



## **Michael J. Burnett**

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### ***SUMMARY***

Served as International Director and Manager in the pharmaceutical industry for 40 years, gaining diversified global experience and exceptional analytical skills. Acquired extensive CMC experience with U.S. and International Government Agencies. Developed analytical, technical and problem-solving skills; including third party contracts, product development and marketing support systems. Planned, organized and managed regulatory and quality assurance programs as well as budgets, hiring and development of technical managers.

### ***PROFESSIONAL EXPERIENCE***

*Director, CMC; Global Regulatory Sciences, Bristol-Myers Squibb: 2004-2006; retired December 2006.*

- Developed program to ensure manufacturing procedures and processes were in compliance with approved Global Registration filings.
- Developed an electronic system to ensure current and accurate Registration Filings were available at all manufacturing sites worldwide

*Director, CMC; Global Regulatory Sciences, Bristol-Myers Squibb: 1990-2004*

- Filed, negotiated and obtained approval for eight new chemical entities in the U.S., Canada, Europe, Australia, South Africa and Asia
- Submitted more than 20 Investigational New Drug Applications, Clinical Trial Applications, Supplemental New Drug Applications, Variations to Marketing Authorization Applications and Annual Reports.
- Successfully organized and conducted numerous meetings with the FDA and EMEA

*Director, Product Registration and Development, Bristol-Myers Pharmaceutical Group (Canada): 1980-1990*

- Improved working relations with the Canadian government while introducing functional and comprehensive registration systems with Provincial Governments.
- Established an efficient status system to ensure improved productivity and follow-up with New Drug Submissions, Pre-Clinical Submissions and Supplemental New Drug Submissions.
- Received government approval for three antineoplastics, two cardiovascular, a tocolytic and a central nervous system compound.
- Developed, in conjunction with the Canadian government, a system of distribution to physicians for a new anti-AIDS drug, allowing patient access in a timely and efficient manner.
- Developed a new chewable acetaminophen formulation that was acceptable for both U.S. and Canada.
- Formulated and developed nutritional products in conjunction with marketing requirements and corporate development.
- Established a functional communication system between U.S. and Canada in the area of pharmaceutical development.
- Reformulated and changed procedures on existing products to improve productivity and cost reduction.



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*Director; Quality Assurance, Bristol-Myers (Canada): 1976-1980*

- Responsible for Quality Assurance and Regulatory Affairs.
- Improved morale and teamwork through reorganization and introduction of management development training programs.
- Effectively managed a staff of fifty people

*Analyst, Supervisor and Manager, The Upjohn Company of Canada: 1965-1973*

- Experience in sterile pharmaceutical production, tablet and capsule manufacturing,
- Quality Assurance and controls.
- Sterile production supervisor using aseptic and terminal sterilization of suspensions, solutions and lyophiles

### ***EDUCATION***

BSc. Phm. University of Toronto 1965

Major: Pharmacy

Executive Program in Business Administration, York University, Toronto