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EXECUTIVE SUMMARY

Over 30 years of experience in parenteral product design and development. Broad training and technical knowledge in organic chemistry, physical chemistry, and pharmaceutical sciences. Notable accomplishments include:

- Expertise in all phases of development of injectable pharmaceutical products in flexible plastic containers, as well as rigid containers, including glass. Technical leader at Baxter in formulation of several marketed pharmaceutical products, including the phosphate ester prodrug, clindamycin phosphate. Also led formulation of vancomycin, fluconazole, tobramycin for inhalation, and nitroglycerin for injection.
- Worked in organic synthesis lab (1983-84) at Baxter Travenol R&D in Morton Grove, Illinois, synthesized potential drug degradation products for identification of unknowns in pharmaceutical formulations. The Morton Grove lab originally developed Synthroid®, the first marketed fully synthetic oral dosage of levothyroxine.
- Developed stable formulation of meropenem, carbapenem, using carbohydrate glass-transition modifying agents (vitrification agents). We were able to demonstrate at least one year of stability frozen. Additive provided a high Tg' (glass transition temperature with ice crystal formation).
- Inventor of two lyophilization processes: "Preparation of submicron sized nanoparticles via dispersion lyophilization", 2014, US Patent 8,722,091; "Preparation of submicron sized nanoparticles via dispersion lyophilization", 2004, US Patent 6,835,396.
- Scientific consultant in development of small-molecule oncology drugs (2013-2015). Wrote the Pharmaceutical Development Section of the 505(b)(2) filing for Evomela®, a propylene glycol-free vial product of melphalan. Product contains the solubilizer/stabilizer, Captisol® (sulfobutylether(7m)-beta-cyclodextrin). This submission was approved within a year.
- Expertise in drug delivery platform development
  - Lead formulator for in-line, low gravity reconstitution systems for National Aeronautics and Space Administration (NASA). Co-inventor of two patents, received several government awards.
- Formulation and delivery of poorly soluble drugs in solution, particularly by use of inclusion complexation with cyclodextrins
  - Research and development of injectables containing cyclodextrins (e.g., sulfobutylether-beta-cyclodextrin). Developed zileuton/Captisol formulation at Baxter (for Critical Therapeutics, Inc.)
  - Spearheaded Baxter marketing effort to acquire CyDex Inc., the developer of Captisol technology
  - Developed computational models for assessment of drug binding to beta-cyclodextrin based on molecular structure. Results were presented at national scientific meetings

- Lead scientist and inventor of Baxter's nanoparticulate drug delivery platform (NANOEDGE^{TM}) – led research and development of nanoparticulate suspensions. Wrote review articles, taught AAPS short course on nanosuspension formulation.
  - Nanoparticle engineering by rapid solvent-antisolvent precipitation and homogenization, as well as dispersion lyophilization.
  - Developed nanosuspension formulations of poorly water soluble drugs, such as itraconazole and prednisolone.
- Experience in development of pharmaceuticals for respiratory therapy (led Baxter development of inhaled tobramycin for cystic fibrosis – TOBI®)
- Creative innovation in development of new drug delivery technology and intellectual property (22 issued patents, and over 35 applications)
- Market surveillance and evaluation of new technology opportunities for Baxter. Continued this work for other pharmaceutical companies.
- Computational modeling to predict properties of drugs in solution, solid state and interfacial phenomena (QSPR/QSAR). Chemometric modeling and data mining, research presented at AAPS meetings. Developed QSPR neural network modeling for prediction of cyclodextrin complexation, solubility, and drug receptor binding (QSAR).
- Taught courses at University of Illinois, Chicago, on chemical kinetics, and ionic equilibria
- Expert witness
  - Served as expert consultant in trade secret misappropriation (2012).
  - Six Hatch-Waxman cases (clients have included medium to large generic pharmaceutical companies).
  - Work on claim construction and discovery

EMPLOYMENT HISTORY

Kipp Pharmaceutical Consulting, Inc.

President, Founder ***January 2014 - Present***

- As consultant for several law firms, I have been providing professional consulting and expert witness services in connection with intellectual property litigation in areas of pharmaceutical technology.
- Wrote CMC/PD section for FDA application for an anticancer agent for an oncology pharmaceutical firm (Evomela®, by Spectrum); this application for an alkylating agent was recently approved.
- Consulted for various pharmaceutical companies on research and development of diverse pharmaceutical technologies and delivery systems including one oral product.

Pharmaceutical Consultant, Sole Proprietorship

Patent litigation, generic pharmaceuticals ***July 2013 – January 2014***

- As consultant for law firm based in the Midwest, I provided expert services (case discovery, issuance of expert report) in regard to intellectual property litigation.

Patent litigation, biotechnology ***March -December 2012***

- As consultant for a patent law firm based in San Francisco area, I worked for Plaintiff on a trade secret misappropriation case (Alnylam v. Tekmira). This case was favorably settled, and our client was awarded damages of $65 million, with milestone payments going forward.

Small molecule pharmaceutical development ***March 2012 – December 2014***

- As consultant for a drug company in southern California, I assisted in R&D efforts in formulating an anticancer drug in solution.
- Consulting services in the development of new intellectual property. Prepared technology platform analysis for legal team.
- Drafted Pharmaceutical Development section of CMC for a new product submission.

New product opportunity surveillance ***August 2013 - Present***

- As consultant for a major drug company in the Chicago area, I evaluated physical-chemical properties of over 250 candidate pharmaceuticals for suitable match to parenteral delivery systems, such as prefilled syringes or flexible, sterile-filled IV bags.

Baxter Healthcare Corporation

Principal Scientist ***2009 – Dec 2011***

- Developed technology platform for formulation of unstable drugs using glass-transition modifying agents (vitrification agents). Proved concept by developing a stable, ready-to-use carbapenem (meropenem) formulation that can be frozen for up to one year.
- Developed new premix formulation for echinocandin antifungal.
- Developed modified method for non-isothermal stress testing of pharmaceuticals. The shelf life of caspofungin at -20 °C was predicted to be greater than 2 years using 6-month accelerated isothermal data. The same estimate could be obtained in 1 day in nonisothermal testing with a linear temperature ramp. Results were presented at 2011 AAPS meeting in Washington D.C.
- Internal consultant for formulation of parenteral tetracycline analog.
- Worked on development of HAART (Highly Active Antiretroviral Therapy) nanoparticles for the NANOEDGE platform. This therapy used nanoparticles to target hard to reach reservoirs of HIV virus.

Senior Baxter Research Scientist ***2003 – 2009***

- Led research and development of a cyclodextrin (Captisol®)-based formulation (zileuton with sulfobutylether beta-cyclodextrin).
- Directed research on premixed carbapenem in frozen, flexible containers (Baxter Galaxy® system). We were successful in developing a method of choosing additives that provided aqueous solutions with high glass transition temperatures (Tg). This allowed storage of frozen drug below Tg, thereby favoring high stability.
- Led research on feasibility of developing of premixed echinocandins for intravenous infusion, including caspofungin, frozen in Galaxy containers. Demonstrated use of non-isothermal kinetic experiments to rapidly predict long-term stability.
- Developed proprietary methods for nanoparticle drug formulation.
- In concert with collaborative team from University of Nebraska and Baxter, demonstrated that HAART nanoparticles could be trafficked, in-vivo, to sites of inflammation. Mononuclear phagocytes acted as vehicles for dissemination to reservoirs of HIV infection, and thus phagocytic cells could be ideal drug carriers, particularly for brain targeting.
- Invented new polymeric prodrug for treatment of Parkinson's disease.
- Developed method using ultrasound for reducing particle size and potentially monitoring size reduction and phase transitions by simple sonocalorimetry.
- Developed QSPR methods for prediction of physical and chemical properties of pharmaceuticals in solution and suspension (e.g., solubility in various solvents, binding constants to cyclodextrins). Applied these techniques in product development for internal and external customers. Presented results for neural net model at AAPS meeting in San Antonio (2006).
- Wrote software to predict pH and pCO_2 in continuous peritoneal dialysis (CAPD) dual-container system. This was instrumental in development of plastic formulations and bag design (e.g., thickness and headspace volume).
- Taught course in chemical kinetics at University of Chicago, College of Pharmacy.
- Presented short course: Particle Engineering -- Engineering Friable Particles by Rapid Precipitation, AAPS Annual Meeting, Baltimore, November 2004

Baxter Scientist ***1996 – 2003***

- Lead inventor and developer of Baxter's NANOEDGE™ technology platform, designed to address the formulation of water insoluble drugs ("brick dust").
- Co-developed microprecipitation and comminution methods for preparing small drug particles, 200-300 nm. Either ultrasonication or piston-gap homogenization could be employed for particle size reduction.
- Led R&D group to develop injectable formulations for water-insoluble drugs including iopamidol, ACEA-1021 (licostinel), and RSR-13 (efaproxiral).
- Developed in-silico screening methods for evaluating early proprietary pipeline drugs for which physical or chemical data are sparse or entirely lacking. Examples include solubility, pKa, and particle size and stability of drug nanoparticles produced by the NANOEDGE process.
- Spearheaded intellectual property development for the Product Development group -- organized legal team and scientific staff to coordinate the development of patents for core technologies.
- Assembled cross-functional team between Business Development, Marketing, and R&D, for development of new product database for selection of late-stage drugs for potential premix infusion products.
- Developed and patented a surfactant-free formulation of amiodarone, a poorly water soluble drug. A US patent was issued (U.S. Patent 6,479,541).
- Led support team in development of parenteral nutrition formulations, 3-in-1, Prosol®, Alphamine®, and Premasol®.

Senior Research Scientist ***1990 – 1996***

- Technical Leader: Directed development of IV premix products within Pharmaceutical Sciences R&D. Examples: fluconazole (Diflucan®), vancomycin. Responsibilities focused on coordination and technical consultation in all aspects of parenteral development from preformulation through stability batch production, NDA submission and approval.
- Devised method of determining realistic storage effects in various product warehouses. This enabled simple laboratory experimentation to calculate combinations of "virtual" relative humidity and temperatures that could be applied to predict shelf life in any environment.
- Lead technical leader for Tobramycin for Inhalation (TOBI®):
  - Worked with PathoGenesis (now part of Novartis) as technical leader (with Dr. Bruce Montgomery at PathoGenesis) in the development of Tobramycin for Inhalation, for treatment of cystic fibrosis.
  - Lucrative product (>$1 billion globally) for Novartis.
- Directed development of fluid reconstitution system for NASA space shuttle and proposed space station. This system enabled formulation of infusion solutions in zero gravity. Received two awards from NASA for this contribution. Two patents were filed and issued.

Research Scientist ***1985 – 1990***

- Technical Leader: Headed development of premixed infusion products (antibiotics, antifungals, cardiovascular agents) for intravenous therapy. Directed formulation, and helped craft CMC section of NDA files. Examples: clindamycin phosphate (CLEOCIN® PHOSPHATE), vancomycin, and RTU nitroglycerin in glass bottles.
- Led formulation development of the poorly water-soluble antibiotic, clindamycin, as its phosphate ester prodrug. The phosphate ester has a much higher solubility making it safer to inject.
- Developed methods for calculation of complex solution equilibria, including the effect of temperature. Wrote a program (PHCALC and PHTEMP) to determine equilibrium concentrations of up to 105 species in solution, given equilibrium and mass constraints. Articles were published in the Journal of Pharmaceutical Sciences and Journal of Chemical Education.

Senior Research Associate (Travenol Laboratories) ***1983 – 1985***

- Project management and support: Organic synthesis, isolation, identification and characterization of degradation products from product formulations. Was able to synthesize an Amidori-rearrangement adduct of cimetidine and D-glucose. Extensive use of analytical and preparative HPLC and TLC.
- Developed software for analysis of nonisothermal stress testing data. Published several articles in Int. J. Pharm. and J. Pharm. Sci., and presented seminars at academic institutions (e.g., University of Texas at Austin). Served on a dissertation committee for graduate student of Professor Solomon Stavchansky.

The University of Michigan **Ann Arbor, MI**

Teaching Assistant in Chemistry ***1977 – 1982***

- Taught courses in Organic Chemistry and Qualitative Analysis, directed lab activities, proctored examinations, and assisted in grade assignment.

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