Gregory P. Martin

1022 Heather Court
Pottstown, PA 19465

484-686-2558
gpmartin226@yahoo.com

PRINCIPAL TECHNICAL CONSULTANT

Pharmaceutical Analysis … GMP Compliance … Business Process Improvements

High-impact, broadly experienced Process Leader with an Analytical Chemist background and demonstrated expertise in driving maximum benefit to cost, facilitating groups to develop unanticipated results, understanding and implementing GMPs, and excellent reputation with dissolution (and related calibration issues), residual solvents, analytical instrument qualification, and insight to balance the benefits versus regulations to gain maximum benefit. Key accomplishments demonstrated in areas, to include:

- Dissolution
- Regulatory Musts vs. Wants
- GMP Compliance
- Worldwide Analytical Team
- Commercialization Design Team
- Knowledge Integration Team
- Residual Solvents
- Method Validation
- Analytical Instrument Qualification

PROFESSIONAL EXPERIENCE

COMPLECTORS CONSULTING LLC, Pottstown, PA **2008-present**

Principal Technical Consultant

- Developed and presented an interactive one-day training course "Using Good Science to Develop and Troubleshoot Dissolution Methods" at Eastern Analytical Symposium, successfully transferring knowledge and skills required to allow participants to build models in compliance with key regulations.
- Provided critical content review, course development and delivery support, ultimately presenting "Residual Solvents: A Practical Approach" in conjunction with USP, enabling participants to apply a new chapter using a pragmatic approach which minimizes resources, building on learning and knowledge developed as editor of the general chapter.

MERCK RESEARCH LABORATORIES, West Point, PA **1981-2008**

Director, Pharmaceutical Analytical Chemistry (2006–2008)

- Directed the activities of analytical research group supporting early phase pharmaceutical product development and microbiological group supporting both pharmaceutical and biological product development.
- Provided comprehensive people management and development for 20 scientists, including 11 senior scientists.
- Facilitated the development of a vision for Pharmaceutical Analytical Chemistry (PAC) and for Worldwide Analytical Team (WAT) that was then implemented through identification and execution of Strategic Imperatives minimizing departmental silos, promoting effective sharing of workload and evaluating where GMPs were and were not required.
- As founder of WAT, continued in leadership role, personally introducing global training for dissolution and introduction of a WIKI, significantly improving the consistent use of harmonized SOPs and Guidances. Led development of a four-day course on dissolution, which was presented worldwide. Also presented an abbreviated, one-day version of dissolution training as invited speaker at Eastern Analytical Symposium in 2007 and 2008.

- Built an overall GMP-compliant system that successfully underwent internal and external inspections, systematically addressing personnel training, equipment and electronic systems qualification and data documentation and review. Worked with internal GMP Compliance group to propagate the approaches used to other departments.
- Core member of Knowledge Integration Team, which addressed cross-training between departments, rotational assignments to improve inter-departmental understanding, development of robust departmental training programs for five major departments, and a system for periodic review of course content and procedures to maintain the cutting edge.
- Provided direction and a tangible body of adopted solutions as the PAC representative on a Six Sigma Black Belt team which harmonized resource-sparing approaches for data collection and review, instrument qualification, calibration and documentation, including notebooks, memos and regulatory CMC filings.

Director/Senior Manager/Section Leader, Pharmaceutical Analysis and Control (1995-2005)

- Directed the activities of the Research GMP Analytical Laboratory, responsible for chemical and microbiological release and stability testing for pharmaceutical products under development (from Phase 1 through Filing), and for excipients, comparators and radioactive formulations (for ADME studies).
- Provided comprehensive people management and development for up to 30 scientists, including 6 senior scientists.
- Leader of the Pharmaceutical Research and Development Regulatory Musts vs. Wants Team, which had dramatic effects in the ways in which PR&D addressed development, especially with regard to regulatory requirements. From 400 ideas collected, over 150 were implemented, including a phased approach to GMPs based on stage of development, development and implementation of templates for CMC filings, use of platform formulations to speed introduction of drug candidates to clinical populations, and streamlined approaches for development of assay and dissolution methods, collection of stability data, establishment of specifications and reevaluation dating.
- Developed the working model for a major organizational change as an integral member of the team, creating a new Commercialization Department from portions of Pharmaceutical Research and Production organizations. This team won 'Best Overall' award in the 2006 Merck Operational Excellence competition, competing with over twenty major corporate projects.
- Co-leader of global Dissolution Task Force which developed and implemented policies which harmonized and streamlined dissolution development, validation and specification setting.
- Co-leader of Interdivisional Specifications Team which developed and implemented a process for establishing specifications and agreeing on acceptance criteria for regulatory and internal tests for drug substance and drug product.
- Founder and initial leader of the Worldwide Analytical Team, in which leaders from four research sites (US, Canada, UK and Japan) aggressively addressed issues spanning method development and validation, laboratory data systems, creation of templates for regulatory CMC documents to systems to assure GMP compliance.
- Led successive teams (addressing increasingly larger groups) to maximize productivity by using good science, thorough understanding of regulatory requirements and an understanding of customer needs. Results included reduction of analytical turnaround times by 67%, reducing stability testing effort for early phase studies by over 50%, streamlining dissolution development, analytical data documentation and review.
- Responsible for assuring GMP and IT infrastructure met departmental needs, to assure regulatory compliance and maximize productivity.

Senior Chemist, Pharmaceutical Analysis and Control (1986-1995)
Research Chemist, Pharmaceutical Analysis and Control (1981-1982)

- Developed analytical methods to support new product development, including over two dozen dissolution methods, and performed and supervised release and stability testing of formulations for clinical studies or regulatory submissions.

KIWI BRANDS, Douglassville, PA **1982-1986**
Manager, Quality Control
- Had overall responsibility for quality for U.S. operations, including manufactured and purchased goods and raw materials, which included full responsibility for a staff of 6 chemists.
- Introduced the use of scientific principles to dramatically improve quality, identifying solutions to eliminate 95% of quarantine issues.

WILLIAM H. RORER, INC., Fort Washington, PA **1975-1980**
Senior Bioanalytical Chemist/Junior Chemist, Drug Metabolism Laboratory
- Performed drug metabolism studies on animals, using radioisotopically labeled drugs, and analyzed resultant samples. Introduced use of HPLC and computers to dramatically improve productivity.

Short Courses Taught

- Using Good Science to Develop and Troubleshoot Dissolution Methods (Internally, as four half-day sessions, and externally, as one day session, on multiple occasions)
- Validation of Compendial Procedures (in conjunction with USP)
- Developing Compendial HPLC Procedures (in conjunction with USP)
- Residual Solvents: Practical Applications (in conjunction with USP)

EDUCATION

MS Analytical Chemistry, Villanova University
BS Chemistry (ACS), Drexel University

PROFESSIONAL ACTIVITIES

USP Council of Experts – General Chapters, Vice Chair (2005-2010)
- Lead or Co-lead responsible for revisions to General Chapters on Analytical Instrument Qualification, Residual Solvents, Chromatography, Validation and Verification of Analytical Procedures, Karl Fischer, Transfer of Analytical Procedures and others.

USP Council of Experts – Pharmaceutical Analysis 4 (2000-2005)
USP Project Team 6 – Biopharmaceutical Issues (1999-2001)
PhRMA – Member of Dissolution Expert Committee, Representative to USP PT6 (1999-2004)
- Core member of team responsible for introduction of mechanical calibration as (FDA-accepted) alternative to use of Performance Verification Tablets

COMMUNITY ACTIVITIES

Active leader in several organizations, including Knights of Columbus, St. Thomas More Church, Boy Scouts, Girl Scouts, Band Chaperone, Advocates of Gifted Education and YWCA Literacy Tutor.

List of publications and presentations available on request.