



William J. Winter

SUMMARY

Pharmaceutical Development Executive with extensive experience in the international pharmaceutical industry. Demonstrated capability in achieving goals and objectives through the application of innovative technology and decisive leadership. Extensive knowledge and experience in pharmaceutical product development including the bridge from research and development to the market. Advanced degree in chemistry coupled with significant expertise in API Quality Assurance and Analytical Science and Technology. Highly effective managerial and interpersonal skills coupled with a broad range of technical expertise.

PROFESSIONAL EXPERIENCE

Pharmaceutical Consultant: 2007-Present

Providing clients broad and in-depth capabilities for drug development through commercialization with expertise in quality, analytical and chemistry fields.

Senior Director Analytical Development, Bristol-Myers Squibb: 2004-2007

Global leader of analytical science and technology for the Quality and Manufacturing network. Responsibilities included: technical support for production of marketed products, analytical technology related to the testing and release of product, technology transfer and global assay robustness.

- Transitioned the analytical technology organization from a development function into a technical support group for Manufacturing and Quality Control. New organization included one-hundred and seventy technical staff in five countries covering small molecules as well as biologics. Scientific scope of the organization included analytical science, forensics, stability, microbiology, testing standards and method development/validation. During this period, three executive positions (API, Drug Product and Analytical) were reclassified from Vice President to Senior Director.
- Coordinated analytical resources located throughout the BMS manufacturing network to provide an analytical support function which focused on customer needs including product supply to the market. Resources were located in seven domestic and four international sites. No significant compliance issues related to analytical testing occurred during this period.
- Provided analytical expertise for all Quality investigations which required analytical expertise, including compliance issues, product complaints, recalls, stability and particulate forensic analysis. Input to these numerous investigations was accurate, reliable and provided in a timely and efficient manner.
- Coordinated and insured the timely and efficient transfer of analytical technology during new product startups as well as product inter-site transfers. On the average, approximately two hundred and fifty analytical transfers were coordinated, documented and successfully completed on an annual basis.
- Defined, implemented and completed a global assay robustness initiative. In order to insure that current Quality test methods met the requirements of global regulatory bodies agencies, a review of all test methods was performed versus ICH (International Conference on Harmonization) requirements (>5000 methods). A gap assessment was performed, remediation plan defined, and a total of >800 methods were successfully remediated over a two year period, thereby eliminating a serious product compliance risk.



William J. Winter

Vice President Analytical Development, Bristol-Myers Squibb: 2001-2004

Responsible for establishing a new Analytical Development organization in Technical Operations. Mission and vision were defined for this new area, as well as a strategy for harmonizing procedures and processes for all domestic and international analytical groups that interface with PRI (new products) and support the BMS Manufacturing network (marketed products including small molecules and biologics).

- Established a new Analytical Development organization (>120 staff members) that consolidated technical resources located throughout the BMS manufacturing network, including twelve sites (domestic and international) with direct staff reporting responsibilities.
- Harmonized analytical technology throughout BMS Technical Operations, including new products, life-cycle products and biologics.
- Supported site product-development efforts and insured the timely and efficient transfer of analytical technology during new product startups.
- Improved the productivity of Technical Operations development and manufacturing.
-

Vice President Bulk QA and Worldwide QC, Bristol-Myers Squibb: 1999-2001

Held executive position in BMS-Quality with Bulk Quality Assurance responsibilities for all bulk products in the BMS network as well as QC/QA responsibilities (bulk and drug product) for two Puerto Rico sites. Position required a thorough working knowledge of the regulatory environment and considerable personal interaction with FDA and European regulators.

- Created a commitment to quality throughout the worldwide bulk organization.
- Established a clear focus on quality performance and customer service at the bulk manufacturing sites.
- Developed constructive relationships with regulatory agencies.
- Completed numerous successful domestic and regulatory inspections for new products as well as life-cycle products.
- Championed an organizational culture in the bulk quality area that promoted behaviors that lead to superior business performance.

Senior Director Chemical Development, Bristol-Myers Squibb: 1997-1999

Responsible for the leadership of Chemical Development in Syracuse (Chemistry, Engineering and Pilot Plants), including all aspects of late-stage product development, synthesis of clinical supplies for new products and the generation of critical process information needed for the transfer of safe, rugged and cost-efficient processes to the manufacturing sites in the global network.

- Extensive experience in process development both as a scientist and project team leader for numerous products that were successfully launched.
- Leader of Process Development in Syracuse with responsibilities including process chemistry, process engineering and analytical chemistry. Close alignment with all functions on the site was established as well as a clear focus on customer needs throughout the network.



William J. Winter

EDUCATION

NSF Postdoctoral Research Fellow, Texas Christian University

Research: Mechanistic studies concerning the cycloaddition of fluoro-olefins and the oxygenation of hindered olefins.

Ph.D., Ohio State University

Major: Organic Chemistry

B.A., State University of New York Potsdam

Major: Chemistry