PETER A. KRESEL

MANAGEMENT DEVELOPMENT OBJECTIVE

To maintain a position within Allergan that allows me to utilize my drug development skills while providing Allergan with input to both R&D and overall business strategy.

EDUCATION

1965	B.S.	Microbiology Syracuse University
1973	M.S.	Microbiology State University of New York, Upstate Medical Center Syracuse University
1978	M.B.A.	Syracuse University

EXPERIENCE

1997 - Present

Senior Vice President, Global Regulatory Affairs
Allergan, Irvine, CA

Provides Corporate Global Regulatory Strategy. Organizes and manages the resources of the Pharmaceutical, Skin Care, BOTOX® and Optical Regulatory Affairs departments and provides input to the organization and management of Surgical Regulatory Affairs departments to ensure the timely approval of new products worldwide and coordinates the support of existing products for markets throughout the world. Facilitates the movement of new products through U.S. regulatory agencies. Ensures that development project plans meet worldwide regulatory requirements. Provides leadership for EHS and Project Management departments. Serves as a member of the R&D Management team responsible for maximizing the flow of quality, innovative products.

1993 - 1997

Vice President Global Regulatory Affairs
Allergan, Inc., Irvine, CA

1965 - 1993

Bristol-Myers Squibb Pharmaceutical Research Institute (BMSPRI), Buffalo NY

1990 - 1993

Director, Worldwide Drug Regulatory Affairs

Reported to the Senior Vice President, Regulatory Affairs (BMSPRI) in Princeton, New Jersey and was responsible for all regulatory affairs for dermatological products worldwide, which included Bristol-Myers Squibb pharmaceuticals, Westwood products (15 percent OTC and cosmeceutics and 85 percent ethical pharmaceuticals); and consumer products (such as moisturizers and sun screens) previously developed and marketed by Westwood Pharmaceuticals and now marketed through Bristol-Myers Squibb Consumer Products Group. Responsibilities included the entire range of regulatory activities for both ethical pharmaceuticals products and consumer products, including all Phase I through Phase IV filings and management of the NDA approval process, CMC and manufacturing changes in a multiple site manufacturing environment, all advertising and promotional review, and all registration activity outside the U.S. Supervised a staff of eight.

Representative activities and achievements include:

- Accelerated the NDA filing for an oral cephalosporin antibiotic, and managed the approval process. This NDA was the largest NDA ever filed by Bristol-Myers Squibb and consisted of 203 volumes. The NDA was approved in 19 months with very advantageous labeling. Sales were $28 million in the "launch month".

- Redesigned the strategy for a major new chemical entity which allowed for significantly earlier than planned NDA submission. This entity is anticipated to have potential sales of $100 million per year.

- Developed programs/systems for Westwood-Squibb for improving the internal regulatory processes, such as a worldwide safety and surveillance program and an internal advertising and promotional review system.

- Actively served on the Skin Care Steering Committee which determined the direction of all Bristol-Myers Squibb skin care business.

- Was a major contributor to the consolidation committees developing policies and procedures subsequent to the Bristol-Myers and Squibb merger.

1988 - 1990 Bristol-Myers Squibb Pharmaceutical Research Institute, Wallingford, CT

1990 Associate Director, Worldwide Drug Regulatory Affairs
Bristol-Myers Squibb Pharmaceutical Research Institute, Wallingford, CT

1988 - 1989 Manager, Drug Regulatory Affairs

Responsible for regulatory affairs for infectious diseases and anti-viral therapeutic areas from the filing of the IND through he NDA approval.

1986 - 1987 Bristol-Myers USPG, Evansville, IN
Senior Research Scientist
Anti-Infective Section, Medical Department

Responsible for Phase IV clinical and regulatory affairs for anti-infective therapeutic group

1965 - 1986 Bristol Laboratories, Syracuse, NY

1984 - 1986 Clinical Research Associate II
Anti-Infective Section, Medical Department

1981 - 1984 Clinical Research Associate

1977 - 1981 Director, Mechanisms of Resistant Service

1965 - 1977 Microbiology Research Scientist

PUBLICATIONS

1970 Spectrophotometric assay for cephalosporin C in fermentation broth. Antimicrobial Agents and Chemotherapy, 1969, pp. 131-134.

1977 Amikacin: Antimicrobial properties and resistance mechanisms affecting its activity. The American Journal of Medicine, June 1977, pp. 14-24.

1979 BBK311: A derivative of amikacin resistant to inactivation by all known aminoglycoside-modifying enzymes. Current Chemotherapy and Infectious Disease, Vol. 1, pp. 413-415.

1980 Intrinsic resistance to aminoglycosides among non-fermenting gram-negative species. Presented at 20th ICAAC, October 1980.

1980 Preliminary results of a survey of the susceptibility patterns of gram-negative organisms related to aminoglycoside usage patterns. Presented at ASHP Mid-year Clinical Meeting, December 1980.

1981 Epidemiological studies of aminoglycoside resistance in the U.S.A. Journal of Antimicrobial Chemotherapy, 1981, Vol. 8, Suppl. A, pp. 89-105.

1982 Evidence for a chromosomal site specifying amikacin resistance in multi-resistance *serratia marcescens*.. Antimicrobial Agents and Chemotherapy, April 1982, pp. 587-591

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