# Mike Shaw

## Objective

To manage, lead or participate on a short, medium or long-term projects within the FDA regulated industries on Documentation, Systems Set Up and Enhancements, Quality Control, Quality Assurance, NDA/ANDA (CMC section) Preparations and Reviews, Auditing, Method and Process Validation, Calibrations, Workflow Analysis and Efficiency Enhancement Projects.

## Skills

* Over 30 years of versatile, industrial experience in various areas of the pharmaceutical industry with such Fortune 500 companies as Bayer Inc, Sterling Drug, and Pfizer Inc. and generic companies.
* Excellent interpersonal, communication, managerial and organization skills.
* Familiar with various manufacturing processes, process and cleaning validation, documentation system, SOP’s, cGMP, GLP, and cGCP as well as NDA/ANDA (CMC Section) preparations and reviews and FDA regulations.
* Very familiar with various monographs and general chapters of USP/NF, EP, other compendium and industry standards.
* Well versed in all modern instrumentation such as HPLC, GC, AA, UV, IR, etc., as well as various other analytical techniques.
* Experience in various dosage forms such as tablets (I.R. and M.R.), capsules, creams, liquids, suspensions, aerosols, ointments, suppositories, gels and sterile products.
* Well versed in generation, maintenance and revision of SOPs, specifications, procedures, batch records, training, OOS investigations, and other documentation systems.
* Wide exposure to quality control, quality assurance, manufacturing, validation, compliance and regulatory areas in a pharmaceutical manufacturing environment.
* Proficient with common computer software.

## Employment

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| Independent Consultant | March 2002 – Present |
| Consultant to the Pharmaceutical Industry  Affiliated with R.A.Q.A. ASSOCIATES, INC. |  |

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| Director, Quality Control | October 2000 – March 2002 |
| Vintage Pharmaceuticals | Huntsville, Alabama |

* Directed all activities of the quality control department for three separate plants at two different locations.
* Responsible for all activities of Quality Control Department to ensure compliance with company, compendia and regulatory requirements.
* Directly and indirectly responsible for all activities of Quality Control department with staff of over 75 people.

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| Senior Director, Chemical Testing | October 1999 – September 2000 |
| Parkedale Pharmaceuticals | Rochester, Michigan |

* In broad sense, directed all activities of the quality control department, including raw materials, packaging materials, intermediate, finished, and clinical trial product testing, validation, as well as stability testing to ensure compendia, company, corporate, and regulatory compliance.
* Documentation responsibilities included SOPs, specifications, and procedures and stability data review of new and existing products.
* Investigated customer complaints, OOS investigations and troubleshooting of manufacturing and packaging deviations as well as execution of process validation.
* Supported manufacturing, pharmaceutical technology and compliance departments in investigations, process validations, deviations and customer audits.

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| Manager, Quality Control | August 1998 – September 1999 |
| Schwarz Pharma Mfg. Inc | Seymour, Indiana |

* Total responsibility of analytical testing for all raw materials, packaging materials, in process, finished products and stability testing.
* Responsible for generation and update of specifications, procedures and SOPs, including reviews of CMC sections of NDA/ANDA.
* Managed a staff of 42 people.

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| Director, Quality Assurance/Quality Control | April 1997 – August 1998 |
| R.P. Scherer Inc. | Windsor, Ontario |

* Duties involved are similar to those outlined at Bayer Inc.

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| Owned OMNI Chemical Industries | October 1994 – March 1997 |
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* Exported industrial solvents.

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| Director, Quality Assurance/Quality Control | September 1980 – September 1994 |
| Bayer Inc. | Toronto, Ontario |

* Started as Supervisor of Quality Control and subsequently promoted to manager and then appointed as the Director of the Quality Assurance/Quality Control Department.

### DUTIES

* Through 15 years of employment, exposure to various different aspects of responsibilities such as quality control, quality assurance, regulatory affairs, manufacturing and packaging.
* Responsible for activity of the Quality Control/Quality Assurance department for documentation, testing, compliance, CMC compilation and review, technology transfer, analytical method development process validations and cleaning validation.
* Coordinated all QA/QC related activities between various Bayer locations to introduce new products and manage changes to existing products in a timely and cost-effective manner.
* Prepared, executed and maintained departmental budget of approximately three million dollars.
* Planned and purchased instruments and equipment in addition to outlining work force requirements.
* Supervised a staff of sixteen to thirty personnel.

### ACHIEVEMENTS

* Reduced testing costs and lead-times by 40% by developing HPLC methods for fat/water-soluble vitamins, creams, and tablets.
* Reduced costs by 20% by re-evaluating and reducing stability testing, still meeting regulatory requirements and quality standards.
* Introduced automated dissolution methods for slow-release tablets.
* Trained staff on modern instrumentation and techniques.
* Validated AMAPS and MAPICS, the computerized inventory system to ensure GMP and regulatory compliance.
* Set up a total QA system including SOP’s and documentation for clinical trial products.
* During 1992-1993, for two years acted as a manufacturing manager, directly and indirectly supervised forty-five people in manufacturing/packaging area.
* Provided QC/QA support to regulatory department/medical department for new product submissions and customer inquiries/complaints.

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| Supervisor | March 1979 – August 1980 |
| Pfizer Inc. | Morristown, New Jersey |

* Supervised method development and validation of new methods as well as scale up from pilot batches to manufacturing batches.
* Responsible for carrying out the stability studies of all marketed and developmental products and acted as a liaison between package engineering, pharmaceutical technology and research development of Warner Lambert Co.

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| Supervisor | April 1976 – January 1979 |
| Sterling Drug Ltd. | Aurora, Ontario |

* Directed raw material testing and stability studies of approved and developmental products. Prepared stability reports and evaluated/assigned expiry dates. The products included prescription, over the counter, and household products. The dosage forms included tablets, capsules, liquids, creams, ointments, powders, aerosols, sterile products, suppositories, and suspensions.

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| Analytical Chemist | February 1972 – March 1976 |
| Nucro Technics Ltd. | Toronto, Ontario |

* Worked as an analytical chemist performing analysis of pharmaceutical and chemical products, developed methods for bio-studies, and performed bioassays using various analytical techniques and modern instruments. Familiar with USP, NF, BP, AOAC, BPC and JP requirements.

## Education

1971 M.S. in Organic Chemistry from University of Washington at Seattle

1968 B.Sc. in Chemistry from University of Bombay, India