PAPPU K PUTHUPARAMPIL PhD, RAC
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OBJECTIVE

Seeking to resume my career in Regulatory Affairs area

CERTIFICATION

Regulatory Affairs Certification: RAC in US Regulatory Affairs (RAPS, autumn 2011)

EDUCATION

Regulatory Affairs Certificate: Pharmaceuticals & Medical Devices (RAPS Online University, course ongoing)

Core courses including

Ethics, Global regulatory strategy on Pharmaceuticals/devices; Pharmaceutical/devices-lifecycle, role of regulatory professional

Elective courses including

Pharmaceuticals/Device: US regulations, GMP/QSR, Compliance & Audits, Pharmacovigilance, understading and managing clinical trial process

Ph.D in Organic Chemistry: Kerala University, India

HIGHLIGHTS

- 2-3 years working experience in regulatory environment including cGMP laboratories. Cross-functional interaction with analytical, QA/QC teams in generating internal regulatory documents pertaining to drug substance production/manufacture.
- 10 years experience in biotech/CRO industry in R&D involved with new drug candidates, synthesis of pharmaceutical intermediates, streamlining synthetic route
- Thorough knowledge of drug discovery, development processes. Directly involved in laboratory production of drug candidates for Phase 1 & 2 studies adhering to FDA guidelines. High quality products delivered to customer satisfaction before timeline. Organized the overall activities
- Vast experience in documentation of scientific findings, writing status reports
- Knowledge of current FDA guidelines and regulations, IND/NDA/ANDA,510(k),PMA submissions, post approval compliance, labeling, advertising
- Awareness on regulations of Orphan drugs, HCTP's, Blood & Blood products
- Familiarity with GCP, GLP, clinical trial regulations, compliance, quality systems and compliance, FDA inspections and enforcement
- Participated in several cGMP trainings as part of internal regulatory requirement in drug candidate production/manufacture for various clinical phases
- Attention to detail

SKILLS

- Computer literacy: MS Word, Excel, PowerPoint, chemical structure drawing programs like ChemBioDraw

- Chemical Database search: Scifinder, Beilstein, Patent search
- Preparing technical sections on API manufacture for toxicology, Phase 1 & Phase 2 clinical trials coordinating R&D, analytical findings assisting project manager
- Writing Batch Production Records and SOP's in collaboration with cross-functional research teams of QA/QC, writing deviation reports ensuring compliance with internal regulatory affairs specifications
- Writing technical packages for scientific findings (scientific publications, patents, compilation of research reports for customers).
- Good planning and time management skills and ability to manage multiple projects under strict timelines
- Excellent verbal and written communication skills

PROFESSIONAL EXPERIENCE

2011 Jan - Present Research Scientist, *Princeton Global Synthesis, Bristol, PA*

- Multistep synthesis, purification and characterization of various Pharmaceutical intermediates,
- Synthesis and analysis of organic impurities in Pharmaceuticals
- Documenting scientific findings, organizing activities

2008 Jan- 2010 Dec Research Scientist. *Seven Hills Chemicals Inc., Princeton, NJ*

- Carried out synthetic studies on oral insulin sensitizer for Type II diabetes, triacetyluridine (an antidote in chemotherapy), various fatty acid (omega-3) conjugates for screening against various chronic and acute disease conditions
- Documented research findings and wrote technical reports for tech transfer

2005 Sep-2007Dec Senior Research Scientist. *Cambrex Corporation, New Brunswick, NJ.*

- Played key role in the overall production of two Oncology candidates under cGMP for Phase1 & 2 clinical studies keeping close interaction with analytical, QA/QC teams
- Synthesized the controlled substance-sufentanil, patented the process

2003 June-2005 Aug Senior Scientist. *Suven Life Sciences, Monmouth junction, NJ, USA*

- Contributed to a variety of early stage pharmaceutical products, developed numerous processes, conducted process R&D, scale-up, production, instrumental analysis for purity determination, mentored junior chemists,
- Documented research findings and prepared technical packages for customers

2001Feb-2003 May Senior Scientist. *Synthon Chiragenics Corporation, Monmouth junction, NJ, USA*

- Involved in drug discovery program on antibacterials, compound purification, analysis, SAR studies and lead identification. Various patents issued on this study

1999Jan-2001 Jan Post doctoral fellow. *Molecumetics, Bellevue, WA, USA.*

- Contributed to the drug discovery program involving orally active inhibitors of Caspases and thrombin(solid phase combinatorial synthesis) leading to several active compounds

AWARDS

- Employee of the Quarter by Synthon Chiragenics Corporation, NJ, USA
- National Science Council Fellowship, Taiwan
- Senior Research Fellowship by Council of Scientific and Industrial Research, India.
- Junior Research Fellowship by Council of Scientific and Industrial Research, India.
- L. J. Chittoor Memorial Award for Best Outgoing Student (undergraduate studies).

AFFILIATION

Regulatory Affairs Professional Society (RAPS)

PUBLICATIONS	13
PATENTS	9 (industrial)
IMMIGRATION STATUS	US Citizen