Thomas K. Wong, PhD, MPH

Experience

2001 - current Xenia Group Inc. Durham, NC 27705

Pharmaceutical and Venture Consultation

- Consultation for start-up and established companies, covering infrastructure building, clinical operation, clinical monitoring, product team building, and product development. Experienced in therapeutic areas of AIDS, infectious disease, respiratory, dermatology and oncology. Also developing public/private enterprises in the near-term and working on pharmaceutical investments for the future. Past consulting assignment was as advisor for a pivotal Phase III global oncology trial in breast cancer patients treated with a new oncologic agent.
- Current consulting assignments for clients include pharmaceutical technology and IT assessment, developing a 5-year strategic plan for a biotech company moving from research to clinical development and implementing that plan, evaluating data management softwares, EDC development/transition, and managing the hiring plan for the data operations group. Other clinical operations assignments include writing an oncology protocol for hematologic malignancies and managing two first in human trials for two new biologic agents. The Phase I tasks include CRF design and instruction, study manual development, working practice development, project management, project team coordination and oversight, and safety monitoring.

2000–2001 EMD Pharmaceuticals Durham, NC 27707

Senior Dir., Clinical Operations

- Head of clinical research and development operations for EMD Pharmaceuticals, a subsidiary of Merck KGaA, including responsibility for US clinical operation for the German parent company. Responsible for building the infrastructure for the clinical operational group to meet EMD business goals. Managerial responsibilities included providing leadership and strategic planning role for clinical operation group for EMD projects, defining project personnel and budget needs, using appropriate resources for protocol development, and supervising trial conduct. Held strategic role in developing quality guidance principles and in selecting preferred CROs and vendors for Merck

KGaA group companies. Initiated continuous quality improvement in program operations and staff development.

1997–2000 Lexigen Pharmaceuticals Corp.
Durham, NC 27707 and Lexington, MA

Senior Dir., Clinical Development

- Started clinical operational office for Lexigen in NC. Responsible for oversight of clinical research development group, including clinical and data operations. Also responsible for developing strategies for infrastructure development and for complementary out-sourced capabilities to meet Lexigen's clinical development needs. Lexigen was bought by Merck KGaA in late 1999 and pharmaceutical operation was shifted to a new entity, EMD Pharmaceuticals. Played prominent role in integration of Lexigen clinical operations into Merck KGaA global unit.

1994–1997 SRS International Durham, NC and Wash. DC

Dir., Clinical Research

- Started clinical operational office for SRS International in NC. Assumed responsibility as Head, Clinical Research for SRS and the Sym-Biopharm Group. Directed the marketing efforts of the group as well as providing strategic R&D planning role for the CRO. Established the clinical trials programs and managed the operation of the pharmaceutical, biotechnology and diagnostic programs. Duties include: strategic business and program plan development; corporate development of strategic alliances; oversight of budgeting and fiscal management; clinical trial management. Increased regional sales from $25 million to $350 million.

1990–1994 Research Triangle Institute Res. Tri. Pk., NC 27709

Program Director, Medical Studies

- Established commercial pharmaceutical program at RTI. Duties and responsibilities include the development of business plan; hiring and development of managers and staff for the program; incorporation of TQM measures into pharmaceutical program; development of SOP's for clinical research program; identification of pharmaceutical segments for program marketing; strategic alliance formation. Achievements included: realization of near- and intermediate-term goals in business plan; steady and successful performance record in gaining pharmaceutical and biotechnology segments; project director for several clinical trials; implementation of pharmaceutical working group across different centers at RTI; formation of and executive committee member of the Consortium

for International Drug Development in 1991 and penetration of RTI commercial programs into the biotechnology and pharmaceutical companies.

1987–1990 Glaxo, Inc. Res. Tri. Pk., 27709

Asst. Director, Dermatology Product Development, Div. New Product Development

- Responsible for development and coordination of clinical research programs for dermatologic compounds. Duties included: designing and administration of strategic project plan; supervising clinical research scientists and matrix personnel; liaison with appropriate consultants; interacting with biostatisticians to generate appropriate analyses; developing IND and NDA submissions; and negotiating budgets/grants/contracts for programs.

Asst. Dir., Pulmonary Group, Division of New Product Development

- Responsible for management of pulmonary clinical research program for new chemical entities. Duties included coordinating with US and UK project staff; defining project personnel and budget needs; identifying and using appropriate resources in protocol development; identifying clinical investigators for trial participation; supervising clinical trial monitors; and negotiating study budget with clinical investigators.

1985–1987 Searle Pharmaceuticals, Inc. Skokie, IL

Senior Clinical Research Scientist

- Responsible for development of long-range clinical plans and research strategy to evaluate safety and efficacy of bronchodilator and cardiovascular drugs; execution and management of clinical projects with investigational and marketed drugs; identification and negotiation of budgets with qualified clinical investigators; development of blinding and packaging strategies for clinical drug supplies; and analysis of study data.

1981–1984 National Institute of Health Res. Tri. Pk., NC 27709

Senior Staff Fellow

- Divided post-doctoral fellowship in two groups: Biochemical Risk Analysis Branch and Epidemiology Branch. In the former group, I was Group Leader, Placental Pharmacology and Toxicology Group and was responsible for development and coordination of research programs aimed toxicological and epidemiological evaluation of clinical subjects in Taiwan with dietary exposure to used polychlorinated biphenyls (PCBs) dibenzofurans (PCDFs).

Published several papers on the inducibility of mixed-function oxidases in placentae of exposed women and identified specified forms of cytochrome P-450s isozymes induced in placentae of exposed subjects. Also published several papers on the roles of receptors for the observed individual variations in biologic response and the roles of specific dibensofuran species in the development of toxic response in humans. In the Epidemiology Branch, I was responsible for development of laboratory-based epidemiologic programs to develop assays generating sensitive measures of the effects of environmental exposure on human populations. Co-principal investigator on a series of clinical studies investigating specific components of tobacco smoke and placental MFO activity among women who smoked during pregnancy, relative importance of genetic and environmental contribution to human placental MFO activity, and altered passage of cadmium in placentae among hypertensives.

1980–1981 Uniformed Services Univ. of the Health Sciences
Bethesda, MD 20036

Visiting Asst. Professor, Dept. of Pharmacology

- Conducted research on the metabolism of polyclyclic aromatic hydrocarbons and the relation of the molecular mechanisms of carcinogen activation and detoxification with their biologic activities in bacterial mutagenesis bioassay system. Published several papers on the comparative metabolic activation of methyl-substituted benzo(a)pyrene and of benzo(a) pyrene by rat hepatic microsomes.

1978–1980 Research Triangle Institute Res. Tri. Pk, NC 27709

International Program Analyst and Coordinator

- Duties included development and coordination of international progrms in biochemical, energy and environmental areas. Was also involved in research activities that led to design and development of in vitro mammalian cell culture system for toxicological screening of environmental agents. Specific project activities included biotesting of synfuel production effluents and mutagenicity studies of ambient air particulates. Was also member of organizing committee for NATO conference entitled “Toxicity Testing of Environmental Agents: Current and Future Possibilities” which was funded jointly by NATO, EPA, NIEHS, and NCI and held in Monte Carlo in 1979.

1976–1978 Univ. of North Carolina Chapel Hill, NC 27514

National Cancer Institute Post-Doctoral Fellow

- Conducted research on regulation of viral gene transcription in SV 40-transformed cells.

Education

Univ. of North Carolina Chapel Hill, NC 27514
- MPH Candidate in Epidemiology

1979 Univ. of North Carolina Chapel Hill, NC 27514
- MPH, Health Policy and Administration

1975 Univ. of North Carolina Chapel Hill, NC 27514
- Ph.D., Biochemistry

1970 Univ. of California Berkeley, CA
- BA, Biochemistry

Recent Trainings

May 2003 Oracle Applications Seminar Boston, MA

May 2003 Streamlining the Clinical Development Workshop RTP, NC

April 2001 NDA Game, PERI Rockville, MD

October 2000 Cancer: Pathophysiology, Current Therapies, Clinical Trials, and Drug Development, PERI Wash. DC

2000 - 2001 Merck KGaA internal training (6 courses) Various locations in Europe and US

Professional Affiliations

Board Member, Univ. of North Carolina School of Public Health Foundation (2001-current)
BIO, Co-Chair, R&D Subcommittee (1994-2001)
American Association for Advancement of Science
Drug Information Association
American Association for Cancer Research
American Chinese Toxicology Society
American Chemical Society
International Society of Chronobiology
New York Academy of Sciences
Sigma Xi
Society for Epidemiologic Research
Society of Chinese Bioscientists