Mukesh Kumar, PhD, RAC, DABRM

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Professional Overview

- More than 17 years as global regulatory affairs specialist, specializing in clinical and GMP/QSR issues with significant adverse event, non-clinical study and clinical lab experience.
- More than 75 new-INDs for drug, biologic and combination products, 5 NDAs, 2 BLAs, and has made several hundred FDA submissions (Investigators Brochures, Safety reports, CMC sections, Annual Reports, protocols, IND safety reports).
- Extensive experience in medical device regulatory filings (510k and PMA) and safety monitoring. Filed 3 PMAs for medical devices, 2 PMA amendments, and four 510K applications.
- More than 10 years of experience in developing and using software applications for drug lifecycle management, adverse event reporting, and pharmaceutical project management
- More than 100 clinical trial protocols and management of more than 60 multi-national clinical trials (both under IND/IDE and non-IND trials), in the US, Canada, Europe, Latin America, Africa, and Asia.
- More than 150 audits for GMP, GCP, GLP, and GCLP compliance in the US and about 30 countries.
- Conducted hundreds of professional trainings in GMP, GCP, and GLP, and other regulatory and clinical trial issues such as CMC issues and clinical project management.
- Arranged several FDA meetings for CMC/GMPQSR, GCP and GLP issues.
- Trained for several years as a federal technology transfer specialist and in biotech business development.
- A research scientist prior to regulatory affairs career with more than 11 years of experience in virology, gene therapy, and molecular biology.
- Well known presenter and author for regulatory, technical and business trainings courses, workshops, and symposia. More than 500 talks, 40+ articles, and numerous workshops and conferences. Author of *FDA Puran*, a weekly newsletter with about 100,000 subscriptions.
- Professor (Adjunct), Regulatory Sciences, at the School of Medicine, George Washington University, Washington DC, and Montgomery College, Germantown, MD.
- Member, Board of Editors, Regulatory Affairs Professionals Society (RAPS), USA.

Professional Experience

Brij Strategic Consultations (FDAMap.com), Gaithersburg, MD

2014 – Present

Founder and CEO, Global Regulatory Affairs and Quality Assurance

- Lead training seminars, workshop and boot-camps in topics in regulatory affairs.
- Provide consultation to pharmaceutical, biotech and medical device companies.
- Strategic project management, adverse event reporting and management, manufacturing, vendor management, and clinical trial support.

Aurotech Corp, Silver Spring, MD

2015 – Present

Chief Innovation Officer, Drug Lifecycle Tracking Application (DLTA)

- Lead creation and management of project management solutions for clinical trials
- Lead promotion and marketing activities for www.druglifecycle.com

ResQ Pharma, Chicago, IL

2016 – Present

Director, RA and QA

- Lead QA and manufacturing operations
- Lead interactions with FDA and all submissions to the FDA

Amarex Clinical Research, Germantown, MD

2013 – 2016

Senior Vice-President, Regulatory Affairs & Quality Assurance

- Manage 11 Regulatory Analysts, Auditors, Safety monitors, and Regulatory Assistants.
- Lead submissions to FDA, EMA, HC and other regulatory bodies regarding Lead development of IND/IDE/MAA-enabling strategies for drugs, biologics and medical devices.
- Lead submissions to FDA, EMA, HC and other regulatory bodies.
- Lead meetings with regulators in the US and ROW
- Supervise clinical trial projects for compliance with FDA and international regulations.
- Lead Quality Assurance functions including internal and external audits, SOPs, and CAPA.
- Lead GXP audits for clients and vendors.
- Lead corporate business development functions such as bid defense, marketing presentations, brochure development, new product development, and promotional activities.

2008 – 2013

Senior Director, Regulatory Affairs & Quality Assurance

- Manage 6 Regulatory Analysts, Auditors and Regulatory Assitants.
- Lead submissions to FDA, EMA, HC and other regulatory bodies regarding ongoing and new INDs, NDAs, ANDAs, MAA, IMPD, IDEs, PMAs, 510k, and CE dossiers.
- Review new protocols and informed consent forms from regulatory perspective.
- Prepare Clinical Study Reports/publications.
- Supervise clinical trial projects for compliance with FDA and international regulations.
- Training of internal, client and vendor personnel in regulatory, clinical and quality control processes.
- Lead Quality Assurance functions including internal and external audits, SOPs, and CAPA.
- Conduct GXP audits for clients.
- Create, edit and review of clinical development plan for drugs (pharmaceutical, biological and botanical), and medical devices.

2006 -2008
Senior Analyst, Regulatory Affairs

- Process regulatory documents to be submitted to FDA regarding ongoing and new INDs, NDAs, ANDAs, IDEs, PMAs, and 510k.
- Review new protocols and informed consent forms from regulatory perspective.
- Develop and write Investigator brochures, annual reports, CMC sections, pharm-tox reviews, clinical protocols, safety reports and clinical study reports.
- Supervise clinical trial projects for compliance with FDA and international regulations.
- Training of internal, client and vendor personnel in regulatory, clinical and quality control processes.
- Create, edit, and review SOPs.

Technical Resources International, Inc. Bethesda, MD
2004 – 2006
Regulatory Compliance Specialist

- Reviewed new protocols and CMC sections of the INDs from regulatory aspect for human clinical trials for AIDS drug therapies.
- Wrote new INDs for AIDS clinical therapies and AIDS vaccine clinical trials.
- Monitored the day to day maintenance of current AIDS human clinical trial protocols and INDs.
- Managed several HIV clinical trial-related regulatory documents (INDs, clinical protocols, Annual Reports, CMC reviews, Amendments to INDs, non-IND clinical protocols, FDA-initiated conference calls, IND safety reports, letters of amendment, investigator's brochures, responses to FDA comments about INDs/clinical protocols, SOPs and guidelines – wrote, reviewed, implemented and quality controlled).

Office of Technology Transfer, National Institutes of Health, Bethesda, MD
2002- 2004
Part-time Intern – Licensing and Marketing

- Reviewed technologies developed at NIH, CDC and FDA laboratories for commercialization.
- Determined the commercial value of research products for licensing fee negotiations.
- Made decision about and reviewed filing of patent applications for research products developed in federal laboratories.
- Determined the regulatory pathways and development milestones applicable for available technologies
- Marketed of Federal biological research products to commercial concerns.
- Ensured advertisement of Federal biological research products in the Federal Register and other venues.
- Negotiated of the terms and conditions for licensing Federal research products.

NICHD, National Institutes of Health, Bethesda, MD
2000- 2004
Research Fellow

- Research scientist in the field of virology (specialization in HIV and influenza viruses) and gene therapy.
- Trained and supervised technicians, under-graduate, doctoral and post-doctoral trainees in molecular biology, cell biology, virology, and gene therapy.
- Wrote manuscripts based on research carried out in the laboratory for publication in peer-reviewed scientific journals.
- Presented research seminars/posters based on self-conducted research at scientific conferences and meetings.
- Wrote research proposals and grants.
- Submitted research products developed in the lab for patent protection.
- Collaborated with other research scientists and commercial concerns for research.

Baylor College of Medicine, Houston, TX
1999 – 2000
Research Associate

- Researched in the field of gene therapy using HIV-derived gene transfer vectors.
- Supervised of technician and under-graduate student in molecular biology and gene therapy.
- Wrote manuscripts based on research carried out in the laboratory for publication in peer-reviewed scientific journals.
- Presented research seminars/posters based on self-conducted research at scientific conferences and meetings.

NICHD, National Institutes of Health, Bethesda, MD
1997 – 1999
Visiting Scientist

- Researched in the field of virology.

Dept of Biochemistry and Liposome Research Center, Univ. of Delhi, Delhi, India
1993 – 1997
National Research Fellow and PhD Scholar

- Biochemistry, Virology and Gene Therapy

Education

1997 PhD, Biochemistry / Virology: Delhi University, New Delhi, India
1993 M.S. Biochemistry: National Dairy Research Institute, Karnal, India
1990 B.S. Biochemistry: Delhi University, New Delhi, India

Training/Certification

- 2005, "Clinical Vaccine Trials and Good Clinical Practices," Bloomberg School of Public Health, John Hopkins, University, Baltimore, MD.
- 2008, Regulatory Affairs Certification (RAC) in US regulatory affairs by RAPS
- 2016, Diplomat of the American Board of Regenerative Medicine (DABRM)

Patents and Copyrights

- Sarkar, Debi P., Ramani, Komal, Bora, Roop S., Mukesh Kumar, and Tyagi, Sandeep K.: Process for Producing A Targeted Gene. *US Patent #5683866, Nov. 4, 1997*.
- Sarkar, Debi P., Ramani, Komal, Bora, Roop S., Mukesh Kumar, and Tyagi, Sandeep K.: A Targeted Drug Delivery Carrier. *INDIAN Patent Application No. 2389/Del/95 and* A Process for Producing A Targeted Gene or Drug Delivery Carrier. *Patent Application No. 2390/Del/95, dt. 21.12.1995).*
- Mukesh Kumar and Sutton, R.E.: HIV cDNA vectors. Copyright, BCM Technologies, Inc., Baylor College of Medicine, Houston, TX, OTA # 00-38, 2001.
- Mukesh Kumar and Zimmerberg, J: Process for large-scale production of HIV-based vectors. *(US patent pending, Appl. # 60/425,853; Nov. 2002).*

Publications

- About 40 articles in peer-reviewed scientific and professional journals
- More than 500 presentations at scientific and professional conferences and other venues.
- A popular weekly blog in regulatory affairs with more than 125,000 reads per week.

External / Community Activities

- Member of the editorial board for the ***Regulatory Focus*** magazine published by the Regulatory Affairs Professionals Society.
- Professor (Adjunct) Regulatory Sciences, at George Washington University School of Medicine, Washington DC.
- Professor (Adjunct) and Program Director, Clinical Project Management Certification Program, at Montgomery College, Germantown, MD.