CURRICULUM VITAE

Patricia C. Tway

I. EDUCATION

School	Major	Degree
Mt. Holyoke College	Chemistry	B.A.
Rutgers University	Physical Chemistry	M.S.
Seton Hall University	Analytical Chemistry	Ph.D.

II. EMPLOYMENT HISTORY

Merck & Company

Title	From - To
Vice President, Regulatory &Analytical Sciences Merck Manufacturing Division	5/95- present
Executive Director, Analytical Research Merck Research Laboratories	1/91- 5/95
Senior Director, Analytical Research	6/88- 1/91
Director, Analytical Research	4/86- 6/88
Associate Director, Analytical Research	1/84- 4/86
Research Fellow, Analytical Research	10/78- 1/84
Senior Research Chemist, Analytical Research	10/73- 10-78
Research Chemist, Analytical Research	2/70- 10/73
Staff Chemist, Analytical Research	1/69- 2/70

III. CURRENT RESPONSIBILITIES

Regulatory and Analytical Sciences is a central support group within the Quality Organization of Merck Manufacturing Division. There are six main areas for which RAS has responsibility.

RAS-Analytical is responsible for the successful transfer of all analytical methods from Research into MMD and then to the appropriate Quality Operations site groups for release and stability testing of all products. The group does method development, validation and trouble shooting in support of Quality and/or processing concerns for all MMD sites. This group also supports all compendia activities.

RAS-Biologics prepares and maintains the CMC filing for all the vaccine and therapeutic products globally. This group handles initial BLA filings and all CMC post approval submissions.

RAS-CMC is responsible for the preparation of all Chemistry, Manufacturing and Control submissions from initial filing to support clinical trials through regulatory product approval, and in-line support for all pharmaceutical products. This group supports both domestic and international filings, and is responsible to assure that the CMC packages meet regulatory expectations.

RAS-Labeling is responsible for the preparation (design, layout etc.) of label, carton and package circular templates for all API and pharmaceutical products.

RAS-Stability has responsibility globally to support the API and pharmaceutical stability programs to assure that regulatory requirements and expectations are met. This group prepares stability guidelines and protocols, sets expiry dating for all products, and reviews data across sites.

RAS-Validation has global responsibility for providing guidance and oversight for all validation activities, including equipment IQ/OQ/PQ, process and computer validation

IV. PROFESSIONAL AFFILIATIONS

American Chemical Society
Worldwide Merck Business Strategy Team, HIV
Chairperson, Product Quality Research Institute (PQRI) Drug Substance Technical Committee
PhRMA Drug Substance Technical Committee liaison to PQRI

V. PUBLICATIONS AND PATENTS

Patents: U.S. Patent 3,639,327.

PUBLICATIONS

1. Cala, P., Trenner, N. Buhs, R., Downing, G., Smith, J. and VandenHeuvel, W. (1972)
   Gas Chromatographic Determination of Pyrimethamine in Tissue.
   J of Agri & Food Chem 20, (2), 337.

2. Cala, P., Downing, G., Michielli, R. and Wittick, J. (1976)
   Determination of Ronidazole in Swine Tissues by Differential Pulse Polarography.
   J Agr Food Chem 24, 764.

3. Tway, P. C., Wood, Jr., J. S. and Downing, G. V. (1979)
   Determination of Arprinocid in Chicken Tissues by Gas Chromatography-Mass Spectrometry.
   Agr & Food Chem 27, 753.

4. Cline Love, L. J., Tway, P. C. and Upton, L. M. (1980)
   Factor Analysis of Some Physical and Structural Properties Influencing the Fluorescence Lifetimes of an Atabrine Homologous Series.
   Anal Chem 52, 311.

5. Tway, P. C., Cline Love, L. J. and Woodruff, H. B. (1980)
   A Totally Automated Data Acquisition/Reduction System for Routine Treatment of Mass Spectroscopic Data by Factor Analysis.
   Anal Chim Acta 117, 45.

6. Woodruff, H. B., Tway, P. C. and Cline Love, L. J. (1981)
   Factor Analysis of Mass Spectra from Partially Resolved Chromatographic Peaks Using Simulated Data.
   Anal Chem 53, 81.

7. Ritter, A. W., Tway, P. C., Cline Love, L. J. and Ashworth, H. A. (1981)

Microcomputer Flurometer for Corrected, Derivative and Differential Spectra and Quantum Yield Determinations.
Anal Chem 53, 280.

8. Tway, P. C., Wood, Jr., J. S. and Downing, G. V. (1981)
Determination of Ivermectin in Cattle and Sheep Tissue Using High-Performance Liquid Chromatography with Fluorescence Detection.
J. of Agri & Food Chem 29, 1059.

9. Firestone, R. A., Pisano, J. M., Bailey, P. J., Sturm, A., Bonney, R. J., Wightman, P., Devlin, R., Lin, C. S., Keller, D. L. and Tway, P. C., (1982)
Lysosomotropic Agents. 4. Carbobenzoxyglycylphenylalanyl, a New Protease-Sensitive Masking Group for Introduction into Cells.
J Med Chem 25, 539.

10. Tway, P. C. and Cline Love, L. J. (1982)
Linear Solvation Energy Relationships. Solvent Effects on the Fluorescence of Thiabendazole Homologues.
Chemical Physics Letters 87, 204.

11. Woodruff, H. B., Tway, P. C., Downing, G. V. and Gilbert, J. P. (1982)
Bulk Pharmaceutical Research Data Management.
J Automatic Chemistry 4, 161.

12. Tway, P. C. and Cline Love, L. J. (1982)
Photophysical Properties of Benzimidazole and Thiabendazole and Their Homologues. Effect of Substituents and Solvent on the Nature of the Transition.
J. Physical Chemistry 86, 5223.

13. Tway, P. C. and Cline Love, L. J. (1982)
Effects of Excited-State Protrotropic Equilibria on the Fluorescence Energies of Benzimidazole and Thiabendazole Homologues.
J. Physical Chemistry 86, 5227.

14. Tway, P. C., Slayback, J. R. B., Rajm, G. S., Isensee, R. K. and Downing, G. V. (1983)
Confirmatory Assay for Ivermectin in Cattle Tissue Using Chemical Ionization Mass Spectrometry/ Mass Spectrometry (MS/MS).
Biomedical Mass Spectrometry 11, 172.

15. Hirsch, R. F., Wu, G. L. and Tway, P. C. (1987)
Reliability of Factor Analysis in the Presence of Random Noise or Outlying Data.
Chemometrics and Intelligent Laboratory Systems 1, 265.

16. Grinberg, N., Bicker, G., Tway, P. C. and Baiano, J. A. (1988)
Recognition of Artifacts Occurring in TLC.
J. of Liquid Chromatography 11, No. 15, 3183.

17. Grinberg, N., Baiano, J. A., Bicker, G., Tway, P, C. and Ellison, D. (1989)
Title of Chapter: TLC in Pharmaceutical Research.
Planar Chromatography in the Life Sciences (J. Touchstone, ed.)
John Wiley & Sons, New York.

18. Grinberg, N., Bicker, G., Tway, P. C., Price, K., Perpall, H. and Sblendorio, R. (1990)
Quantitative Analysis of a Quinolin-Ethenyl Derivative Using Thin Layers Impreganted with Di-P-Toluyl Tartaric Acid.

J. of Liquid Chromatography, Vol. 13, Symposium Issue 14, 2783.

19. Prabhu, S. V., Wehner, T. A. and Tway, P. C. (1991)
The Determination of Ivermectin Levels in Swine Tissues at PPB Level by Liquid Chromatography with Fluorescence Detection.
J. Agric. and Food Chem 39, 1468.

20. Prabhu, S. V., Wehner, T. A., Egan, R. S. and Tway, P. C. (1991)
Determination of 4"-Deoxy-4"-(epimethylamino)avermectin B1 Benzoate (MK-0244) and Its Delta 8,9-Isomer in Celery and Lettuce by HPLC with Fluorescence Detection.
J. Agric. and Food Chem 39, 2226.

21. Grinberg, N., Bicker, G., Tway, P., Wonnacott, D., Heimbrook, D. C. and Oliff, A. (1990)
Use of Capillary Electrophoresis in the Study of the Quaternary Structure of Proteins.
J. of Liquid Chromatography, Symposium Issue.

22. Prabhu, S. V., Varsolona, R. J., Wehner, T. A., Egan, R. S. and Tway, P. C. (1992)
Rapid and Sensitive HPLC-Method for the Quantitation of Abamectin and its Delta 8,9-Isomer.
J. Agr. Food Chem. 40, No. 4, 622.

23. Moeder, C., Grinberg, N., Perpall, H. J., Bicker, G. and Tway, P. C. (1992)
Flow Injection Determination of Triton X-100 with On-Line Solid Phase Extraction.
Analyst 117, April.

24. Novak, T. J., Blacklock, T. J., Bicker, G. R. and Tway P. C. (1992)
Determination of the Enantiomeric Composition of a Carbonic Anhydrase by Pre-column Diastereomer Formation and Normal Phase HPLC.
Eastern Analytical Symposium Publication.

25. Cohen, H. P. and Tway, P. C. (1993)
High Performance Liquid Chromatographic Detection of Residual Formaldehyde in a Hepatitis-A Vaccine by Use of Hydralazine.
Journal of Liquid Chromatography 16 (8), 1667.

26. Tway, P. C. (1993)
Requirements and Challenges of Process Chemistry Support and Monitoring by HPLC.
Abstracts., Eastern Analytical Symposium & Exposition, Nov. 15,1993.

27. Thompson, R., Grinberg, N., Perpall, H., Bicker, G. and Tway, P. (1994)
Separation of Organophosphonates by Ion Chromatography with Indirect Photometric Detection.
J. of Liquid Chromatography, 17(11), 2511.

PRESENTATIONS

1. "Computer Factor Analysis Techniques Applied to Solute-Solvent Effects on Fluorescence Lifetimes." Paper No. 635, Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, Atlantic City, NJ, March 1980.

2. "A Totally Automated Data Acquisition/Reduction System for Routine Treatment of Mass Spectroscopic Data by Factor Analysis." Paper #FAM0C9, ASMA, May 30,1980, New York.

3. "LC/MS of Lipophilic Compounds Using Nonaqueous Reversed-Phase Chromatography." ASMS Meeting, Minneapolis, Minn., May 1981.

4. "Microcomputer-Controlled Quantum Yield Determinations: A Comparison of Techniques." Paper #640, Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, Atlantic City, NJ, March 1981.

5. "Luminescence Quantum Yields----Measurement and Applications" Paper #494, Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy, Atlantic City, NJ, March 1982 (Invited).

6. "A Totally Automated System for Routine Treatment of Mass Spectroscopic Data by Factor Analysis." Paper #19, Division of Chemical Education, 182nd ACS Meeting, New York, Aug. 24, 1981 (Invited).

7. "GC and Solid Probe Mass Spectrometric Confirmatory Assays for Arprinocid in Poultry Tissues." Paper T06, 30th ASMS Meeting, Honolulu, Hawaii, June 8, 1982.

8. "Development of a Confirmatory Assay for Ivermectin in Animal Tissue Using MS/MS Techniques." Paper #RP12, J. R. B. Slayback, P. C. Tway and G. S. Rahn, ASMS Meeting, Boston, Mass., May 1983.

9. "Analytical Development", AAPS Workshop on Chemistry and Pharmacy Considerations during the Drug Development and Review Process: Challenges and New Initiatives, Arlington, Va., Sept. 1993.

10. "Requirements and Challenges of Process Chemistry Support and Monitoring by HPLC". Eastern Analytical Symposium and Exposition, Somerset, NJ, Nov. 1993.

11. "Use of Chromatographic Methods to Support Process Development". Seton Hall University Dept. of Chemistry 1993 Fall Lecture Series, South Orange, NJ, Dec. 1993.

12. Discussion Leader, "Streamlining the CMC Regulatory Process, NDAs and ANDAs", AAPS Workshop, Washington D.C., June 2001.