Mike Ramstack

Pharmaceutical Development, CMC, and Manufacturing Consultant

Summary

Accomplished scientist/engineer with over 35 years' experience in the design and development of medical devices, pharmaceutical products and manufacturing processes. Successful track record of progressing products from bench-top to commercialization.

Specialties include: drug product development, process development and scale up, project management, managing vendors, CRO's, and CMO's, tech transfer, troubleshooting, authoring CMC regulatory filings, intellectual property assessment, microencapsulation, micro- and nano-particle drug delivery technology, experimental design(DOE), emulsions/suspensions, lyophilization, polymer science, solid state characterization, aseptic process design, and GMPs.

Experience

Principal and Owner
April 2015 - Present

Consulting services include:

- Drug product development and characterization
- Process development and scale up
- Project management
- Identifying and managing vendors, CROs, CMOs,
- Tech transfer & trouble-shooting
- Authoring CMC regulatory submissions
- Microencapsulation
- Nano-, micro- particle drug delivery
- Intellectual property assessment

Recent client experience:

- Provided technical support to law firm for patent defense case against generic product entry.
- Drafted Formulation Development Report and supporting reports for NDA submission of microencapsulation product for small start-up.
- Provided process development guidance on chemotherapeutic nanoparticle product for startup.
- Served as VP of Technical Operations for nanoparticle start-up.
- Preformed 3rd party technology assessment, identified additional consultants, vendors and CMOs for veterinary sol-gel medical device.
- Provided CMC assessment on nasal drug delivery product for small start-up.

• Assisted in troubleshooting and provided formulation guidance on microencapsulation products for several large and small pharma companies.

Scientific Fellow II
July 2013 - August 2015 (2 years 2 months)
Lead company efforts in the process development and manufacture of platinum based drugs and targeting nanoparticles. Managed suppliers and CMOs for production of clinical materials. Developed pilot scale capability for producing drug-loaded polymer and liposome nanoparticles. Guided process development and clinical manufacture of company's first product, BTP-114, a cisplatin pro-drug. Authored IND CMC section.

Principal Fellow, Pharmaceutical Sciences and Manufacturing at Cerulean Pharma, Inc
2008 - July 2013 (5 years 7 months)
Lead company efforts in the development of processes for making drug-loaded nanoparticles. Coordinate activities with suppliers and CMOs for the manufacture of tox and clinical supplies. Troubleshoot manufacturing issues. Guided CMC effort for CRLX301, a docetaxel loaded nanoparticle into Phase I clinical trials.

Research Fellow at Alkermes (previously Medisorb Technologies LP)
1991 - 2008 (18 years)
Directed technical project teams and maintained client relationships in the development of controlled release microsphere products and processes.
Accomplishments include:
• Technical/ Scientific lead in the development of Risperdal® Consta®, the company's first commercially successful product.
• Principal in the development of two succeeding microsphere products: Vivitrol® and Bydureon®
• Guided batch size scale-up efforts from gms to 10's of kgs.
• Developed novel and proprietary microencapsulation method using non-toxic solvents.
• Developed propriety extraction procedure to reduce residual solvents in product.
• Authored pharmaceutical development sections of NDA.
• Led teams to investigate causes and identify corrective measures for product/process defects.
• Consulted as Technical Expert for company patent defense and opposition cases

Product Engineering Supervisor at DuPont
1981 - 1990 (10 years)
Developed extracorporeal therapy devices including plasmapheresis system (instrument and disposables) and immuno-depletion columns. Managed R&D team. Coordinated internal research and external contract projects for instrument design, consumable manufacture, and sterilization.

Senior Research Scientist at Johnson & Johnson
1978 - 1981 (4 years)

Developed cardiovascular surgical products including membrane oxygenator and blood filters. Managed device development laboratory. Developed product specifications and manufacturing processes. Conducted in-house laboratory and external animal product performance tests.

Education

Northwestern University
Ph.D., Chemical Engineering, 1974 - 1976
Northwestern University
MS, Biomedical Engineering, 1972 - 1974
University of Notre Dame
BSME, Mechanical Engineering, 1968 - 1972

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Contact Mike on LinkedIn