



## **Wayne D. Luke, Ph.D.**

### **Affiliate Consultant**

**Summary:** Exceptional, scientific leader with over 30 years of experience in the design, development, and installation of processes for the commercial manufacture of API's in the pharmaceutical industry.

Areas of experience and expertise include:

- Process Development
- API Manufacturing and Intermediates
- CMC Regulatory for IND/NDA
- Commercial API Manufacturing
- Quality by Design
- Small molecules, peptides, oligos
- Antibiotics
- cGMP

### **Professional Experience**

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V-Path Global  
Founding Partner and Consultant, 2009-2010

Waterstone Pharmaceuticals Inc., Senior Advisor, 2009-2010

Eli Lilly and Company  
Senior Research Fellow 2008, Chemical Process Research & Development  
Research Fellow, 2005 - 2008, Chemical Process Research & Development  
Research Fellow, 2004 - 2005, Chemical Process Development  
Senior Research Scientist, 1990 - 2004, Chemical Process Development  
Research Scientist, 1984 - 1990, Chemical Process Development  
Senior Organic Chemist, 1979 - 1984, Technical Service

### **Education/Certification**

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**1980; Ph.D.**, Organic Chemistry, University of California, Berkeley

**1977; MS**, Organic Chemistry, University of California, Berkeley

**1975; BS**, Chemistry, University of Southern California, Los Angeles

### **Drug Development Experience**

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- Synthetic Organic Chemist
  - Extensive experience in the design, development, and installation of processes for the manufacture of API's and API intermediates into commercial development
  - Sound knowledge of formulations and the impact of API chemical and physical properties on drug product formulations
  - Technical experience with manufacturing equipment and operations at commercial manufacturing sites
  - Control strategy development, specification setting, starting material designation and the identification of CPP's
  - Preparation of regulatory documents to support IND and NDA applications
  - Experience in cGLP and cGMP requirements and operations
  - Scientific mentor

- API Process Project Leader
  - Overall project technical leadership from phase 1 through the full commercial life of a project
  - Technical leadership of PAI inspections
  - Coordination of API manufacture and supply
  - Experienced in collaborative work with both domestic as well as foreign partners
  
- Technical Management
  - Experience in the recruiting and technical development of a staff of over 180 scientists
  - Corporate governance and review process in large pharma, guidance of research teams from phase 1 through phase 3 and successful global registration
  - Synthetic development and bulk chemical manufacturing 'due diligence' for acquisition of external assets. Routinely reviewed facilities, technical data, technical capacities, and provided technical guidance during business negotiations as a part of the Lilly business process.
  - Technical evaluation of intellectual property and technical support for intellectual property litigation
  - Experienced as a consultant to both major pharmaceutical companies as well as with small start-up companies seeking venture capital and development of business strategies
  
- Product R&D Support
  - Prasugrel, Aprinocarsen, Arzoxifene, Enenatide, Raloxifene, Loracarbef

## **Selected Patents**

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- US 7,012,153 - W. D. Luke, "Process for preparing benzoic acids"
- US 6,921,827 - W. D. Luke, H. A. Sanderson, H. Zheng, "Process for preparing 3-aryl-benzo[b] thiophenes"
- US 6,894,064 - G.A. Arbuthnot, B. W. Dalder, J.K. Hartauer, W. D. Luke, R. E. Stratford, "Benzothiophenes, formulations containing same, and methods"
- US 6,797,719 - G.A. Arbuthnot, B. W. Dalder, J.K. Hartauer, W. D. Luke, R. E. Stratford, "Benzothiophenes, formulations containing same, and methods"
- US 6,653,479 - J. K. Bush, P. C. Conrad, M. G. Flom, W. D. Luke, "Crystalline form of 6-hydroxy-3-(4-[2-(piperidin-1-yl)ethoxy]phenoxy)-2-(4-methoxyphenyl)benzo [b] thiophene hydrochloride"
- US 6,458,811 - G. A. Arbuthnot, B. W. Dalder, J.K. Hartauer, W. D. Luke, R. E. Stratford, "Benzothiophenes formulations containing same and methods"
- US 5,994,547 - D. W. Hoard, W. D. Luke, "Process for preparing benzo[b]thiophenes"
- US 5,731,327 - W. D. Luke, "Synthesis of 3-[4-(2-aminoethoxy)benzoyl]-2-aryl-6-hydroxybenzo[b]thiophenes"
- US 5,606,075 - D. W. Hoard, W. D. Luke, "Process for the synthesis of benzo[b]thiophenes"
- US 5,569,772 - D. W. Hoard, W. D. Luke, "Process for the synthesis of benzo[b]thiophenes"
- US 5,514,826 - D. W. Hoard, W. D. Luke, "Vinyl sulfenic acid derivatives"
- US 5,512,701 - D. W. Hoard, W. D. Luke, "Process for the synthesis of vinyl sulfenic acid derivatives"
- US 5,142,038 - C. W. Doeke, J. N. Levy, W. D. Luke, M. A. Staszak, "Process of enantiomeric separation of carbacephem intermediates"

## **Professional Activities**

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American Chemical Society

International Union of Pure and Applied Chemistry