

ERIC J. BENJAMIN, Ph.D.

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PROFESSIONAL EXPERIENCE

TRANSTECH PHARMA, High Point, NC

2003 - 2011

Vice President, Pharmaceutical Development

(2006-2011)

Sr. Director, Pharmaceutical Development

(2004-2006)

Director, Pharmaceutical Development

(2003-2004)

Responsible for all CMC activities related to the drug substance and drug product that are being conducted in-house and at contract organizations (CROs). This includes discovery support, manufacture and testing of drug substance, pre-formulation and formulation studies for the development of the formulation and manufacturing process for the drug product, the development of analytical methods and testing of drug product, preparation and packaging of clinical trial material and preparation of the CMC section for the Regulatory submissions. The department consisted of six personnel including 3 Ph.D. level.

- Completed CMC development for 15 new compounds including a fusion protein.
- Filed 15 INDs/CTAs/IMPD.
- Dosage forms included hard gel capsules, tablets, soft gel capsules, parenteral solutions and lyophilized powders, ophthalmic and delivery systems, such as, solid dispersions, liposomes and nanosystems.
- Set up in-house capabilities to perform pre-formulation, analytical development and formulation and manufacturing process development capabilities.
- Successfully formulated insoluble or poorly soluble drugs to improve bioavailability.
- Filed 6 USA patent applications.
- Actively participated in technical presentations and due diligence for licensing (in and out) of projects.

WYETH RESEARCH, Pearl River, NY

1996 - 2003

Associate Director, Solids Formulation Development

(1999-2003)

Section Head, Solids Formulations Development

(1996 - 1999)

Responsible for the development of formulations and processes of oral solid conventional and sustained-release dosage forms of new chemical entities. The section consists of thirteen personnel including seven Ph.D. Group Leaders/Scientists.

- Represented Pharmaceutical Sciences in the Global Development project teams and served as team leader for five projects to coordinate the CMC activities.
- Filed INDs
- Successfully formulated insoluble or poorly soluble drugs to improve bioavailability.
- Developed sustained-release and pulsatile delivery products using matrix, extrusion/spheronization, spray coating and compression coating technologies.
- Led the development of an oral solid delivery system for a protein.
- Filed 9 USA patents applications.

SCHEIN PHARMACEUTICAL INC., Danbury, CT

1991 - 1996

Director, Pharmaceutical R&D

Responsible for the Product Development, Analytical R&D, Process/Product Improvement and Technical Services sections. The department was responsible for the selection and characterization of the drug

sustained-release generic products. The department consisted of forty personnel including seven Ph.D. Group Leaders/Scientists.

- Hired 24 qualified personnel.
- Filed 15 ANDAs.
- Initiated preformulation and process optimization studies.
- Set up analytical lab procedures and guidelines for method validation and data evaluation.

SOLA/BARNES-HIND, Pharmaceutical R&D, Sunnyvale, CA

1988 - 1990

Director, Pharmaceutical R&D

Directed formulation development, clinical packaging, process development and packaging development of ophthalmic dosage forms and contact lens care products. The department consisted of thirteen personnel including four Ph.D. scientists.

- Set up technology for the processing of fluid bed coating of particles.
- Served as team leader for six multidisciplinary project teams.
- Solved stability, formulation or processing problems with six products under development.

ADRIA LABORATORIES, Columbus, OH

1986 - 1988

Director of Pharmaceutical Sciences

Directed formulation development, analytical development, pilot lab., clinical packaging and stability sections. The department was responsible for the development of parenteral, oral conventional and sustained-release solids, topical and transdermal dosage forms of ethical and generic products.

- Built a motivated and qualified staff of 38 personnel.
- Set up technology for the development of multiparticulate sustained-release products as coated pellets in capsules or compressed into tablets.

SYNTEX RESEARCH, Institute of Pharmaceutical Sciences, Palo Alto, CA

1978 - 1986

Research Section Leader, Pharmaceutical Development

(1984 - 1986)

The section consisted of three Ph.D. scientists and six B.S./M.S. chemists who were responsible for the development of parenteral, nasal and ophthalmic dosage forms of drugs including peptides.

Group Leader, Pharmaceutical Development

(1982 - 1984)

Responsible for the development of orally and parenterally administered liquid and solid dosage forms.

- Served as team leader for two projects in advanced development stage.
- Improved stability and solubility of drugs.
- Characterized and enhanced intranasal absorption of peptides and small molecules.
- Conducted basic research to understand and improve the oral absorption of poorly absorbed drugs.
- Lyophilization of drugs using aqueous and organic solutions.
- Published 8 papers in scientific journals and obtained 5 USA patents.

Staff Researcher, Pharmaceutical Analysis

(1978 - 1982)

The major responsibilities of the section consisted of development of stability specific analytical methods for new drug substances in various dosage forms, evaluation of the stability data to predict shelf life and storage conditions, and preparation of documents for registration (INDs/NDAs) purposes.

- Developed automated HPLC methods for the on-line clean-up and analysis of drugs in creams and ointments.
- Published 5 papers in scientific journals and obtained one patent.

PFIZER LABORATORIES, Karachi, Pakistan

1967 - 1971

Supervisor, Sterile Products Division

Responsible for the manufacturing and trouble shooting of both liquid and solid sterile products.

EDUCATION

Ph.D. in Pharmaceutical Chemistry, University of Kansas, Lawrence, KS, 1978

M.S. in Medicinal Chemistry, University of Oklahoma, Norman, OK, 1974

B.S. in Pharmacy, Punjab University, Lahore, Pakistan, 1966

PATENTS AND PUBLICATIONS

- 15 Peer reviewed publications in scientific journals covering API synthesis, formulations, drug delivery and analytical methods.
- 20 USA Patents for API, Formulations and drug delivery.

PUBLICATIONS AND PATENTS

Eric J. Benjamin, Ph.D.

PUBLICATIONS:

- (1) A. Magarian and E. J. Benjamin, "Synthesis of cyclopropyl analogs of stilbene and stilbenediol as possible antiestrogens." J. Pharm. Sci., 64, 1626 (1975).
- (2) J. T. Pinto, R. A. Magarian, R. J. Wright, M. M. King and E. J. Benjamin, "Nonsteroidal estrogens and antiestrogens: Biological activity of cyclopropyl analogs of stilbene and stilbenediol." J. Pharm. Sci., 70, 399 (1981).
- (3) E. Shek, J. Bragonje, E. J. Benjamin, M. J. Southerland and J. Gluck, "A stability indicating high-performance liquid chromatography method for the determination of triple corticoid integrated system in a cream formulation." Int. J. Pharm., 11, 257 (1982).
- (4) E. J. Benjamin, J. Kroeten and E. Shek, "Characterization of spray patterns of inhalation aerosol using thin layer chromatography." J. Pharm. Sci., 72, 380 (1983).
- (5) E. J. Benjamin and D. Conley, "On-line HPLC method for clean-up and analysis of hydrocortisone and sulconazole nitrate in a cream." Int. J. Pharm., 13, 205 (1983).
- (6) E. J. Benjamin, M. Lee, J. Tom, L. Lin, M. Henesian and D. Wu, "Stabilization of sulconazole nitrate in a topical powder formulation." Int. J. Pharm., 14, 209 (1983).
- (7) D. L. Conley and E. J. Benjamin, "Automated high performance liquid chromatographic column switching technique for the on-line clean-up and analysis of drugs in topical cream formulation." J. Chromatogr., 257, 377 (1983).
- (8) E. J. Benjamin and L. Lin, "Preparation and *in-vitro* evaluation of salts of an antihypertensive agent for prolonged activity." Drug Development and Industrial Pharmacy, 11, 771 (1985).
- (9) E. J. Benjamin, B. A. Firestone and J. A. Schneider, "A dual-column HPLC method for the simultaneous determination of DHPG (9-[(1,3-dihydroxy-2-propoxy)methyl]guanine) and its mono and diesters in biological samples." J. Chromatogr. Sci., 23, 168 (1985).
- (10) G. C. Visor, E. Bajka and E. J. Benjamin, "Intranasal delivery of nicardipine in the rat." J. Pharm. Sci., 75, 44 (1986).
- (11) J. Fleitman, D. Neu and E. J. Benjamin, "Analysis of pharmaceutical dosage forms for oxfendazole: II. Simultaneous liquid chromatographic determination of oxfendazole and trichlorfon in equine paste." J. Assoc. off. Anal. Chem. 69, 24 (1986).

- (12) S. T. Anik, E. J. Benjamin, R. Maskiewicz, G. McRae, C. Nerenberg, J. Hwang-felger, J. Schneider, A. Wonden and J. LaFargue, "Nasal absorption of nafareline acetate in rhesus monkeys. II. Effect of formulation variables." Submitted to J. Pharm. Sci.
- (13) E. J. Benjamin, B. A. Firestone, B. Bergstrom, I. Massey, M. Fass and I. Tsina, "Selection of a derivative of antiviral agent DHPG with improved oral absorption." Pharm. Res. 4, 120 (1987).
- (14) E. J. Benjamin, B. Firestone and J. Schneider, "Stabilization of dipropionate ester of DHPG against enzymatic hydrolysis using complexation." Int. J. Pharm. 35, 73 (1987).
- (15) G. C. Visor, L. Gue, L. Lin and E. J. Benjamin, "Solubilization and stabilization of an inotropic agent by complexation with water soluble vitamins and lyophilization from organic solvent." J. Parenter. Sci. Technol. (1987).

PATENTS:

- (1) E. J. Benjamin, M. Lee and L. Lin, "Stabilization of 1-imidazole in talc." USA Patent 4,382,091, May 1983.
- (2) E. J. Benjamin and G. C. Visor, "Cardiotonic phosphodiesterase inhibitors complexed with water soluble vitamins." USA Patent 4,837,239, June 1989.
- (3) B. Vickery and E. J. Benjamin, "Intranasal administration of polypeptides in powder form." USA Patent 6,815,424, November 2004.
- (4) E. J. Benjamin, T. Lin and S. Anik, "Aqueous steroid formulations for nasal administration." USA Patent 4,983,596, January 1991.
- (5) E. J. Benjamin, "Nasally administered calcium channel entry blockers." USA Patent filed August 1985.
- (6) E. J. Benjamin, W. Dulin and J. Suryawanshi, "Pharmaceutical compositions of estrogenic agents." USA Patent filed June 2001, Application 20080269198.
- (7) E. J. Benjamin and M. Rabah, "Stabilized pharmaceutical composition containing basic excipients." USA Patent filed September 2003, Application 20040122048.
- (8) B. Joseph, M. Ashraf and E. J. Benjamin, "Orally bioavailable CCI-779 formulations." USA Patent filed February 2006, Application 20080161336.

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