John A. McCarty

Profile:

John A. McCarty started his career as a Quality Control Manager for a cardiac heart pacer manufacture with responsibility for testing and release of incoming materials and finish products. He cut his teeth in pharmaceutical product development at KEY Pharmaceuticals starting with transdermal patches. Over the last thirty years he has held management positions in Research and Development at Key Pharmaceuticals, Schering–Plough, and Pharmavene (acquired by Shire). He is the founder of PPI a consulting/product development firm that assists pharmaceutical and biotech companies in developing their therapeutic compounds into drug products for toxicological, clinical and commercial applications. His last staff position was as Vice President of Formulation Sciences and Drug Delivery at Azopharma Contract Pharmaceutical Services. He is known for his broad expertise in the development of all major and novel dosage forms and is an inventor on over 17 U.S. and foreign patents.

Experience and Accomplishments:

PharmTech

Sourcing and Management Community of Experts panel member

Elsevier

Editorial staff Journal of Control Release.

Tablet & Capsules

Member of the Editorial Advisory Board and contributor to Eye on Excipient Column.

JRS Pharma

Member Prosolv Advisory Board.

Azopharma Contract Pharmaceutical Services, Miramar, Florida

Vice President Formulation Sciences Drug Delivery 2006-2010

Established the Product Development Department at Azopharma having responsibility for Formulation Development, Pre-formulation, Clinical Trial Material Manufacturing and Analytical Support Groups. Provide leadership and management of the technical staff responsible for the development of over 200 drug products for pharmaceutical and biotech companies in three years ranging from API in a capsule to targeted liposomes. Within 3 years of establishing this Department it was billing over million dollars a month in revenues and had over 60 staff members. Traveled 30% of the time selling company services, which included public speaking as a member of the Phase I Express Team that provided educational presentations of interest to the pharmaceutical biotech and medical device industries.

Pharmaceutical Productions, Inc., Miami Springs, Florida

President/Consultant 1994-Present
Founder of a pharmaceutical consulting firm specializing in product development, clinical manufacturing, technical services, CMC section filings, due diligence, technology assessment, and outsourcing management. PPI has assisted virtual to big Pharma clients in accomplishing product development objectives in a cost effective and timely manner. Agreements are tailored to meet the client's needs and can be on an hourly, per diem, retainer or joint venture basis. A patented proprietary drug delivery platform and its products are available for licensing or partnering.

Pharmavene, Inc. (Acquired by Shire), Gaithersburg, Maryland

Director- Pharmaceutical Development 1992-1994

Directed product development activities for a venture capital backed company. Selected and negotiated contracts with CROs and CMOs. Corporate and project planning with Medical, Regulatory and Business Development. Prepared and presented technical programs to venture capitalists, underwriters, licensees, corporate partners and scientific and corporate board of directors. Projects included buccals, CR tablets and capsules, transdermals, parenteral enzyme, oral peptides and a recombinant microorganism oral delivery system.

- Timely filing of 5 INDs within one year.
- Developed Carbatrol® SR capsule utilizing three controlled release pellets.
- Developed a SVP enzyme for post-surgical apnea and cocaine overdose.
- Formulated a buccal tablet, manufactured clinical supplies and filed an IND in 3 months.
- Formulated dispersed oral peptide delivery systems.
- Consultant to MedImmune, Inc. on formulating a viable oral recombinant bacterial delivery system.

Schering-Plough, Miami, Florida

Manager- Process Development / Improvement 1989-1991

Responsible for scale-up, technology transfer and technical support for novel drug delivery systems. Managed over a million-dollar budget.

- Optimized a transdermal blending process resulting in a 5-fold decrease in processing time.
- Optimized a transdermal process and reduced the cost of goods by 25%.
- Transferred a transdermal into Production within budget and ahead of schedule.
- Interim Packaging Department Manager.

Senior Scientist- Formulation Development 1988-1989

Supervised the development of oral controlled release products. Worked with Analytical, Biopharm, Regulatory, Production and Marketing to reach corporate goals.

- Formulated a tablet that enhanced the oral bioavailability of an insoluble drug.
- Represented R & D as a member of the Uni-Dur® Task Force.
- Eliminated a hazardous solvent process in a commercial controlled release oral product.
- Project manager and technical liaison for an in-licensed buccal tablet technology.

Scientist- Solids Formulation Development 1986-1988

Developed controlled release products and prepared US and foreign documents for product registrations.

- Developed a direct compression estrogen buccal tablet for osteoporosis.
- Developed a once-a-day theophylline tablet (Uni-Dur®) bioequivalent toTheo-Dur®.
- Formulated a multiparticulate controlled release albuterol capsule.

Key Pharmaceuticals, Inc., Miami, Florida

Group Leader 1982-1986

Responsible for novel product development and technical staff supervision.

- Instrumented, programmed and validated a PAT (Process Analytical Tech.) for transdermal production line.
- Determined the cause and actions needed to prevent the loss of GTN activity in a MDI.
- Formulated nicotine and estradiol transdermal patches.

Project Leader 1981-1982
Managed the scale-up, technology transfer and cGMP clinical manufacturing of Nitro-Dur®. Supervised clinical production and packaging lines. Wrote SOPs, batch records and established a clinical inventory and control system. Interfaced with Medical, QC, QA, Production, Engineering and Marketing.

- Key Pharmaceuticals captured a majority share of the initial GTN transdermal patch market.

Research Associate 1980-1981
Formulated and developed novel topical products.

- Optimized a hot-melt adhesive formula to adhere a transdermal matrix to a foil backing.
- Formulated and designed an artificial skin for burn care.

Medcor, Hollywood, Florida

Manager- Material Science and Bio-assurance Laboratories 1978-1980
Managed the QC Lab supporting Manufacturing and Engineering of a Cardiac Heart Pacer Manufacturer. Duties included budgeting, staffing, validations, environmental monitoring and releasing chemicals, components and final products.

Education:

Bachelors Chemistry -Florida Atlantic University, 1977.
Bachelors Microbiology - Florida Atlantic University, 1977.
MBA- Completed most of the course work towards an MBA at FAU, transcript available on request.

Affiliations: American Association of Pharmaceutical Scientists, Controlled Release Society, American Chemical Society, American Association for the Advancement of Science, Parenteral Drug Association, ISPE

Patents: 5,073,374; 5,112,616; 5,484,608; 5,447,729; 5,430,021; 5,897,876; 5,912,013; 24,138,263; EP660,705; EP750,494; EP754,031; EP788,346; JP788,346; AP695,053; WO93/01804; WO95/25504; WO95/25505; WO95/27479; WO97/1967; US7230012

Publications:

Editor and contributor to the Eye on Excipient column in the trade journal Tablets and Capsules

" Direct Powder Blends for Encapsulation and Tablet Compression," Amer. Pharm.

Rev., 2003, Vol. 6, # 2, pp 8-12.

" Direct Powder Blends for Encapsulation and Tablet Compression, Part II" Amer. Pharm.

Rev., 2004, Vol. 7, # 1, pp 94-100.