



Douglas W. Phillipson, Ph.D.

BACKGROUND & EXPERTISE

- Extensive pharmaceutical industry experience - technical and managerial
- Experienced negotiator / manager of CRO – CMO deliverables
- Expert in qualitative and quantitative analytical instrumental techniques
- In-depth technical skills backed by diverse background & training – including: trace organic analytical methods, GMP Analytical Controls/Specifications for CMC campaigns, preparation of IND and sections for two successful NDA submissions, planning and execution of multi-step reaction sequences, FDA-Bureau of Foods, and natural products isolation & structure elucidation
- Expertise includes planning, budgeting (\$ 5M/yr.), and acquiring capital funding (\$ 2.5 M/yr.)
- Determination, breadth, & depth of knowledge, creativity, teamwork, and consensus building

PROFESSIONAL EXPERIENCE

CMC-Analytical Consultant (hourly/part time) – (2014 – Present)

- Authored development reports to support world wide marketing approval applications
- Developed an analytical method for two API's in a topical formulation
- Designed, developed protocol and executed a stability study comparing 14 potential formulations for an IV API

Neurocrine Biosciences Inc. (2014 – 2017) San Diego, CA

Principal Investigator - Manager

- Managed method validation efforts, executed by CMOs, for NDA submission. Ensured methods were validated in accordance with ICH Q2(R1), and US-FDA guidance.
- Established and justified specification for Phase 3, registration campaign, and commercial release of API (as part of committee).
- Made many contributions to module 3 of the Ingrezza NDA submission 3.2.S.2, through 3.2.S.5
- Contributed to IND filings or updates for 4 additional projects.
- Managed and mentored two Analytical Scientists.

Trius Therapeutics Inc. (2007 – 2014) San Diego, CA; became a Cubist Pharmaceuticals Co. in 2013

Senior Principal Scientist (2010 – 2014)

- Co-inventor on patent describing chemical routes to bacterial Gyrase inhibitors issued in 2012
- Using chiral HPLC – isolated, and characterized hundreds of grams each of various of enantio- and chemically-pure starting materials for pre-clinical compound evaluation
- Created quantitative, stability indicating analytical methods for IPC, release and monitoring of pre-clinical compounds
- Determined structures of over 20 related substance impurities related to pre-clinical compounds

Director of Analytical Chemistry (2007 – 2010)

- Made numerous contributions the quality eCTD module for the successful NDA for Sivextro.
- First analytical chemist hired at Trius Therapeutics, a San Diego biotech startup
- Built analytical facility, purchasing used LCs, NMR and LC-MS for < \$500,000 total instrumentation budget



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- Identified and documented every related substance impurity > 0.1 % in our active pharmaceutical ingredient (API), intermediates and starting materials - over 40 compounds total
- Created and transferred specifications and analytical control methods to CMOs in support of the API and two drug products (DPs) for our development compound, tedizolid phosphate - Phase I - III
- Drafted CMC sections for our IND and amendments, the FDA had no CMC questions for PI or PII
- Co-inventor on two process chemistry patents for tedizolid phosphate, & coauthored publication & presentation for project
- Led early formulation activities and participated in all CMC related decisions involving the PI and PII development program
- Hired and supervised DMPK expert, analytical associate, and student interns

Pfizer Inc. (1998 – 2006) Pfizer Global Research & Development, La Jolla, CA

Associate Research Fellow (2006)

- Led the successful technology transfer of analytical control methods for an ophthalmology compound to clinical manufacturing in Ann Arbor MI, and to a formulation analytical group in Groton CT
- Oversaw the transition of a diabetes drug candidate from our discovery line into early development
- Led a 9 person analytical group – providing support to pre-IND API synthesis and formulation efforts

Associate Director/Director of Analytical Chemistry (Includes Agouron Pharmaceuticals and Warner-Lambert) (1998 – 2005)

- Led analytical group that supported Pfizer La Jolla's drug discovery efforts. Recruited and successfully managed the talent essential to double the analytical group size from 15 to 30 in 3.5 years. Managed the continuity and stability of the group through the mergers with Warner-Lambert and Pfizer
- Developed a highly automated method for identifying the biologically active constituent from a combinatorial mixture. This project allowed rapid follow-up on hits from high throughput screening of un-purified combinatorial libraries and drew heavily on my natural products experience
- Outsourced solubility and LogD analysis/Located CRO, negotiated deal & implemented logistics for sample transfer and data reporting
- Automated the acquisition and analysis of analytical scale LC (SFC)-MS data with a throughput of 250,000+ samples/yr. Implemented quantitative chromatographic methods for expected synthesis products using Evaporative Light Scattering and Nitrogen Chemiluminescence detectors
- Led Discovery Safety Committee and was key player in transformation of site safety culture. La Jolla received Pfizer's best site audit ever in 2005

Bristol-Myers Squibb Co. (Includes E.R. Squibb pre-merger) (1988 – 1998)

Research Coordinator/Research Manager/Group Leader BMS-Pharmaceutical Research Institute, New Brunswick, NJ (1992-1998)

- Headed 5 person analytical group in process development division, responsible for isolating and/or identifying the structures of impurities in intermediates, API and DP in support of IND and NDA filings
- Created and/or improved in process analytical methods for process chemists, improved IND DS release methods for AR&D, and served as a resource for analytical method development, spectroscopy and cGMP equipment cleaning
- Maintained, supervised, and trained group members in the use of the group's Finnigan TSQ-700 LC/MS; Micromass Trio 2, GC/MS; HP MSD GC/MS and other analytical instrumentation



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Research Investigator/Senior Research Investigator Squibb-Institute for Medical Research, Princeton, NJ (1988-1990) & BMS - Pharmaceutical Research Institute, Wallingford, CT (1990-1992)

- Isolated and identified putative TXA₂ ligands from mammalian blood
- Isolated & determined structures of Lanomycin and Scopularin, natural products with anti-fungal activities
- Constructed 30 new Lanomycin-like molecules for SAR using semi-synthetic modification
- Determined the biosynthetic origin of every carbon atom of Lanomycin using stable isotope and radio-labeled precursors
- Prepared hundred gram quantities of purified Lanomycin and Scopularin to support European-based semi-synthetic modification efforts. Sent to Germany to facilitate project transfer

Additional professional experience:

American Cyanamid Co.

Senior Scientist Lederle Labs, Natural Products Department, Pearl River, NY

- Elucidated the structures of two isomeric, large molecular weight antibiotics with commercial potential
- Screened for natural products with anthelmintic and insecticidal activities. Furnished large amounts of several pure fermentation products to Cyanamid's agricultural division for testing in animals

University of Utah, College of Pharmacy, Salt Lake City, UT

Postdoctoral Assistant to Prof. J. A. McCloskey

- Isolated and determined structures of 4 new nucleosides and a dinucleotide photoproduct from tRNAs using EI, FAB and LC/MS and or 500 MHz NMR. The total sample quantity for these structural studies was typically less than one milligram

University of Illinois at Urbana-Champaign, Urbana, IL

Doctoral Research Assistant, Department of Chemistry

- Isolated and elucidated the structures of the Plakortins, four related, novel, peroxide-containing carboxylic acids, possessing mild anti-fungal and other antibacterial activities
- Trained extensively in the use of a variety of Varian (MAT) mass spectrometers. Used low and high-resolution EI and FAB and low-resolution FD and GC-MS techniques
- Collected marine organisms (for my thesis projects as well as for other group members) using SCUBA

U. S. Food and Drug Administration, Washington, D.C.

Research Scientist, Bureau of Foods (GS-7/GS-9)

- Developed trace (parts per trillion) analytical methodology employing electron capture GC and GC-MS for quantitation of chlorinated dibenzofurans and dibenzodioxins in foods



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EDUCATION

Ph. D. in Organic Chemistry, with Dr. K. L. Rinehart,
University of Illinois; Urbana, Illinois

B. S. in Biology-Chemistry (interdisciplinary),
Antioch College; Yellow Springs, Ohio

PROFESSIONAL AFFILIATIONS

American Chemical Society
American Society for Mass Spectrometry
American Association for the Advancement of Science

AWARDS

- Pfizer 2005 LJ Team Recognition Award – ADMET Team decreasing turnaround time and increasing capacity
- Pfizer 2004 LJ Labs Green Chemistry Award – Introduction of SFC to Drug Discovery
- Pfizer 2004 Team Recognition Award – To the EH&S Steering committee for transforming safety culture
- Received a BMS "President's Award" for identification and control of odor causing impurity in 1997
- Received a second "President's Award" in 1997 for rapid isolation and structure of an impurity in a marketed product
- Received a Graduate Student "Fuson Award" to attend the 1983 Fall National meeting of the ACS

SELECTED PRESENTATIONS

2012 – A Practical Integrated Approach to the Rapid Identification of Pharmaceutical Related Substance Impurities – Tedizolid Phosphate (TR-701) as an Example – (with Grayson Hough) - American Society for Mass Spectrometry - National Meeting, Vancouver BC, Canada.

2000 – High Throughput Bioassay-Guided Fractionation - A practical enabling technique for determining the active component in screening hits from exploratory combinatorial libraries and other screening mixtures. (w/ L. Rusnak, D. Haggerty, E. Milgram, A. Yanovsky, B. Farrell, X. Xiong, M. Proefke) - American Society for Mass Spectrometry - National Meeting, Long Beach, CA.

1999 - The Analyst View of Combinatorial Chemistry: An Industrial Perspective - Third Annual San Diego Combinatorial Chemistry Symposium – (lead off speaker), UCSD, San Diego, CA.

1983 – Potent Anti-fungal Peroxy Acids from Two Caribbean Sponges – (w/ K. L. Rinehart Jr.) - Fall National meeting of the American Chemical Society, Washington, DC.

1978 – Chlorinated Dibenzofurans in Arochor 1260 and Aroclor 1260 Based Transformer Fluids –(w/ T. J. Farrell and B. J. Puma) - AOAC National Meeting; Washington, DC.