Raghunandan Reddy K. M.Pharm., Ph.D.

706, Block F, Bhavyas Tulasivanam, Kukatpally, Hyderabad, India 500072
[+91-9845519692] [nandanmpharm@gmail.com]

Summary:

- Accomplished clinical scientist with ~16 years of experience in leading and managing clinical projects aimed at successful completion of clinical studies for respiratory, ophthalmic, diabetic, cardiovascular, cancer and neurodegenerative diseases.
- Effective and confident biopharmaceutical interpreter, both oral and written, making complex scientific design accessible to clients of various backgrounds.
- Creative, self-motivated individual and team player with easy-integration in a multicultural environment with unique combination of detail-oriented mindset, driven personality, analytical skills and proven ability to meet tight deadlines by working in a fast-paced work environment with a quality output.

Core Competencies

- Clinical research professional with ~16 years of experience in management of clinical studies.
- Primary responsible to handle end-to-end Clinical Programs (Clinical Trials Phase I, II & III and Patient PK studies) w.r.t Budget Assessment, study feasibility, Study start up, site selection, Study maintenance, project management, Pharmacokinetics, Quality review, Clinical Supplies Management, Identification of study level risks, co-Monitoring (Sponsor oversight), CRA meetings, Study close out and Regulatory submission to support NDA & 505b2 applications
- Proficient in developing clinical strategy / clinical development plan for studies for R&D products.
- Therapeutic area experience in Ophthalmic, Dermatology, Osteoarthritis, respiratory, Anti-infective and Oncology.
- Expertise in review of Protocol, Clinical Study Report, Clinical & Non-Clinical Summary, Regulatory Query Responses, ICF, CRF.
- Comprehensive understanding of Clinical Research Practices and Global regulatory guidelines.
- Workforce management and recruitment Clinical affairs division.
- Coordinate the day to day activities for assigned studies in the in vitro lab provide business development support

Professional experience

- Presently associated & working as Assistant General Manager-Clinical affairs division of **Shilpa Medicare Ltd. Unit-7, Hyderabad**, (CPVQA) India from October 2020 to till date

Previously worked as

- Senior Manager-Clinical development of **Bluefish Pharmaceuticals, Bangalore**, India from December 2013 to September 2020
- Group Leader in Pharmacokinetics and statistics unit-Bioequivalence department of **Alembic Pharmaceuticals Limited, Gujarat**, India) from August 2012 to December 2013.
- Scientist in Pharmacokinetics and statistics unit- Clinical pharmacology department of **APL Research Centre, Aurobindo**

Raghunandan Reddy K. M.Pharm., Ph.D.

706, Block F, Bhavyas Tulasivanam, Kukatpally, Hyderabad, India 500072

[+91-9845519692] [nandanmpharm@gmail.com]

during teleconferences.

- Representing management review meetings for Clinical affairs division
- Possess excellent inter-personal and organizational skills with proven abilities in team management, process enhancement and training & development.

Shilpa Medicare Limited:

- Responsible for design and conduct of phase-1, Phase-2 and phase-3 of Clinical trials and BA/BE studies for Shilpa Medicare limited for small and large molecules.
- Handled IVPT and IVRT (dermatological studies) Pre-clinical & Clinical end point studies.
- Handling of regulatory queries on dossiers submitted.
- Handling of various regulatory inspections related to clinical affairs division of Shilpa Medicare Limited and its affiliated companies.
- Workforce management and recruitment Clinical affairs division.
- Coordinate the day to day activities for assigned studies in the in vitro lab provide business development support during teleconferences.
- Ensure Quality management system compliance is adhered.
- Representing management review meetings for Clinical affairs division.
- Identifying CMA of drug substance and excipients, critical formulation components and critical process parameters that are expected to affect BA/BE.

Bluefish Pharmaceuticals:

- Involved in planning and conduct Pharmacodynamic studies (Clinical end point) and pharmacokinetic studies for Orally inhaled and nasal drug products (OINDPs).
- Decide the Bio strategy including study design, number of volunteers, sampling time points, primary and secondary evaluation parameters, bio-waiver based on regulatory guidelines.

Pharma Ltd., Hyderabad, India) from Jul'2006-Jul'2012.

Software and instruments handled:

Phoenix WinNonlin version: 6.3., R statistical software version 3.2., **SAS** versions 9.3, DD solver version 1.0

Instruments handled: HPLC & LC MS/MS

Educational Qualification:

- Ph.D. in Pharmaceutical Sciences (Pharmacology), A.U College of Pharmaceutical Sciences, Andhra University, Andhra Pradesh, India (2010-2014). Awarded Dec 2015.

[Title: Studies on the mechanisms of drug interaction between selected drugs (Aprepitant, Ticlopidine, Ornidazole and Secnidazole) and Gliclazide in normal/diabetic rats and in normal rabbits]

- Master of Pharmacy [Pharmacology], Biju Patnaik University of technology, Orissa, India (2004-2006).
- Bachelor of Pharmacy in Pharmacology, Kakatiya University, Andhra Pradesh, India (1999 - 2003).

Regulatory Audits Faced:

<u>Bluefish Pharmaceuticals</u>

- MHRA, CDSCO- zonal office, Drug controller office, Bangalore & MPA, Sweden

Raghunandan Reddy K. M.Pharm., Ph.D.

706, Block F, Bhavyas Tulasivanam, Kukatpally, Hyderabad, India 500072

[+91-9845519692] [nandanmpharm@gmail.com]

- Review study protocols and Interpret statistical aspects of clinical studies.
- Site selection, site monitoring for the proposed clinical study.
- Review In-vitro dissolution data, COA, physico-chemical and PK-PD properties of drugs, available historical BE study data if any, in order to correlate with probable In-vivo results.
- Handling of toxicology studies with respect to inhouse developed formulations.

Alembic Pharmaceuticals Private Limited:

- Involved in designing & review of study protocols for solid orals, liquids, suspensions, injections and biosimilars.
- Involved in preparing and reviewing the Statistical Analysis Plan.
- Involved in preparation Randomization schedule for Clinical studies.
- Monitoring of biostudies out sourced to other CRO's as per ICH-GCP and SOPs.
- Involved in preparing and reviewing the Statistical Analysis Plan, preparation Randomization schedule for Clinical studies.
- Compilation of Module 2 of eCTD in ICHE3 format and biostudy report compilation as per regulatory agencies like Canada & US.
- Handling of the queries from various Health Authorities (HA) and sponsors.
- Involved in Statistical analysis of data.

Aurobindo Pharma Limited:

- Pharmacokinetic data analysis of BA/BE studies for various study designs including two stage designs, replicate designs, Reference Scaled Average Bioequivalence studies and Multiple dose study designs.
- Providing Statistical Inputs and sample size calculations

Alembic Pharmaceuticals limited

- Moh-Turkey & DCGI

Aurobindo Pharma limited

- US-FDA, TPD health canada, EMA, Brazil-ANVISA, WHO, South Africa, MCC, Various internal quality audits in APL Research Centre, Aurobindo Pharma Ltd and Pfizer.

Seminars and workshops:

- Use of Biowaivers as in-vivo surrogate, Basic concepts of Invitro-Invivo correlation & Understanding statistical outcome of BE studies through examples for non-statisticians by pharma edge centre Pvt. Ltd. Mumbai, January 2014.
- 3rd International conference and exhibition on Biowaivers, Biologics & Biosimilars by Omics group; Hyderabad, October 2014.
- Participated in Training on Introduction to **Phoenix WinNonlin** organized by Certara (Pharsight corporation US) held at Mumbai, Aug-sept-2012.
- Undergone training in **Project management Workshop** by Infocareer held at Bangalore on 03rd, 04th and 05 October 2018.
- *Seminar as a Speaker*

"Bioequivalence strategies and design for low bioavailable drugs"

Raghunandan Reddy K. M.Pharm., Ph.D.

706, Block F, Bhavyas Tulasivanam, Kukatpally, Hyderabad, India 500072

[+91-9845519692] [nandanmpharm@gmail.com]

- for Clinical studies.
- Involved in statistical Analysis of data.
- Developed protocols for Hormones and Oral Contraceptives which are intended to be conducted in healthy females of child bearing potential and postmenopausal women.
- Answering the queries from various Health Authorities (HA).
- Monitoring of biostudies out sourced to other CRO's as per ICH-GCP and SOPs.
- Development of SOPs and training fellow collegues.

in Drug Formulation & Delivery Summit at Mumbai on 26th-27th July 2018.

Awards & Honors:

- Received the best performer of the year (2013) at Bioequivalence unit of Alembic Pharmaceuticals Pvt. Ltd., Vadodara, India.

Hobbies

- Playing cricket
- listening to music

Research Articles and Publications:

Available on request.

Professional Reference(s)

Available on request

Declaration:

I do here confirm that the above information is true to the best of knowledge and belief.

K. Raghunandan Reddy.