



Daniel P. Carney, Ph.D

SUMMARY

Sr. Advisor specializing in pharmaceutical drug product development for small molecules as well as peptides and proteins. Over thirty years experience in industry and academia covering all phases of pharmaceutical R&D, including discovery compound evaluation, drug substance form selection, preformulation, formulation development, technology transfer, and formal stability studies.

PROFESSIONAL EXPERIENCE

Accomplishments

- Implemented new groups within the organization including an in-house stability lab, the development QC function, the development QA function and a microbiology lab.
- Responsible for most of the SOP's and internal guidances used by the department and authored several multi-department directives and standard practices.
- Developed strong relationships with drug safety, quality control and quality assurance.
- Developed the first development to QC technology transfer guidance at BMS
- Coordinated the Registrational Specifications Committee
- Represented the department during critical compliance inspections

Pharmaceutical consultant: January 2007- present

Conduct GMP and/or due diligence audits of manufacturing, testing and quality systems operations for small molecule and medical device manufactures. Served as advisor for laboratory and product investigations. Review of analytical development, method validations, product transfers and related activities for OTC products. Due diligence reviews of clinical data and reports for NDA registrations.

Director, Analytical R&D, Bristol-Myers Squibb: May 1996 to November 2006

- November 2004 to November 2006

Led the Analytical Quality Resources group which included a GLP support laboratory, an Industrial Hygiene testing laboratory, the analytical microbiology laboratory and the department documentation group. Coordinated the Registrational Specifications committee (since 1996), a cross-division committee responsible for establishing global registrational specifications. Analytical Project Leader for the development of a new compound targeted for nasal spray delivery. Member of the Quality Scientific Review Committee responsible for final disposition decisions for clinical supplies with quality related questions or manufacturing issues. Led the department in the preparations for and during the conduct of an MHRA GMP inspection (2006).

- October 2000 to November 2004

Lead two integrated development teams (in NJ and Montreal) responsible for the development of products from pre-phase I through post-launch; analytical quality systems, the AR&D Quality unit; and the analytical outsourcing group responsible for all outsourcing activities for AR&D.

- March 1999 to October 2000

Direct a multi-site team of analytical scientists responsible for the development of projects through phase II of clinical development. Activities included collaborations with process chemistry, biopharmaceutical development and drug safety evaluation. Member of the senior leadership team of Analytical R&D with



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oversight of all department activities. Analytical Project Leader for a project involving the selection and development of a new nasal spray delivery device.

- May, 1996 to March, 1999

Develop and direct a team of scientists and analysts, in three separate locations, responsible for methods development and release testing of clinical supplies and evaluation of dosage forms used in drug safety studies.

Associate Director, Analytical R&D, Bristol-Myers Squibb: November, 1991 to May, 1996

Direct a team of scientists responsible for all Quality Assurance functions for the BMS Pharmaceutical Development organization. Group activities include internal and external GMP audits of analytical testing, manufacturing and packaging facilities, clinical API and drug product batch record review and release. Lead the team responsible for the selection, development and implementation of the research LIMS system. This position required relocation to New Brunswick, NJ.

- November, 1991 to April, 1994

In addition to all responsibilities of previous position, additional staff was hired to complete the batch record review and release of clinical products and provide method development and testing support for the site Chemical Development Department effectively transferring a research support work function from the site QC group. This and previous positions were located in Evansville, IN.

Manager, Analytical Research, Bristol-Myers Squibb: May 1989, to August 1991

All managerial responsibilities as described in previous position with the additional responsibility of coordinating all research analytical activities at the Evansville Site; working with the site directors of chemical development, product development and toxicology, plan and prioritize research analytical activities including those provided by the quality control support units; Chairman of the research site specifications (1/89); QA release officer for clinical drug substance (1/89).

Senior Research Scientist, Bristol-Myers Squibb: September 1986, to May 1989

Continuation of work described in previous position with the additional responsibilities of group management; group activities include structural and purity testing of synthesis intermediates and final drug candidates from chemical development scale-up efforts and toxicology dosage form analysis; managerial responsibilities (added 1/87) include planning and scheduling group activities, approval of operating and capital expenditures, participation in project planning, review of regulatory submissions and responding to FDA inquiries; member of the research specification committee; report to Director of Analytical Research at out-of-state facility; oral and written; inter-group, inter-department and inter-divisional communications.

Research Scientist, Bristol-Myers Squibb: September, 1984 to September, 1986

Develop, validate and conduct chromatographic test methods for the assay and stability testing of drug candidates used in safety studies; provide support to drug discovery and scale-up synthesis efforts by testing the purity and integrity of new compounds.



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Teaching Asst., Southern Illinois University, Dept. of Chemistry & Biochemistry: *August, 1978 to May, 1984*
Teaching general chemistry, quantitative analysis and instrumental analysis, laboratory theory, techniques and grading.

Analytical Consultant, Olin Corporation: *February, 1982 to August, 1983*

Develop, evaluate and perform analytical procedures for new materials and products for a propellant R&D facility; prepare summaries and reports on results and procedures; provide suggestions for alternate analytical methods and product improvements.

Manager, Hazardous Waste Control, Southern Illinois University, Dept. of Pollution Control: *August, 1979 to May, 1981*

Research assistantship involving development and administration of all hazardous waste programs at SUI-C; supervise undergraduate student workers and volunteers who carry out programs; update and revise programs to the standard of present and upcoming legislation; inter-department communications and advisory duties regarding hazardous waste handling and disposal; laboratory analysis of environmental samples.

Research Associate, American Critical Care: *December, 1976 to August, 1978*

Develop and conduct on an independent basis, tests and experiments of moderately complex nature; prepare reports for submission to project leader; provide support to senior scientists through solutions of problems and through suggestions for further experimentation.

Analytical Technician, American Critical Care: *November, 1975 to December, 1976*

EDUCATION

Ph.D. 1984 and M.S. 1981, Analytical Chemistry
Southern Illinois University, Carbondale, Illinois
Research Director: Dr. John B. Phillips

B.S. Biological Sciences, May, 1975
Minors: Chemistry, Psychology
Northern Illinois University, DeKalb, Illinois

AWARDS, AFFILIATIONS and OTHER

Dissertation Research Award, Summer 1984
Member Parenteral Drug Association
Member American Chemical Society
Member American Association of Pharmaceutical Scientists
Session chair, GMP Clinical supplies Forum, 2004-2006
Chair, Homeowners Finance Committee 1996 – present.

SCIENTIFIC PUBLICATIONS



Daniel P. Carney, Ph.D

K. Jinno, D. P. Carney, J. B. Phillips, Thermal Desorption Modulator for Liquid Chromatography, Analytical Chemistry, **58**, 1248, 1986.

J. E. Carter, J. S. Dutcher, D. P. Carney, L. R. Klein, L. A. Black and P. W. Erhardt, Analysis of Procainamide Hydrochloride and Acecainide Hydrochloride in Rat Feed, Journal of Pharmaceutical Sciences, Vol. 69 (12), 1439, December, 1980.

D. P. Carney and J. B. Phillips, The Generation of HPLC Signals by Temperature Pulses, Journal of HRC & CC, Vol. 4, 413, August, 1981.

K. Jinno, J. B. Phillips, D. P. Carney, Temperature controlled High Speed Microcolumn Liquid Chromatography, Analytical Chemistry, **57**, 574, 1985.

D. P. Carney and J. B. Phillips, Electrochemical Modulator for Liquid Chromatography, Analytical Chemistry, **58**, 1251, 1986.

PRESENTATIONS

K. Jinno, J. B. Phillips and D. P. Carney, Chemical Concentration Modulators for Multiplex HPLC, 36th Pittsburgh Conference and Exposition, New Orleans, LA, February, 1985.

D. P. Carney and J. B. Phillips, Recycle Multiplex High Performance Liquid Chromatography, 28th IUPAC Congress, Vancouver, B.C., Canada, August, 1981.

J. E. Carter, H. Hessler, L. R. Klein, D. P. Carney, A. H. Amann and L. A. Gardella, A quantitative, Stability Indicating, GLC Assay for Bretylium Tosylate, Meeting abstract, American Pharmaceutical Association, 126th Annual Meeting, Anaheim, CA, April, 1979.