KENTON SHULTIS

SUMMARY

Extensive experience as an executive in active pharmaceutical ingredient manufacturing and process R&D. Co-founded and launched custom synthesis laboratory that was acquired by a global drug discovery and development company. Directed manufacturing operations and the production of pre-clinical supplies. Led the development of improved processes through innovation and process control. Developed and implemented processes for dozens of drug candidates including the blockbusters lovastatin and paclitaxel. Experience with secondary metabolite fermentation and recovery, protein purification and modification, semi-synthesis from secondary metabolites, synthesis using enzymes, as well as classic synthetic organic synthesis.

PROFESSIONAL EXPERIENCE

Partner, Rondaxe LLC., January 2008-Present

Enable emerging pharmaceutical companies by applying scientific and strategic solutions by enhancing the value of their products through feasibility assessment, robust development and reliable commercialization. Responsibilities include: Process troubleshooting and development, cost of goods analysis combined with an analysis of development projects and the commercial-scale viability of process options, market and sales analysis for chemical intermediates, and the establishment of quality systems as a part of a robust commercial process.

Vice President and General Manager, Organichem Division, Albany Molecular Research, 2003-2007

- Responsible for the Organichem Division, a site of five manufacturing facilities, including the maintenance, engineering, materials sourcing, safety, and environmental functions.
- Founded Technical Services and greatly expanded its role in manufacturing and new process introduction.
- Established project management as a discipline in AMRI.
- Built two suites for highly potent compounds, a new QC laboratory, and converted a purpose-built plant to multi-purpose operations.
- Established cost standard method of accounting for all manufacturing.
- Established a continuous improvement program for Organichem.
- Increased pre-commercial revenues three-fold, keeping revenues at Organichem roughly flat, despite significant reductions in commercial revenue due to loss of exclusivity for client's product.
- Investigated manufacturing operations overseas as possible opportunities for expansion of services.

Vice President of Operations and Quality, Albany Molecular Research, Inc., 2000-2003

- Designed and built new analytical laboratories, new medicinal chemistry laboratories, expanded the small scale GMP operation.
- Involved in the design and construction of the new laboratories and prep labs for the Syracuse Research Center, an 8,000 ft^2 facility with 32 hoods and eight large prep hoods.
- Successfully led the operation through a FDA systems audit.
- Established the computer validation practices (now accepted company-wide).
- Improved many practices and relationships between the groups involved in cGMP operations.
- Established the Non-clinical Safety Study (NCSS) product line and the policies to make and test materials.

Co-founder and President, American Advanced Organics, Inc., 1998-2000

- Co-founded American Advanced Organics (AAO), a custom synthesis laboratory in Syracuse, N.Y. Specialty was rapid-response chemistry, supplying scaffolds and clinical starting materials to customers in pharmaceutical research.
- Built prep-scale operation up to 100 L reactor size. Grew the firm to 14 employees and sold AAO to Albany Molecular Research, Inc. in February 2000. AAO is the genesis of AMRI's Syracuse Research Center.

Director of Chemical Development Pilot Plants, Bristol-Myers Squibb, 1984-1998

- Directed the activities of three pilot plants.
- Created design requirements, staffed, and started up three new units: new pilot plant to produce cytotoxins for cancer therapy; expansion of organic synthesis pilot plant; facility to conjugate monoclonal antibodies with cytotoxins.
- Received two President's Awards for particpation in high performance teams.
- Led a plant cell fermentation project, aiming to produce paclitaxel at dramatically greater scale. Coordinated development efforts of three companies at four locations in four countries. Contributed to the development of the technology. This is the first FDA-approved use of plant cell fermentation to produce an active pharmaceutical ingredient.

Research Engineer, Natural Products Isolation, Merck and Co., Inc., 1981-1984

- Produced clinical supplies and launch goods for imipenem, a carbapenem antibiotic. Designed, started up, and operated the pilot plant launch facility.
- Produced clinical supplies for lovastatin. Implemented the forerunner of the current recovery process.

Fermentation Development Engineer, Abbott Laboratories, 1979-1981

- Monitored the recovery efficiency of Gibberellin A_3 and Gibberellin A_4/A_7, plant growth hormones, for manufacturing.
- Produced Fortimicin, an aminoglycoside antibiotic, for clinical supplies. Developed an endotoxin control procedure and an improved product precipitation process.
- Developed an ultrafiltration process for *Bacillus thurengensis* var. *israeliensis* microbial insecticide recovery, greatly improving the yield and making the product feasible.

KENTON SHULTIS

EDUCATION

M.S., University of Minnesota, Minneapolis, MN: 1980
Major: Chemical Engineering
B.S., University of Wisconsin, Madison, WI: 1977
Major: Chemical Engineering

PATENTS

No. 5,075,454 to Benigni, Shultis, and Wong. Claims 7-O-DPM Mitosane.
No. 5,175,303 to Benigni, Shultis, and Wong. Claims the process for 7-O-DPM Mitosane.
No. 5,352,798 to Benigni and Shultis. Claims the use of 7-O-DPM Mitosane.
No. 5,832,973 to Goldschmidt, Shultis, Faigle, and Esenther. Sanitary charging system.
No. 5,880,380 to Goldschmidt and Shultis. High containment sampler.

PUBLICATIONS

Keller and Shultis, "Oxygen Permeability of Ultrathin Artificial Lung Membranes by Gas to Liquid Transfer Methods", Transactions of the American Society of Artificial Internal Organs, 1979.
Shultis, “The Dilemma of Process Development”, Drug Discovery Today, Vol. 7, No. 16, August 2002.