

## DAVID RICHARD DODDS

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### SUMMARY

Established successful interdisciplinary consultancy serving small/start-up pharma, biotech, and industrial biotech companies. Work with academics, company scientists, business-development and legal personnel as well as investors in start-up organizations. Directed multi-disciplinary process development groups in major pharmaceutical corporations. Built new, practical technology base within both small company and large corporate environments. Delivered profitable IP, process scale-up, and novel automation. Extensive project management experience covering process chemistry, molecular biology, biotransformations & biocatalysis, plus fermentation of natural products and recombinant enzymes. Developed and scaled processes for the biological production of commodity chemicals from biomass. Extensive experience under GMP; experience in CMC sections of IND & NDA filings. Excellent communication skills; frequently invited to explain technical issues to patent, licensing, regulatory, and business groups, and to serve on due-diligence teams. Expert witness experience, including patent interference and infringement. Service as North American Editor of international peer-reviewed journal and as Chairs of international symposia in the field of biocatalysis. United States and Canadian citizenships.

### APPOINTMENTS

2002 - President, Dodds & Associates LLC  
2009 - Kent BioEnergy Scientific Advisory Board  
2005 - Sr. Advisor, Rondaxe Pharma LLC  
2002 - zuChem Scientific Advisory Board & CSO, zuSyn Inc., (zuChem subsidiary)  
2003-06 Technical Advisor, Michigan Biotechnology Institute (MBI)  
2002-08 Codexis Industrial Advisory Board  
2000-01 Director, Fermentation & Biocatalysis Development, Bristol-Myers Squibb  
1999-00 Associate Director, Enzyme Development  
1998-02 North American Editor, *Journal of Molecular Catalysis B: Enzymatic*  
1991-99 Manager, Biotransformations Group, Schering-Plough Research Institute  
1986-91 Sr. Protein Biochemist, Sepracor Inc.

### EDUCATION

1984-86 MRC Post-doctoral Fellow in Molecular Biology, University of Colorado, Boulder  
Prof. Marvin H. Caruthers  
1979-84 Ph.D. Organic Synthesis, University of Toronto  
Prof. J. Bryan Jones  
1977-79 M.Sc. Biological Chemistry, University of Toronto  
1973-77 B.Sc. Biochemistry, Trinity College, University of Toronto

## PROFESSIONAL EXPERIENCE

### DODDS & ASSOCIATES LLC

Founded Dodds & Associates in 2002 to provide strategic technical planning and project management to the pharmaceutical, biotech, industrial biotech, and chemical industries. D&A serves small and start-up companies needing interdisciplinary experience at a senior level to establish technical strategy, and to provide project management at contract sites when in-house facilities do not exist. Executed contracts with over 20 clients since 2002; client references available. Completed and current projects include:

- Expert witness service & experience in patent infringement cases, including affidavits, depositions and cross-examinations
- Intellectual property review and strategy, technical assessment and due-diligence
- Project Management:
  - CMC support for IND & NDA, batch record drafting and review for GMP production
  - process review, development, and scale-up for both pharma and non-pharma projects, including industrial biotechnology for production of commodity, non-fuel chemicals from biomass
- Interim technical executive for small entities and start-ups; PI on multiple grant applications, presentations to regional development committees
- Experience with venture funding for industrial biotechnology; identification of technical opportunities and presentation to the fund, including white-papers for particular areas
- Service on technical Advisory Boards; technical presentations to Corporate Board and to investors

### BRISTOL-MYERS SQUIBB

Invited to BMS in 1999 to lead a new group of 50 scientists organized into chemical process development, molecular biology, fermentation development, and GMP analytical functions.

Developed chiral chemical processes, plus fermentations for natural products, enzyme production, and biocatalysis. Projects included fermentation and isolation of natural products, establishing culture banks and seed train for large-scale fermentations supplying clinical material under GMP; biocatalysis via whole cell, resting biomass, and isolated enzymes; screening, cloning, chemical gene synthesis, expression and immobilization of enzymes, plus all necessary process organic chemistry.

Reviewed all external technology presented to BMS for paclitaxel production for corporate response. Renewed and managed multi-million dollar taxane project with external company. Performed technical due diligence for licensing and investment projects.

### SCHERING-PLOUGH RESEARCH INSTITUTE

Invited to SPRI in 1991 to establish a new group to develop biocatalysis for syntheses of APIs. The Group had a total of 37 public releases plus 13 patent disclosures (6 issued as patents, one kept secret).

Introduced biological catalytic activities in chemical process at scales ranging from the small-scale lab synthesis of metabolites, to pilot plant processes providing 100s of kgs of intermediates for the synthesis of clinical material. Established enzyme process now used commercially in synthesis of Posaconazole®. Established processes using isolated enzymes under both aqueous and non-aqueous conditions, using resting biomass under non-physiological conditions, and classical submerged fermentations, including scale-up and optimization of downstream processing. Increased titer in commercial large-scale fermentation process.

### SEPRACOR

Managed biocatalysis research, creating commercial opportunities for Sepracor's core membrane platform by identifying technical opportunities for bioreactor processes. Inventor of commercial (licensed) enzyme process for resolution of Diltiazem® intermediate. Synthesized unique class of ester substrates unusually susceptible to highly enantiospecific hydrolysis by proteolytic enzymes, and which also permitted unusual transesterification reactions.