S. Craig Dyar, Ph.D.

SCD Pharma Consulting
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SUMMARY

Pharmaceutical research and development consultant with the following strengths:

- Highly organized critical thinker with strong engineering and mechanical knowledge
- Recognized expert in drug delivery technology for oral, sublingual, topical, parenteral, ophthalmic, and transdermal drug delivery systems

CAREER HIGHLIGHTS

- Consultant to the pharmaceutical industry on drug development including ensuring quality products are developed from discovery to post-launch, life-cycle planning, intellectual property, project management, compound licensing and business development with a focus on drug delivery technologies including immediate, sustained (including osmotic systems) and dual release oral tablets, topical solutions, creams and ointments (dermal and ophthalmic), sublingual tablets, transdermal formulations, targeted delivery systems (dendrimer and others), orally dissolving tablets, and others.
- Directed Drug Delivery Assessment group to enable compound development and product enhancement for early- and late-stage compounds.
    - Served on global drug delivery group to define strategy for external collaborations based upon a careful review of the current portfolio
    - Managed the science for drug delivery projects for immediate and sustained release oral tablets, topical creams and ointments, sublingual tablets, transdermal formulations, targeted delivery systems (dendrimer and others), orally dissolving tablets and others
    - Designed, developed, and maintained a global database of 300 drug delivery technology companies by directly contacting each company
    - Adapted technology from the food, plastics, and other industries for use in the pharmaceutical industry to solve issues related to polymer mixing
    - Directed scale-up of a hot-melt extruded solid dispersion formulation for a launched product, troglitazone
- Led Pharmaceutical Sciences Teams on ophthalmology and dermatology projects
    - Serve as the single point of accountability and technical expert for projects from Preclinical to Phase III stages of development. Responsible for managing the timelines and resources including a multimillion-dollar budget
    - Led multi-disciplinary global teams composed of 8 – 12 colleagues in analytical, formulation, regulatory, quality assurance and supply chain areas
    - Led team in the resolution of several manufacturing and formulation issues and developed guidelines to improve the manufacture practices to ensure the quality of the products
- Utilized Quality by Design principles to develop novel conventional and controlled-release solid dose for tablet and capsule drug delivery systems using solubility and bioavailability enhancement techniques such as hot-melt solid dispersions, supercritical fluids, and lipids
- Defined procedures and led compound licensing activities for pharmaceutical science in Michigan and served on global licensing team. Responsible for the due diligence activities for 8 licensing opportunities, which led to 3 Phase III licensing deals
- Authored numerous Good Manufacturing Practice/Good Laboratory Practice guidelines (GMP/GLP) and standard operating procedures (SOP)
- Managed the COX-2 (celecoxib and others) franchise for Worldwide Pharmaceutical Science at Pfizer

  - Served as the pharmaceutical science member of COX-2 lifecycle team composed of members from Marketing, Regulatory, Clinical PK, Medical, Legal
  - Chaired celecoxib reformulation team composed of members from above groups
  - Developed proposal and obtained endorsement for multimillion dollar proof of concept studies leading to a program in late-stage development
  - Defined pharmaceutical science strategy for COX-2 programs and obtained endorsement from senior leaders in marketing, medical, regulatory, and legal
  - Provided guidance to pharmaceutical science COX-2 teams regarding above strategy
  - Pioneered endorsed idea, which used an alternate formulation approach reducing cost ($8 M) and time (2 years), required to reach the market
  - Chaired two cross-functional product enhancement management teams
- Taught graduate level courses in Pharmacokinetics and Pharmaceutics covering topics such as formulation development of solutions, tablets (immediate and controlled release), emulsions, transdermal, injectable and topicals (dermal and ophthalmic) including release profiles.
- Chaired local Pharmaceutical Science Technology Board and was an inaugural member.
- Acted as Intellectual Property Liaison for scientists, management, and patent attorneys.
  - Ensured intellectual property protection by interfacing with scientist and patent attorneys on a daily basis. Recognized expert in defining compound IP strategy.
- Defined site and global IP strategy and procedures while serving on the global Intellectual Property Board composed of 3 senior scientists and 3 patent attorneys.

EXPERIENCE

SCD Pharma Consulting
- **President** 2008-Present

Roivant Sciences
- **Senior Director, Quality Operations** 2022-Present

South University – School of Pharmacy
- **Assistant Professor** 2008-2016

Pfizer US
- **Associate Research Fellow** 2004-2008
- **Senior Principal Scientist** 2001-2004
- **Senior Scientist** 2000-2001
- **Scientist** 1998-2000

Registered Pharmacist, Pharmacist in Charge 1987-1994

EDUCATION AND PROFESSIONAL DEVELOPMENT

Doctor of Philosophy in Pharmaceutical Science, Medical University of South Carolina, Charleston
Bachelor of Science in Pharmacy, Medical University of South Carolina, Charleston
Bachelor of Science in Biology, University of South Carolina, Spartanburg
Level II and III Management Training, University of Michigan, Executive Education Center
Kepner-Tregoe Certification in Problem Solving and Decision Making

ACHIEVEMENTS AND AWARDS

Member of Rho Chi Honor Society and American Association of Pharmaceutical Sciences
Fellow of the American Foundation for Pharmaceutical Education (AFPE)
Chair, AAPS Year-round Task Force on Novel Drug Delivery Technology

PATENTS, PUBLICATIONS, PRESENTATIONS and POSTERS

S. Craig Dyar, Curtis E. Jones, John P. Kennedy, Kiowa Kavovit, and Andrew Kavovit. Patent publication entitled "Liquid Bandage", December,3, 2015 – US Patent Application Publication (US 20150343112 A1)
Curtis E. Jones, **S. Craig Dyar**, and Andrea L. McKeever, Small-Team Active Learning in an Integrated Pharmacokinetics Course Series Am J Pharm Educ. 2012 Oct 12; 76(8): 153.
S. Craig Dyar, Numerous lectures (25-30 per year) in Pharmaceutics and Pharmacokinetics at South University School of Pharmacy on topics such as Chemical Kinetics, Solutions, Suspensions, Topicals, Transdermals, Solid Oral Dosage Forms, Novel Drug Delivery Systems, Protein and Peptide Delivery Systems, and numerous other physical pharmacy topics. (2008 to Current).
S. Craig Dyar, Invited panelist and moderator on "How to Pursue and Assess Potential Technologies as Synergistic Fits for your Program" at the Institute for International Research's 12th Annual Drug Delivery Partnerships Conference. San Diego, CA (2008).
S. Craig Dyar, Invited presentation on "Navigating the Challenges of Early Phase Development in Ophthalmology" at Financial Research Associates' 2nd Annual Drug Delivery Conference. San Diego, CA (2007).
S. Craig Dyar, Patent publication entitled "Pharmaceutical Compositions of Amorphous Atorvastatin and Process for Preparing Same" (WO06059224 A1 2006, CA2589537 AA 2006, EP1819319 A1 2007).
S. Craig Dyar, Keynote Panelist on "The Next Wave of Partnerships and Investment in Drug Delivery and Specialty Pharmaceuticals" at Strategic Research Institute's 11th Annual Forum on Drug Delivery Technologies & Deal-Making. New Brunswick, NJ (2006).
S. Craig Dyar, Patent publication entitled "Process and System for Controlled-Release Drug Delivery" (AT293439 E 2005, BRPI0105909 A 2002, CA2363902 AA 2002, C 2006, DE60110192 D1 2005, DE60110192 T2 2006, EP1213014 A2 2002, A3 2002, B1 2005, ES2240313 T3 2005, JP2002212061 A2 2002, MXPA01012456 A1 2005, US2002119197 AA 2002).
S. Craig Dyar, Invited presentation on "Language of Marketing – A Scientist's Interpretation" at Strategic Research Institute's 11th Annual Forum on Drug Delivery Technologies & Deal-Making. New Brunswick, NJ (2006).
S. Craig Dyar and Michael Wider, Workshop on "Constructing Mutually Beneficial Drug Delivery Licensing Agreements" at CBI's 7th Forum on Drug Delivery Systems. Philadelphia, Pa (2004).
S. Craig Dyar, Panelist on "Technology Differentiation: How are Similar Technologies Effectively Evaluated?" at the 8th Annual Drug Delivery Partnerships meeting. Beverly Hills, CA (2004).
S. Craig Dyar, Melt-Extruded Particulate Dispersions in Pharmaceutical Extrusion Technology (I. Ghebre-Sellassie, ed.), Marcel Dekker, Inc, New York, (2003), pp. 261-276.
S. Craig Dyar, M. Mollan, S. Khan, L. Tang, J. Cook and I. Ghebre-Sellassie, Evaluation of three dissolution enhancement methods on bioavailability, AAPS Poster in New Orleans (1999).
S. Craig Dyar and Robert E. Notari, A nomogram to evaluate intrinsic absorption rate constants of potential oral prolonged-release candidates, Pharmaceutical Development and Technology, 4(3): 305-312 (1999); AAPS Poster in San Francisco (1998).
S. Craig Dyar and Robert E. Notari, Hydrolysis kinetics and stability predictions for a mixture of R and S temocillin isomers, International Journal of Pharmaceutics, 173(1,2): 225-236 (1998).
S. Craig Dyar and Robert E. Notari, Defining the rate-controlling step for absorption following oral administration of zero-order prolonged-release formulations, Pharmaceutical Research, 14(11): 243 (1997); AAPS Poster in Boston (1997).