Mathew Cherian Ph.D.

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PROFESSIONAL SUMMARY

Over 30 years of diverse, international experience in development and manufacturing of finished dosage forms and active drug of small molecules, proteins and peptides, complex branded and generics, novel drug delivery technologies, process development, scale-up, technology transfer and manufacture of liquid, lyophilized and powder-fill dosage forms. Hands-on experience in liposomes and emulsions, nanotechnology, micro- spheres, phospholipid -based drug delivery, controlled release technology, biopharmaceuticals, emulsions, and intellectual property for life cycle management. Instrumental in developing a proprietary drug delivery technology based on lipids currently scaled up and validated. Experienced in Regulatory and cGMP compliance relating to development and manufacturing, Prepared Investigative New Drug Applications (IND), New Drug Applications (NDA), including 505(b) 2 submissions and ANDAs. Was member of Pfizer's business development leadership team responsible for in- licensing of products, and external research, and actively involved in due diligence and product and facility acquisitions

WORK EXPERIENCE

Vice President Operations & Development, ReVive Biotechnology, Champaign, IL 2023- Present

- Directing CMC and clinical development of nano- bubble technology for delivery of oxygen to critical ischemic tissues like eyes and brain

Consultant, Oak Brook, Illinois 2018-Present

- Directing development of the active drug (API) and finished dosage form of an NCE for photodynamic therapy. The drug product is lipid encapsulated nanoparticle. Administered intravenously. Responsible for all aspects of development including tox, pharmacology, chemistry, manufacturing & control. The work is for a US start- up company.
- Technical collaboration with a pharmaceutical start- up in the Kingdom of Saudi Arabia. Involved in portfolio selection, product development, personnel recruitment, and training, and facility design.
- Advising a start-up on sterile injectable and ophthalmic drug development.
- Directing formulation development for a start-up, for CAR-T Cell Therapy using LNP nanotechnology

Pfizer, Lake Forest, Illinois
Director and Senior Fellow, Global Pharmaceutical Development 2010-2018

- Directed development of a suite of biopharmaceuticals / biosimilars and complex generic injectable products, starting with early-stage development, active drug development, thru full development, process development for the same, and preparation of Regulatory Dossier

- Collaborated on regulatory filings for multiple products in the US, and ex- US

- Represented Pharmaceutical Science for in- licensing new products and technologies, and external research, used in multiple therapeutic areas including immunology, oncology, anti- infectives, and women's health. Executed due diligence and recommended to Senior Leadership. Member of Pfizer Business Development team.

- Made written and oral presentations on status of current projects to Senior Leadership.

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- As member of Business Development Leadership Team, identified potential external product opportunities and screened them for progressing further in acquisition process. Did complete scientific and technical assessment of these assets and advised senior management

- Provided science and technical leadership for development of biopharmaceutical products in syringes and other combination drug delivery devices. Headed Pfizer Centre of Excellence for Syringes.

- Provided direction for developing an antibiotic active drug (API) and scaled up aseptic spray- drying process for it.

- Was responsible for development and execution of strategies for life- cycle management of currently marketed products, including development of value- added presentations based on currently approved products

- Provided technical leadership for development of differentiated delivery systems for currently marketed products

- Actively involved in the development of bio-similars of currently marketed biopharmaceuticals

- Responsible for annual operating budget for the 3 global sites. Coordinated Chief Science Officer's capital budget for Global Pharmaceutical Development.

BAXTER HEALTHCARE

Director, Research, and Analytical Development, Medication Delivery 2009- 2010

- In charge of labs in Northern Illinois and Nivelles, Belgium, responsible for development of formulation and analytical methods for parenteral products, and dispersed dosage forms
- Directed efforts at development of IV emulsions containing Omega- 3 oils.
- Management of Intellectual Property and patent strategy for Medication Delivery, Nutrition
- Responsible for outsourcing of development and manufacturing of parenteral dosage forms
- Direction of development of new technologies for dispersed dosage forms, and instrumental methods of analysis

THERMOFISHER (PATHEON) PHARMACEUTICAL SERVICES 2005 – 2008

Senior Technical Director, Analytical Development & Formulations, USA (2007-2008)

- Technical and scientific direction of all sterile projects for Patheon worldwide
- Scouting and in- licensing of new technologies for sterile and oral products
- Development of oral delivery systems using lipid based delivery
- Co-ordination of clinical and commercial supply

Director, Pharmaceutical Development Services, Analytical & Formulations, Rome, Italy (2005- 2008)

- Development of injectable liquid and lyophilized formulations of peptides, proteins, monoclonal antibodies and small molecules
- Development of active drug and its scale up for an oncology indication
- Analytical and process development for finished dosage forms
- Nanotechnology applied to poorly soluble drugs
- Management of sterile manufacturing facility for CTM
- Design for expansion and validation of aseptic facility

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AMERICAN BIOSCIENCE, CHICAGO **2003-2005**

Director Pharmaceutical Development (Analytical, Formulation & Process)

- Member of the development team that developed a protein- encapsulated cancer drug
- Member of team for acquisition and setting up of a development lab and design of a production facility for sterile products.
- Other responsibilities include in- licensing new molecules, and development of drug delivery technologies.

PFIZER (PHARMACIA / PHARMACIA & UPJOHN) **1991 - 2003**

Director, Pharmaceutical Sciences (Analytical Development & Formulations), Skokie, IL (2001-2003)

- Led multi- disciplinary inter-site (US, Europe and Japan) teams involved in developing new drug moieties. Work entailed development the active drug (API) and its synthesis, and finished dosage form.
- Represented Global Pharmaceutical Sciences in Corporate Exploratory Development Teams and ensured cross- functional collaboration within pre- clinical development, forecasted and coordinated approval of major expenditures.
- Represented Pharm Sci on Corporate Drug Delivery Technology Team charged with developing and licensing new drug delivery technologies.
- As a member of the In- Licensing and Evaluation Team for Pharmacia/ Pfizer, actively participated in in- licensing negotiations and due diligence efforts on drugs and technologies.
- Patent Scientist for the Pfizer/Pharmacia R&D site at Chicago and member of Global Patent Committee that reviewed and approved patenting activities.
- Led development team for 3rd Generation COX-2 molecule for oncology, arthritis and inflammation
- Led development team for iNOS for inflammation, asthma and oncology.
- Led the development of ready-to- use Human Growth Hormone (hGH) for delivery by B-D Micromedica delivery system.
- Led Fragmin (low molecular weight heparin) Micromedica team
- Member of lifecycle management team for Pfizer/ Pharmacia's leading cancer drug Camptosar

Director, Sterile Products Analytical, Process & Formulation R&D, Nerviano, Italy (1997- 2001)

- Direction, guidance and co-ordination of all research and development, process development and manufacturing activities pertaining to injectable formulations. Duties included evaluation of new chemical entities (NCE) for pre-clinical screening, development of new formulations and analytical methods for the same, purchase, installation and validation of new equipment , and scale-up to manufacturing.
- Evaluation of new technologies for licensing and scouting for new moieties for development.
- Oversaw relocation of R&D laboratories and sterile injectable Pilot Plant from Pharmacia's labs in Albuquerque, NM to Nerviano, Italy
- Directed formulation development of a highly insoluble anthracycline analog, using nano technology.
- Directed formulation of several monoclonal antibodies for use in oncology
- Managed a large sterile injectable aseptic pilot plant and directed scale up and production of clinical supply for world- wide use.

Director of Pharmaceutical Research and Process Development, Albuquerque, New Mexico (1992- 1997)

- Headed a group of scientists developing and manufacturing liquid, lyophilized, liposomal and emulsified formulations of anti -neoplastics, antibiotics and immuno – modulators, and biologicals.

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- Directed analytical method development and isolation and characterisation of related substances pertaining to the above.
- Directed validation, maintenance and day-to-day operation of a GMP-compliant Sterile Pilot Plant, and scale-up of products.
- Directed development of a proprietary technology for poorly soluble drugs, and used it on a lipid-complex formulation of 9-aminocamptothecin - a highly insoluble anti-neoplastic. Developed analytical methods for the active moiety, and excipients, validated them and compiled Investigative New Drug (IND) application for the same. Patent granted.
- Represented Pharmacia and Upjohn on the Steering Committee with National Cancer Institute (NCI) on the CRADA for development of 9-aminocamptothecin.
- Developed a colloidal, nano dispersion, injectable formulation of Tin Ethyl Porphyrin, an anti-neoplastic drug, based on photodynamic therapy (PDT) technology.
- Instrumental in the award of a multi-million dollar development contract by National Cancer Institute (NCI). Drafted and submitted the Request for Proposal (RFP) that resulted in the contract.
- Principal co-investigator on several formulation development projects with National Cancer Institute (NCI). These development projects involved formulation development and/or analytical method development on several anti-cancer and anti-HIV peptides and small molecules, and their scale-up. Assembled CMC sections for IND's for the same.

Section Head, Formulations and Analytical, Pharmacia, Columbus, Ohio (1991-1992)

- Headed the Formulations Development Department of Adria. Instrumental in designing the new Development Center and Sterile Pilot Plant at Adria-SP, Albuquerque, and relocating the Development Department from Columbus to Albuquerque. Recruited and trained several new personnel for the new Development Center.
- Led efforts to file NDA for Zinecard – approved for cardiomyopathy in oncology patients
- Led development of Rifabutin an anti-mycotic oral dosage form.

PRESENTATIONS/PAPERS & PATENTS

- 'mRNA Technology for Vaccines & Therapeutics', Webinar sponsored by International Pharmaceutical Society, The Hague, Netherlands, Sept 29, 2021 (Moderator)
- 'Polymorphism Basics and Co-crystal Technology', Shireesh Apte & Mathew Cherian, Journal of Excipients & Food Chemicals, Vol 14, 1 (2023)
- **'**Alternatives to Vial Lyophilization', Invited Chapter in' Lyophilisation of Biological & Vaccines', Springer Verlag, New York (2015)
- *"Antibody Drug Conjugates", Invited lecture sponsored by International Pharmaceutical Society, the Hague, Netherlands, November 24, 2013*
- *"Use of Single- Use Systems for Biopharmaceuticals", invited lecture at ANVISA Brazilian Regulatory Agency / Sinduspharma Ssymposium, Brasilia, Brazil, July 22, 2013*
- *"Antibody Drug Conjugates", Invited lecture at International Workshop on Sterile Products, Cairo, Egypt, April 13, 2013*
- *Conference on Pharmaceutical Technologies", Co- Chair and presenter, Cairo, Egypt, February 6-8, 2012*
- *"Aseptic Compounding & Processing", Pharmaceutical Technology, May 2011*
- *"Advances in Parenteral Science", Co- Chair and presenter, 3- day Workshop held at King Saud University, Saudi Arabia, February 2009*
- "*Critical Quality Attributes and Critical Process Parameters in Freeze Drying Biologicals*", Quality International, London, November 27, 2007

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- "*Sacle-up of Biologicals",* Workshop on Pharmaceutical Manufacturing and Practice, World Congress of Pharmacy, Beijing, China, August 31- September 1, 2007
- "*Protein- Surfactant Interactions",* Workshop on Pharmaceutical Manufacturing and Practice, World Congress of Pharmacy, Beijing, China, August 31- September 1, 2007
- "*Aseptic Processing and Isolator Technology",* Advances in Parenteral Technology, Pharmaceutical Manufacturing Science Workshop, International Pharmaceutical Federation (FIP), Salvador Bahia, Brazil, August 25, 2006
- "*Fundamentals of Freeze Drying",* Advances in Parenteral Technology Workshop, International Pharmaceutical Federation (FIP), Salvador Bahaia, Brazil, August 25, 2006
- Mathew Cherian and Joel Portnoff. *"Scale-up of Dispersed Parenteral Dosage Forms."* Invited contribution to "Pharmaceutical Dosage Forms" vol. III edited by Banker, G., Lieberman, H., and M. Rieger, pages 395-422, Marcel Dekker, New York, 1998.
- Mathew Cherian. *"Passive Targeting - Phospholipid Based Drug Delivery."* Fine Particle Society Meeting, Chicago, 1996
- Arun Chalgeri and Mathew Cherian. *"Method Validation for Determination of Rifabutin Related Substances."* American Association of Pharmaceutical Scientists 8th Annual Meeting, Orlando, Florida 1993.
- Mathew Cherian. *"A Mathematical Model for Size Dependence of Charged Liposomes."* International Conference on Pharmaceutical Science and Technology, August 1993, Chicago, Illinois.
- Robert Butler, Mathew Cherian and Fakrul Sayeed. *"Compatibility of Gallium Nitrate with Selected Drug Products."* ASHP Annual Meeting, New Orleans, Louisiana, December 1991.
- Mathew Cherian and Stanley Barnett. *"Diffusion of Surfactants Across Oil/Water Interface"* Diamond Jubilee Meeting of American Institute of Chemical Engineers, Washington, D.C., November 1984.
- Mathew Cherian and Stanley Barnett *"Oil/Water Dispersions And Thermodynamic Role of Surfactants"* Annual Meeting of American Chemical Society, Boulder, Colorado, 1981
- *"Lyophilizate of Lipid Complex of Water Insoluble Porphyrins"* US serial # 20020058643.
- *"Lipid Complexes and Liposomes of Highly Insoluble Platinum Complexes"* , US serial # 6287593
- *"Method for Removing High Boiling Solvents from Drug Formulations by Vacuum Drying"* US serial # 6045808
- *"Heat Treating Liposomes",* WO 90-03808
- *"Platinum Complexes of Single Isomer Neo-alkyl Acids",* EP 0356332
- *"Lyophilizate of Lipid Complex of Water Insoluble Camptothecins."* US Serial # 6548071B1
- "*Lipid Complex of Alkycyclines*", EP 1227795 A2

EDUCATION

Ph.D. in Chemical Engineering, University of Rhode Island **Kingston, Rhode Island, 1984**
Thesis: Mathematical Modelling, Computer Simulation and Experimental Studies on Spontaneous Emulsification.

MS in Chemical Engineering, University of Rhode Island **Kingston, Rhode Island, 1981**
Thesis: Stability of Oil/Water Emulsions.

MS in Chemical Engineering and Petrochemicals, Indian Institute of Technology, Kharagpur, India, 1976
Thesis: Hydrocracking of Petroleum Fractions Using Nickel/Tungsten Catalyst

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BS in Chemical Engineering Osmania University, Hyderabad, India **1972**

PROFESSIONAL AFFILIATIONS

Member, American Institute of Chemical Engineers (AIChE)
Member, American Association of Pharmaceutical Scientists (AAPS)
Member, Drug Information Agency (DIA)
Member, Controlled Release Society (CRS)
Executive Committee Member, International Pharmaceutical Federation (FIP / Industrial Pharmacy)
Member, International Society of Pharmaceutical Engineers (ISPE)
Elected to Sigma Chi, National Scientific Honor Society
Elected to Phi Kappa Phi, National Scholarship Honor Society