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Summary

- Senior executive with over 25 years' experience in development, manufacture and registration of novel devices, drugs and combination medical products, with emphasis on creating value through intellectual property development.
- Strategic perspective that integrates design, manufacturing, quality, regulatory, clinical, toxicology, and marketing requirements to identify the least burdensome and most efficient route to commercialization of safe and reliable products.
- Experience with successful FDA interactions relating to device, drug and combination product development, from early through late stages. International experience includes working with companies in Europe and Asia.
- Sixty-three (63) US and foreign patents; twenty-three (23) publications.

Experience

Oct 2020 – Present: President, PharmaCRO, LLC
PharmaCRO, LLC is a consulting company offering product development consulting services in the area of drug development, combination medical products and medical devices.

Sep 2018 – Sep 2020: Exec. Vice President, Respivant Sciences
Respivant was developing drugs for the treatment of allergic and inflammatory diseases.

* Responsible for API, drug formulation, device design, contract manufacturing, CMC regulatory and QA, and Intellectual Property.

Jan 2014 – Aug 2018: Co-founder, CTO, Patara Pharma
Patara was developing drugs for the treatment of allergic and inflammatory diseases. Patara was acquired by Roivant Sciences in August 2018.

* Responsible for API, drug formulation, device design, contract manufacturing, CMC regulatory and QA
* Company Officer

Jul 2011 – Sep 2012: Senior VP and CTO, Elevation Pharmaceuticals
Elevation was a respiratory drug delivery company that developed a nebulizer product for the treatment of advanced stage COPD. The company was successfully acquired by Sunovion Pharmaceuticals in Sept 2012 for $430MM.

* Responsible for API, drug formulation (single and combination), device design, contract manufacturing, CMC regulatory and QA, project management, and technical interactions with potential partners
* Company Officer

April 2007 – Jul 2011; Sep 2012- Jan 2014: President, PharmaCRO, LLC

PharmaCRO, LLC is a consulting company offering product development consulting services in the area of drug development, combination medical products and medical devices.

Providing product development and contract manufacturing support services to: **a)** a multi-national company developing a combination medical product for inhalation; **b)** a multi-national company in India developing drug delivery systems for the oral route of administration; **c)** a pre-IPO start-up developing a continuous glucose monitoring system; **d)** a pre-IPO biotech company developing lateral flow molecular diagnostic assays and therapeutics; **e)** a medium sized, public medical products company developing products based on iontophoretic drug delivery; **f)** a multi-national company in Europe developing combination products for drug delivery; **g)** A pre-IPO company developing a novel formulation for dry powder inhalers (DPI) and metered dose inhalers (MDI); **h)** a multi-national company developing a nebulizer for delivery of drug for cystic fibrosis; **i)** a pre-IPO company developing a patch-pump for extended delivery of a drug.

Oct 2002 to April 2007: Alexza Pharmaceuticals, Inc.

Alexza is a mid-stage company involved in the development of inhalation drug delivery systems for systemic delivery via the lung for the treatment of acute and intermittent conditions.

Vice President, Product Research and Development

Responsible for product design, process development, project management and pre-clinical and clinical manufacturing for inhalable drug delivery systems (combination products) that are compliant to the US (FDA, DEA, DOT and ATFE) and EU regulations. Company Officer and member of the Executive Staff.

* Developed, from research stage through clinical trial manufacture, design and manufacturing process for novel inhalable drug delivery products, both single and multi-dose, involving the use of flash heating to form drug vapors that condense to form aerosol.

* Rapid product and process development led to submission of five IND's in a span of four years. The products were targeted for the treatment of migraine, acute panic, breakthrough pain and agitation. This strong product pipeline led to a successful IPO in March 2006, and positive safety and efficacy results in pre-clinical and clinical studies.

* Responsible for all project management activities.

* Participant in the Executive Team for the development of product portfolio, regulatory, pre-clinical, clinical, commercial manufacturing, partnering, financial and organizational strategies.

June 1994 to July 2002: Cygnus Inc

Cygnus, a Drug Delivery and Medical Device company, developed the first 7-day contraceptive transdermal patch (technology acquired by J&J in Dec 1999: NDA approved in 2001 and product launched in May 2002 as Evra), and the first non-invasive, automatic glucose monitor, GlucoWatch Biographer based on reverse iontophoresis technology; PMA approved in 2001, product launched in April 2002.

Vice President, Engineering ***Jan 1998 to July 2002***
Responsible for product development, manufacturing equipment design, manufacturing process development and scale-up for the GlucoWatch Biographer AutoSensor. Member of the Executive Staff.

* Designed the hydrogel based AutoSensor, from research stage through large-scale manufacturing. FDA approval of the PMA was granted in March 2001, and three design modification PMA supplements were also approved in 2001.

* Developed and set-up a pilot scale manufacturing operation which was used to manufacture clinical supplies for development and pivotal clinical studies.

* Developed the equipment for semi-automated and fully automated manufacturing processes. PMA supplement for the use of the semi-automated equipment in manufacturing was approved in Sept 2001.

* Led product development strategy for the evolution of the GlucoWatch Biographer. Generated a multi-phase plan involving products with progressively enhanced features.

* Led the second generation Biographer project team. Developed and tested a design embodying separate sensor and display units connected with a wireless link.

* Played a key role in generating the least-burdensome regulatory strategy for the approval of the various design, process and site changes.

Executive Director, Product and Process Development ***April 1996 to Dec 1997***
Responsible for product and process development for transdermal systems and the glucose monitoring system.

* Co-authored a business plan for the development of extended duration drug delivery systems using bio-erodible polymers. The business plan served as a basis for potential alliance discussions with several companies.

* Led the testosterone transdermal system development project team, demonstrated feasibility and sought funding from potential partners.

* Developed the formulation and manufacturing process, and manufactured clinical supplies for the contraceptive transdermal system. Our partner J&J obtained NDA approval of the product (Evra) in Nov. 2001.

* Demonstrated feasibility of a melt-processible transdermal system for the treatment of schizophrenia and sought funding from potential partners.

* Developed a transdermal system for the treatment of benign prostatic hypertrophy (BPH). The milestones for the first phase of the project were met and Phase I clinical trials were completed by our partner Yamanouchi.

Director, Product and Process Development ***May 1995 to March 1996***
Responsible for product and process development for transdermal systems.

* Optimized the adhesive component of a seven-day estradiol Transdermal system (FemPatch). Our partner Parke-Davis obtained NDA approval of the product in Dec. 1996.

* Developed the formulation for a matrix transdermal system for delivery of higher doses of nicotine than Nicotrol (second generation Nicotrol)

* Developed the process for two mucosal delivery formulations. Funding was sought from potential partners for completing the development of these products.

Manager, Materials Development ***June 1994 to April 1995***
Responsible for Materials Development and Research in high-flux transdermal systems.

* Developed a method for minimizing crystallization of estradiol in high-flux Transdermal formulations.

* Identified and optimized adhesives and excipients for the estrogen, estrogen/progestin and contraceptive transdermal delivery systems.

June 1979 to May 1994: Raychem Corporation
Raychem was the established leader in the design, manufacture and sales of high performance materials based products for the Electronics, Telecommunication, Aerospace, Military, Energy Transmission and Industrial Heat Tracing and Corrosion Protection markets. In 1998, with sales of $1.5 billion, it was acquired by Tyco Corporation.

Chemelex Division, Manager of Materials and Process Development and Technical Services ***June 1992 to May 1994***
Chemelex, with sales of $120 million, was focused on development, manufacture and sales of heat tracing systems for the Industrial markets.

* Developed a high temperature, self-limiting heat-tracing system for the oil transmission market.

* Achieved 50% improvement in yield of a process used for manufacturing self-limiting heaters.

Interconnection Components Division (ISD) ***March 1986 to May 1992***
ISD, with sales of $ 90 million, was focused on development, manufacture and sales of interconnection products for the Military, Aerospace and Electronics markets. I held three different positions: Manager of Fiber Optic Systems Development; Technical Services Manager; and Engineering Manager, Devices Products.

* Developed crimp splices, EMI protection gaskets and heat-shrink Solder Sleeve™ devices. Launch of these products helped enhance the portfolio of interconnection systems offered by the Division.

* Managed the Technical Services group which provided documentation, testing, application engineering and materials development services to the Division.

* Developed and transferred to production sealing adhesives for military specification interconnection systems.

* Developed a fiber-optic connector and a silicone buffer for optical fibers intended for use in the military.

Corporate Research and Development ***June 1979 to Feb 1986***
Held four different positions with increasing responsibilities: Staff Member, Physics of Materials; Group Leader, Materials Science; Department Manager, Materials Science; and Section Technical Director, Electroactive Materials Technology.

* Developed, prototyped and transferred to production electrically shrinkable, self-limiting heaters. Two products, Electrofit in the US and AutoFit in Europe, were launched. Achieved a breakthrough in the understanding of the behavior of conductive polymers.

* Conceived and directed a program for the development of polymer based piezoelectric sensors. An intrusion detection system was developed and transferred to manufacturing. The business was sold to the Cookson Group, UK in 1987, and the product was offered by Ormal Ltd in the UK under the brand name Vibetek.

* Developed formulations for conductive polymer based re-settable fuses (PolySwitch™ devices). These formulations were later implemented as the first products of the PolySwitch Division of Raychem.

Education

Ph.D. Macromolecular Science and Engineering
Case Western Reserve University, Cleveland, Ohio
B.S. Chemical Engineering
L.I.T., Nagpur, India

Continuing Education

Completed courses on a variety of subjects including:

Design for Manufacturing; SPC; QFD; FMEA; Managerial Finance; Marketing; Economics; Accounting; Project Management; Continuous Improvement Methods; Deming Quality Enhancement; Experimental Design and Taguchi Methods; Pharmacology of Drugs; Drug Delivery Technology; Pharmacokinetics and ADME; cGMP; Pharmaceutical Toxicology; Design Control; Risk Analysis and Management; Quality by Design (QbD) and Process Analytical Technology (PAT)