



John Woolever

SUMMARY

A senior level expert, with over thirty years experience in pharmaceutical analytical development and establishing specifications for both small and large molecules. Efforts focused on for new chemical entities, including preparation and participation in regulatory filings which covered the entire spectrum from starting materials, intermediates, final active pharmaceutical ingredients (APIs), formulations, and drug products (DPs).

PROFESSIONAL EXPERIENCE

Director, Separation Science Group and Chairman Research Specification Committee, Bristol-Myers Squibb Company: 1999-2001

- Director of large separation science group responsible for development and validation of assays and conducting analyses to support all aspects of Phases II and III of the drug registration process.
- The specification committee was responsible for reviewing, revising, and approving specifications for all raw materials, intermediates, drug substances, and finished products used in clinical trials and FDA filings.
- As chairman, responsible for final review and signature of all specification documents including those submitted in NDA filings.

Director, Quality Assurance Group, Bristol-Myers Squibb Company: 1996-1999

- Group responsibilities included:
 - release of all clinical supplies for products in Pharmaceutical Development.
 - audit of all activities related to manufacture of clinical supplies.
 - representing BMS Pharmaceutical Research Institute in an FDA of Pharmaceutical Development activities.
- Represented Pharmaceutical Development Group in BMS corporate Quality Assurance Committee.

Associate Director, Quality Assurance Group, Bristol-Myers Squibb Company: 1994-1996

- Managed analytical group responsible for GMP and GLP analysis of conventional small molecule pharmaceuticals.
- Group's analytical techniques included spectroscopic (nmr, mass spec) as well as separation sciences.
- The group also provided analytical support for characterization and development of biotechnology derived.
- Continued to contribute and gain experience in IND and NDA filings.

Group Leader, Quality Assurance Group, Bristol-Myers Squibb Company: 1987-1994

- Managed chromatography group (1987-1991).
- Continued management of chromatography group and gained experience in preparing analytical documents for use in IND and NDA filings.
- Established and managed Bioanalytical group (1991-1994).
- Assumed added responsibility to establish a bioanalytical group for the analysis of proteins, antibodies and other large biotechnology derived molecules.

Senior Research Scientist, Bristol-Myers Squibb Company: 1983-1987

- Managed Chromatography lab (1983-1987).
- Managed growth of laboratory in number of personnel and in responsibilities.



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- The lab's responsibility was expanded to developing and validating GMP and GLP methodology and conducting GMP and GLP analyses.
- Represented Analytical Chemistry on site specifications committee (1985-1986).
- Chairman of site specification committee in 1986.

Research Scientist, Bristol-Myers Squibb Company: 1979-1983

- Supervised chromatography lab.
- Promoted to supervisor of chromatography laboratory.
- Developed and validated methodology to support drug substance and drug product in the development process and coordinated activities of lab personnel.

Associate Research Scientist/Research Organic Chemist, Bristol-Myers Squibb Company: 1974-1977

- Synthesized new drug molecules for gastrointestinal and cardiovascular programs.
- Liquid Chromatographer: developed methodology for and analyzed new drug candidates and synthetic intermediates in support of drug discovery.

Textile Chemist, Mohasco Industries: 1972-1974

- Researched products and procedures to improve manufacturing and final performance of carpet products.

Research technician, Niagara Chemical Div of FMC Corporation: 1966-1969

- Worked in organic synthesis and formulations laboratories.
- Gained experience in synthesis of complex organic molecules and chromatographic and wet chemical analysis of formulated product.

EDUCATION

MS, SUNY College of Forestry: 1972

Major: Organic Chemistry

B. S., Rochester Institute of Technology: 1969

Major: Chemistry

AAS, Rochester Institute of Technology: 1966

Major: Chemical Technology