DILEEP BHAGWAT, Ph.D., MBA

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EXECUTIVE PROFILE

Entrepreneurial, results oriented pharmaceutical consultant with extensive global Regulatory, CMC, Quality & Clinical experience and excellent project management skills. 20+ years of core CMC - Pharmaceutical Product Development management experience (Solid/liquid oral, Topicals, injectables, MDI etc.) in multiple therapeutic areas (Oncology, Dermatology, GI, CNS, cardiovascular). Specific capabilities and experience are detailed below.

Global Regulatory

- Led multi-functional teams in defining the EU Regulatory strategy to MAA filing (including eCTD, centralized procedure) and MAA review process management to MAA opinion and final label negotiations. Strategy, management of Post-Approval changes
- Full responsibility in last three positions for all CMC documentation for regulatory submissions (IND, NDA, ANDA, MAA, NDS)
- Present and defended CMC data packages and company position to FDA, EMA, Health Canada.

CMC - Pharmaceutical Development Management

- Led Rx and OTC global Product Development, Technology Transfer, contract R&D, contract manufacturing, Scale up and commercialization teams. Pre-formulation; analytical/formulation development; IQ, OQ, PQ; analytical method validation; ICH stability studies; RM, in-process, finished product specifications; Cleaning validation; process validation; MBR

- Holder of 16 US issued patents plus many international patents

Quality Assurance – Full responsibility for Quality at last three positions: GMP audits of API/Drug Product manufacturing facilities in the US and Europe. Pre-FDA /EMA audit diligence and preparation of sites for audits.

Clinical Study Management: Including all aspects of two large (200 and 500 patient) randomized blinded studies in pain.

Project Management: Led multi-functional project teams establishing strict goals, timelines and budgets. CROs, CMOs, licensee and KOL relations, University R&D liaison. Business development due diligence. Retained and managed consultants – Regulatory, Quality, CMC, Clinical, Toxicologists, Statisticians and Legal.

WORK EXPERIENCE

WPDC, LLC **MARCH 2013 TO PRESENT**

CEO and Sr. Consultant (examples of work experience)

Sr. Regulatory consultant - To leading Japanese Pharmaceutical company on multiple projects. **April 2016 to present**

Sr. Regulatory consultant - To leading French Pharmaceutical company. Updating CTD CMC sections to Company templates and incorporated prior Annual Report information for biological products. Authored Annual Reports. Supervise team of authors. Worked with Regulatory software/data bases (e.g. Documentum) **July to December 2015**

Sr. Regulatory consultant – To Pharma Company based in Israel, Responsible for all CMC Sections of NDA. NDA filed June 2015 **July'14 to May 2015**

Sr. Regulatory consultant – To top 10 global Pharmaceutical Company, in Basel, Switzerland **November 2013 to July 2014**

Worked in Basel, Switzerland on authoring CMC sections and review/edits of Drug Substance and Drug Product CTD CMC Sections. Development had QBD elements. Pharmaceutical Development and Regulatory skills to develop strategy and finalize Development reports for NDA/MAA after direct interface and visit with small Development Company in Jerusalem, Israel.

Sr. Regulatory consultant – To Fortune 100 Company in the US **August 2013 to November 2013**

Consulting assignment for global CMC (API) Regulatory and Quality matters. Assessed the impact of potential API manufacturing site change on global regulatory filings for API and Drug Products manufactured with API by customers. Comprehensive report with recommendations generated for management.

Sr. CMC consultant – To small development stage companies **Ongoing since July 2011 (as requested)**

Formulation Development/optimization strategy and ICH stability studies. IND and scale up.

EPICEPT CORP., TARRYTOWN, NEW YORK **2004 to DECEMBER 15, 2012**

Sr. Vice President, Pharmaceutical Development

Member of EpiCept's management team, reporting to the CEO. Responsible for all aspects of drug product development (Phase I – III) and GMP manufacturing/commercialization/supply chain of pain and oncology compounds in the EpiCept pipeline. Responsible for QA and global Regulatory CMC submissions for NDA, NDS and MAA.

- Product development of oncology (including NCEs) and pain Rx products
- Developed and scaled up to manufacturing scale a topical pain Rx cream formulation. Responsible for all CMC issues (API and Drug Product) for NDA and MAA (successful End of Phase 2 meetings with FDA and EMA) recently completed.
- Developed challenging NCE injectable formulation for IND and early Phase 1 – 2 studies.
- Led a multi-functional project team in the regulatory filing (on time and within budget) of an eCTD MAA in Europe via the Centralized procedure of EpiCept's lead compound (Ceplene – first-in class drug for remission maintenance in Acute Myeloid

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Leukemia). Managed Regulatory, Clinical, Statistical, Toxicological and CMC consultants and organized KOL meeting in Europe for this application. Responsible for all CMC filings

- Responsible for all API and Drug Product GMP manufacturing (Scale up, validation) and commercial packaging to successful commercial launch on time.

- Led a team to generate stability data on a recombinant DNA (biological) Rx product. Data was filed and after much negotiation (EMA CMC, Quality and Clinical) was accepted by the EMA resulting in a much needed EMA approved changed to the package insert.

BRADLEY PHARMACEUTICALS, FAIRFIELD, NEW JERSEY 1999 – 2004
Chief Scientific Officer

Responsible for all scientific activities at the company reporting to the President and CEO. Responsible for Product development, Operations Dept. (manufacturing and supply chain), setting up and managing a Clinical program, Regulatory and Quality Assurance and compliance. Developed and launched a number of OTC/Rx products resulting in company sales increasing over 300% during the 5 year period. Worked with Marketing on promotional material oversight (DDMAC) and with Sales on Sales Training. Conducted US and International seminars for physicians presenting scientific data on company products.

- Responsible for Bradley's Operations Dept. and for all manufacturing and compliance of Rx and OTC products. Included selection and qualification of contract manufacturers and supply chain internationally. Scale up of development projects to commercial scale. Regulatory filings. Quality Assurance.

PENWEST PHARMACEUTICALS CO., PATTERSON, NEW YORK 1994 – 1999
Vice President, Scientific Development and Regulatory Affairs

Hired by TIMERx Technologies as Vice President, Pharmaceutical R & D, reporting to the President, to organize and modernize (cGMP compliance) the R & D efforts of PENWEST's emerging Oral Controlled Release business. Organized, staffed, trained and managed Pharmaceutical Development, Pharmaceutical Analysis and QA / QC Depts. Introduced the cGMP mind-set taking drug development into clinical studies. Hired / trained many Ph.D. (Director / Manager level), scientists / technicians in these Depts. Responsible for the installation and validation (IQ, OQ, PQ) of an in-house Clinical Manufacturing facility (in compliance with cGMPs and a new Quality system). Subsequently, Regulatory Affairs responsibility was added. Worked with a Sr. Management R & D Team when the TIMERx and Mendell (excipient) businesses were combined under Penwest Pharmaceuticals Co.

- Sr. R & D Team member in developing a Once a Day Oral TIMERx Nifedipine XL (ANDA) product (antihypertensive) bioequivalent to Procardia XL using TIMERx Technology. Responsible for working with the Licensee in getting TIMERx technology (a new technology) through the FDA review process. ANDA was approved.
- Led a multi -disciplinary team in the Technology Transfer of TIMERx Nifedipine XL to European licensee. Worked with licensee on regulatory requirements (Biostudies, Clinical studies, stability and submission information on TIMERx Technology). Product filed (MAA) and approved in record time.
- Developed the Regulatory strategy with Licensee of TIMERx's first European Oral Controlled Release Once a Day incontinence drug MAA filing. Product was approved with no comments by the agency on TIMERx Technology (a new Technology to the Agency).
- Led a multi-disciplinary team for PENWEST's largest Joint Venture Oral Controlled Release Analgesic development project. Led project with Sr. VP R & D of partner company in completing Phase I studies, filing an IND and moving the project into Phase II / III on time and in budget. Jointly evaluated and selected a CRO company to develop a Clinical Development Plan and undertake clinical studies. Presented project updates to Joint Alliance Committee (Sr. Management of both companies).
- Developed novel Oral Controlled Release antidiabetic product using the TIMERx Technology. Two US patent issued. Formulation was licensed after the first pilot biostudy because it gave the desired 24 hour profile.

Prior positions at:
PURDUE FREDERICK RESEARCH CENTER, YONKERS, NEW YORK

- Excellent all round hands on Laboratory experience in pharmaceutical analytical, formulation development research and manufacturing. Progressed from Summer Intern with successive promotions and increased responsibility to Assistant Director, Pharmaceutical Development

EDUCATION **Ph.D. (Industrial Pharmacy) St. John's University, New York; MBA (International Business) - Pace University, New York**

HONORS AND PROFESSIONAL AFFILIATIONS :

Rho Chi Pharmaceutical Honor Society
Drug Information Association (DIA)
American Association of Pharmaceutical Scientists (AAPS)
American Pain Society (APS)

PERSONAL **US citizen**