Analytical Chemistry Division.

► Participated & presented an oral presentation in the Andhra Pradesh Science Congress-2017 on “ The Role of Modern Pharmacists in a Changing Health Care Environment and The Role of Industrial Pharmacist in Discovering, Evaluating and Manufacturing Medications ”held at Andhra University, Visakhapatnam during 7th-9th November, 2017.

► Given various guest lectures in Andhra University, other Pharma Academic institutions pertaining to Data Integrity,

Current Pharma trends and Advanced Analytical techniques viz. LC-MS/MS, GC, FT-IR, HPLC, Regulatory requirements to Pharma Industries, Development of Cost effective Analytical methods which are Eco friendly etc.

► **B.Pharmacy Degree from Nagarjuna University, Vijayawada from 1998-2002 (Scored marks with 71%).**

Technical Skills:

► **Electronic Data Capture (Whatson-LIMS), Nichelon Soft Ware, DMS (Document Management System), QMS(Quality Management System), Nugenesis-SDMS, Validated Excel Soft wares, MS Applications inc. MS Word and Power point presentation etc.**

MEMBERSHIP

► Licensed as Registered Pharmacist in the Andhra Pradesh State Pharmacy Council (APSPC).

► Member of Indian Pharmaceutical Association (IPA).

PERSONAL DETAILS

Date of Birth: 30-03-1980

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References

1. Prof. D.Venkata Rao, M.Pharm, Ph.D

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4. Mr.N.Murali Krishna

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