

MATTHEW A. AUGUSTINE, Ph.D.
Pharmaca Consulting, LLC

CONSULTING SERVICES IN PHARMACEUTICAL PRODUCT DEVELOPMENT

A broad-based professional, with over thirty years experience in Pharmaceutical Formulation Development of Oral and Topical Dosage Forms: Technical aspects of Project Management: Licensing & Acquisition of Pharmaceutical Delivery System and Strategic Planning.

PROFESSIONAL EXPERIENCE

HARMONY LABS INC. Kannapolis, North Carolina

August, 2002-October, 2007

Chief Technical Scientist

Vice President Research and Development

Vice President, Operations

Management of contract manufacturing for the development of all dermatological products for use as cosmetics, over-the-counter and prescription drugs. Co-ordination of activities leading marketing of DESI topical products, and AND A and medical device (510k) filings. Oversight responsibility for the manufacture and packaging of all contract manufacturing operations. Conduct project management activities to coordinate cross-functional responsibilities to meet goals of clients. Actively involved with new pharmaceutical business development and in the evaluation of new and novel topical drug delivery concepts.

BRISTOL-MYERS SQUIBB, Hillside, New Jersey

August, 1996 to August, 2002

Worldwide Consumer Medicines Division

Senior Manager, Global Project Management

Senior project manager for Rx to OTC switch projects in the areas of Women's Healthcare, Skincare, Analgesics and products for the treatment of various cardiovascular diseases. Function in conjunction with Project Team leaders to strategize, coordinate and implement the successful marketing of new OTC drugs which were formerly available by prescription only. Work closely with personnel from both the consumer and ethical clinical/ product development, marketing, legal groups in the coordination of activities and assessment of realistic timelines required for timely registrations of new-consumer products for both domestic and international markets.

Bristol-Myers Products Division, Hillside, New Jersey

August, 1991-1995- August, 1996

Senior Manager, External Product Development

Responsible for technical evaluation of product/technology opportunities in the areas of skin care and emerging markets (including analgesics) which would be applicable for licensing for the OTC market. Member of interdisciplinary Skin Care/ Emerging Markets Category team which guided and recommended new technologies and products for Rx to OTC switch. Interfaced with the Bristol-Myers Products Operating Company to assist in evaluation of opportunities for line extensions for the Keri®/SeaBreeze® product lines. Member of Bristol-Myers Squibb Skin Care Council, which reviewed dermatological opportunities within the various divisions of the corporation.

CHEMEX PHARMACEUTICALS, INC., Fort Lee, New Jersey
Vice President Pharmaceutical Development & Mfg.

April, 1993 to August, 1995

Organizationally responsible for formulation and assay development of all dermatological compounds developed by Chemex and their joint venture partner, Block Drug Co.. A member of the Joint Venture Licensing Committee. Involved in the selection of manufacturing sites for bulk drug molecules and liaison with contract research and development organizations in support of development programs. Directed a staff of four professionals in the development of topical dosage forms. Filed the CMC section of Aphthasol® Gel NDA which was developed by Chemex.

CHASE PHARMACEUTICAL COMPANY, Newark, New Jersey
Vice President, Product Development

November, 1990-April, 1993

Responsible for the development of generic products (tablets/capsules) using both conventional and sustained release technologies. Designed and equipped new R&D tablet facility; hired and trained staff of four professionals in new venture within an established contract softgel manufacturing company. Responsible for development of the CMC section for tablet AND A submissions.

BOOTS PHARMACEUTICAL COMPANY, Shreveport, Louisiana
Director, Research Program Management

June, 1990-November, 1990

Direct and coordinate all .US development programs for compounds developed by Boots, UK. Managed a staff of four project management professionals. Liaison with management staffs in US and UK regarding direction and timeliness of all R&D programs.

RORER PHARMACEUTICAL/REVLON HEALTH CARE, Horsham, Pennsylvania.
Director, Bone Metabolism Project Management

July 1988-June, 1990

Responsible for budgets, forecasts and coordination of all R&D activities within the Rorer Central Research departments for the development of new therapeutic entities in the area of bone metabolism (osteoporosis-Clodronate®, hypercalcemia-Calcitonin Nasal Spray®).

Director, Pharmaceutics Department

April 1985- July 1988

Rorer Central Research/Revlon Health Care Group

Direct group of 35-40 professionals in the development of ethical drug products emanating from drug discovery and from licensed sources. Formulation development of solid, liquid, topical aerosol and parenteral dosage forms. Preparation of clinical supply materials for domestic and international use.

Director, Research Planning & Coordination,

Revlon Health Care Group

November 1980 April 1985

Coordinate research and development activities for ethical drug development division. Conduct and chair all project teams for development candidates. Represent R&D in licensing of new drugs/technology. Developed computerized project tracking system using a proprietary software system. Moderated all monthly R&D management project review meetings for senior level managers.

BEECHAM PRODUCTS, Parsippany, New Jersey
Section Head, Proprietary Drug Development

September, 1978- Nov. 1980

Direct staff of 7 professionals in three product development groups in the formulation of proprietary drug products; including Sucepts® lozenges and Nice® cough/cold products.

JOHNSON & JOHNSON RESEARCH. Dermatological Division, New Brunswick, N.J.
Group Leader. New Product Development *January 1976- Sept.1978*

Directed group of four professionals in the development of topical drug products for the treatment of acne, inflammation and infection. Developed novel delivery systems for dermatological products and mechanisms for evaluating in-vitro drug release rates.

SQUIBB INSTITUTE FOR MEDICAL RESEARCH,
Pharmaceutical Research & Development, New Brunswick, New Jersey
Sr. Research Investigator, Formulation Design *December 1970- January 1976*

Formulation of oral/topical and parenteral dosage forms of new molecular entities. Pre-formulation studies of novel steroidal, antibiotic and anti-inflammatory compounds. Co-Developed initial commercial formulation of Halog® Cream (and corresponding US Patent).

COMMUNITY PHARMACY: Pharmacist/Assistant Pharmacy Manager (Connecticut) 1961-1970

EDUCATION: University of Connecticut, Storrs, Connecticut Ph.D.
(Pharmaceutics) 1970 B.S. (Pharmacy) 1961

Publications and References available upon request