



Stuart G. Levy Ph.D.

SUMMARY

Sixteen years of industrial experience in all aspects of chemical development. Innovation in the conception of practical synthetic routes to pharmaceuticals, development of chemical processes for the manufacture of APIs and chemical process troubleshooting. Hands-on, results-oriented leadership of multidisciplinary teams focused on process discovery, process development, scale-up and cGMP kilo lab production. Expertise in technology transfer of chemistry from the research laboratory to kilo labs, pilot plants and contract research and manufacturing organizations. Effective management of R&D, production and manufacturing outsourced to CROs. Significant accomplishments in many areas of organic synthesis: chelating agents, bioconjugate chemistry, nucleosides and nucleotides, amino acids and peptidomimetics, heterocycles, alkaloids, cannabinoids, dyes, asymmetric synthesis and catalysis, self-assembly mediated by nanoparticles, organophosphorus chemistry. Experience in the development and manufacture of liquid, solid and semi-solid dosage forms.

PROFESSIONAL EXPERIENCE

SGL Chemistry Consulting, LLC, Arlington, MA

Principal Consultant

2010 - present

- The focus of SGL Chemistry Consulting is to facilitate and accelerate the advancement of discovery chemistry leads to the development candidate stage, and to advance them into preclinical and clinical development stages at emerging, entrepreneurial biotech pharmaceutical companies.
- Provide strategic, technical and logistical expertise for all chemistry and CMC activities necessary for early development of a drug lead, candidate nomination, preclinical and clinical supply of API and dosage form and analytical method development.

PPD Dermatology (formerly Magen Biosciences), Waltham, MA

Therapeutic Focus: Dermatology, particularly inflammatory and autoimmune-based skin diseases
Director, Chemistry

Leader, PPD Dermatology New Project Sourcing Team

2008 - 2010

- Devised and executed CMC strategy for the development of a drug candidate for topical treatment of inflammatory skin disease
- Initiated and led all CMC activities related to the development of a Magen candidate for treatment of a number of dermatologic disease indications
- Transferred a gram-scale chemical synthesis to an API vendor for scale-up and optimization
- Devised a strategy for the synthesis of a ¹⁴C-labeled version of the chosen candidate, and managed the outsourced preparation of 250 mg of ¹⁴C MAG131, having a specific activity of 60 mCi / mmol, and 50mg of ¹⁴C MAG131 having a specific activity of >330 mCi/mmol
- Drafted and reviewed supporting documentation and content for the CMC section of the IND submission for the lead compound
- Prepared and gave presentations summarizing chemical and formulation development progress at



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company-wide meetings, scientific advisory board meetings and investor due diligence meetings

- Supervised two experienced PhD organic chemists
- Evaluated potential in-licensing and partnering opportunities from a chemistry perspective

Elixir Pharmaceuticals, Cambridge, MA

Therapeutic focus: Metabolic Disease (diabetes and obesity)

Director, Pharmaceutics and Manufacturing

2005-2008

- Managed and led the CMC effort for EX-1350, an Elixir internal candidate for the growth hormone secretagogue receptor (GHSR, ghrelin) antagonist program
- Managed outsourcing and performed technology transfer for CMC activities and NDA preparation for an in-licensed late-stage commercialization opportunity for Mitiglinide, a type II diabetes treatment
- Functional Project Leader, Ghrelin Agonist Preclinical Development Program: Identified, engaged and managed resources necessary for undertaking all activities related to the development of a small molecule growth hormone secretagogue receptor agonist, EX-1314, in-licensed from BMS
- Performed due diligence and feasibility assessments of preclinical and clinical candidate in-licensing opportunities.
- Key participant in the evaluation of new therapeutic targets in metabolic disease from a chemistry perspective

EPIX Pharmaceuticals, Inc., Cambridge, MA

Therapeutic Focus: Targeted Cardiovascular MRI Diagnostic Agents

Senior Staff Scientist, Chemical R&D

2001 – 2005

- Managed the outsourced development of a solution-phase synthesis of an undecapeptide, a key component of the EPIX Thrombus Program API, EP-2104-R
- Managed technology transfer, vendor production and cGMP manufacture of the chelating portion of EP-2104-R. Timely delivery of this material was instrumental in achieving the cGMP manufacture of EP-2104-R by Q4, 2003, a corporate goal at EPIX
- Directed and participated in internal EP-2104-R process R+D, making major improvements in yield, optical purity and operational simplicity of a nine step synthesis of the chelating portion of EP-2104-R
- Led a multidisciplinary project exploring the use of gold nanoparticles as a scaffold for delivery of imaging agents to biological targets
- Synthesized chelating agents, small molecules, linkers and bioconjugates as a participant in discovery projects



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Ricerca, LLC, Painesville, OH

Senior Research Chemist / Project Leader

2000 – 2001

- Directed a team in process research and development in preparation for kilo laboratory and pilot plant scale-up of an API (from 13 g to 10-50 kg). The first 2.5 kg of cGMP material was delivered within 5 months of receiving the technology transfer package. This was the most lucrative project (\$1.6 million) at Ricerca at the time. Successful completion resulted in Ricerca getting a second project from the same client worth twice as much as the first one (\$3.2 million). This drug has recently received FDA approval, as Fospropofol, for Eisai
- Guided the discovery and implementation of a new, commercially feasible process for the above drug candidate, significantly reducing the production cost
- Achieved efficient technology transfer to the pilot plant at Ricerca, for cGMP manufacture of a 20kg lot

SUGEN, Inc., South San Francisco, CA

Therapeutic Focus: Oncology

Process Development Chemist

1998 - 2000

- Initiated process development research at SUGEN; Set up and ran the first chemical process development laboratory at SUGEN
- Managed international (US, Canada, EU) contract and toll manufacturing of three SUGEN clinical API candidates
- Improved an existing chemical manufacturing process for SUGEN candidate SU 6668, a cytostatic cancer treatment
- Participated in the preparation, assembly and evaluation of technical documentation for SUGEN candidate INDs and NDAs

SERES Laboratories, Inc., Santa Rosa, CA

Scientist

1995 – 1998

- Conceived, developed and implemented multistep synthetic routes for the preparation of APIs and pharmaceutical intermediates. Performed research, scale-up and production from mg to kg scale. Designed and performed syntheses of APIs under cGMP controls
- Prepared proposals and estimates for inquiries regarding contract research, R+D and cGMP manufacture
- Developed a process for the multigram production of Swainsonine.HCl; Synthesized a homologous series of optically pure (R)-2-alkyl-t-butylsuccinate hemiesters, intermediates for the synthesis of peptidomimetic matrix metalloprotease inhibitors; Participated in the multigram synthesis of the siderophore Exochelin; Developed a process for the ion-exchange chromatographic purification of the therapeutic dye Rhodamine 123



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Department of Medicine, University of California, San Diego, La Jolla, CA

Therapeutic Focus: Diseases of the Immune System, e.g., Rheumatoid Arthritis, Leukemia

Postdoctoral Fellow, Bioorganic / Medicinal Chemistry

1992 – 1995

- Designed and synthesized prodrugs of cytotoxic nucleotides
- Synthesized a lipophilic prodrug of 2-chlorodeoxyadenosine monophosphate, demonstrating that the strategy of kinase bypass was applicable to this compound
- Conceived and completed the synthesis of an isopolar difluoromethylphosphonate analog of 2-chlorodeoxyadenosine monophosphate in nineteen steps from D-xylose (see list of publications)

Department of Chemistry, DePaul University, Chicago, IL

Instructor, Organic Chemistry

1991 – 1992

- Taught a two-quarter graduate sequence in organic chemistry, physical organic chemistry followed by synthetic organic chemistry
- Taught an upper-division undergraduate course in spectroscopic methods in organic chemistry

Department of Chemistry, University of Illinois at Chicago, Chicago, IL

Graduate Research and Teaching Assistant

1987 – 1992

- Dissertation Title: Chiral Catalysis in the Synthesis of Methylphosphonate Dinucleotides Using the Phosphoramidite Method

EDUCATION

- B.S., Biochemistry, University of Illinois, Chicago, 1987
- Ph.D., Chemistry, University of Illinois, Chicago, 1992
- Dissertation Advisor: Robert M. Moriarty

PATENTS, PUBLICATIONS & PRESENTATIONS

- Available on request

PROFESSIONAL AFFILIATIONS

- American Chemical Society
- ACS Organic Division Member
- ACS New England Section
- American Association of Pharmaceutical Sciences