

CURRICULUM VITAE

(updated 3/14/2024)

Daniel L. Norwood, MSPH, PhD

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Education

- Virginia Polytechnic Institute and State University – Bachelor of Science in Biochemistry (1976)
- University of North Carolina at Chapel Hill; School of Public Health – Master of Science in Public Health (Environmental Chemistry) (1981)

Thesis: "An Application of Linked-Scanning at Constant B/E (an MS/MS Method) to the Analysis of Complex Environmental Samples"

- University of North Carolina at Chapel Hill; School of Public Health – Doctor of Philosophy in Environmental Chemistry (1985)

Dissertation: "Aqueous Halogenation of Aquatic Humic Material: A Structural Study"

Professional Experience

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| 4/19-present | Principal Consultant , Feinberg Norwood & Associates Pharma Consulting (formerly SC $\bar{I}$ O Analytical), P.O. Box 16774, Chapel Hill, NC 27516. (203-482-4377). |
| 4/17-7/21 | Senior Independent Consultant , Smithers Rapra, 425 West Market Street, Akron, Ohio 44303. (330-762-7441). |
| 6/15-4/19 | Executive Partner , SC $\bar{I}$ O Analytical, LLC, P.O. Box 16774, Chapel Hill, NC 27516. (203-482-4377). |
- Consultant to the pharmaceutical development and manufacturing industries in areas such as general pharmaceutical development and manufacturing problem solving, preparation of documents and regulatory submissions, data analysis, regulatory compliance auditing, regulatory compliance training, and technical

training.

- Particular expertise in all analytical chemistry areas, including structural analysis of pharmaceutical impurities and degradation products, and assessment of extractables and leachables.
- Expert Witness in pharmaceutical and related patent litigation.

3/09-4/15

Distinguished Research Fellow, Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877-0368. (800-243-0127).

- Principal scientist for Analytical Development US in the areas of structural analysis, trace organic and inorganic analysis, packaging/delivery system characterization, and other technical areas in pharmaceutical development.
- Technical advisor to senior pharmaceutical development management and other Boehringer Ingelheim operating units both nationally and internationally in areas of pharmaceutical development expertise.
- Represents Boehringer Ingelheim Pharmaceuticals in external consortia, industry working groups, committees, and scientific organizations.
- Responsible for development of new technologies and experimental approaches to further corporate pharmaceutical development goals.
- Manager of the Analytical Sciences Structural Analysis Section (Mass Spectrometry, Gas Chromatography, and Nuclear Magnetic Resonance spectroscopy laboratories) with 9 scientists currently (5 PhD level).
- Member of Analytical Sciences Department senior management structure.

1/06-3/09

Director Physical and Chemical Analysis, Boehringer Ingelheim Pharmaceuticals, Inc.

7/04-1/06

Associate Director Physical and Chemical Analysis, Boehringer Ingelheim Pharmaceuticals, Inc.

- The Physical and Chemical Analysis Section included Structural Analysis (Mass Spectrometry and NMR), Physical Measurements (Physical Properties and Microscopy), and Preclinical Analysis (Toxicology Analysis, Chemical Development Analysis, and Gas Chromatography) groups, with 27 total scientists (13 PhD).
- Along with Section Management responsibilities, additional responsibilities included strategic planning, budgeting, advising and assisting the Vice President Analytical Sciences, and acting as part of the Analytical Sciences Department senior management structure.

Documented role in NDA approvals for Atrovent® HFA and Tipranavir®.

10/99-7/04

Senior Principal Scientist (Structural Analysis), Boehringer Ingelheim Pharmaceuticals, Inc.

7/95-10/99

Associate Director Pharmaceutical Development (Structural Chemistry, Mass Spectrometry, NMR, Physical Organic Chemistry); Magellan Laboratories, Inc., P.O. Box 13341, Research Triangle Park, North Carolina 27709. (Established the Structural Chemistry Group). *Note that this organization is now Catalent Pharma Solutions, 160 Pharma Drive, Morrisville, NC, 27560; 919-481-4855.*

- 6/90-7/95 **Research Investigator, Research Leader, Senior Research Leader;** Analytical Sciences Department, Structural Chemistry Section, Mass Spectrometry Laboratory, Glaxo Research Institute, Five Moore Drive, Research Triangle Park, North Carolina 27709. *Note that this organization is now GlaxoSmithKline; 919-877-7547.*
- Documented major role in NDA approvals for Serevent® Metered Dose Inhaler, Imitrex™, Ventolin™ Nebules, and Zantac™ GELdose.**
- 7/87-6/90 **Assistant Medical Research Professor;** Mass Spectrometry Facility, Division of Pediatric Genetics and Metabolism, Duke University Medical Center, Durham, North Carolina 27710.
- 10/85-6/87 **Research Analytical Chemist (Post-Doctoral);** Division of Analytical and Chemical Sciences, Mass Spectrometry Laboratory, Research Triangle Institute, Research Triangle Park, North Carolina 27709.
- 8/79-10/85 **Graduate Research Assistant;** Department of Environmental Sciences and Engineering, School of Public Health, University of North Carolina, Chapel Hill, North Carolina 27514.
- 1/82-1/84 **Chemist;** National Institute of Environmental Health Sciences, Environmental Chemistry Mass Spectrometry Laboratory, Research Triangle Park, North Carolina 27709.
- 10/76-8/79 **Research Technician II and III;** Department of Environmental Sciences and Engineering, School of Public Health, University of North Carolina, Chapel Hill, North Carolina 27514.

Membership in International Societies and Awards

Phi Eta Sigma (Virginia Tech)
 Phi Sigma Society (Virginia Tech)
 Phi Lambda Upsilon (Virginia Tech)
 Sigma Xi (Univ. of North Carolina)
 American Chemical Society (member with 47 years of service)
 American Association of Pharmaceutical Scientists (member)
 Philosophy of Science Association (full member)
 American Society for Mass Spectrometry Poster Award (1988)
American Chemical Society Environmental Division Graduate Student Award (1986)
American Water Works Association First Place Academic Achievement Award (1987)
Glaxo CEO's Award (1994; Serevent® MDI NDA approval)
 North Carolina Section, American Chemical Society (Chair-elect, 1996; Chair, 1997)
 Boehringer Ingelheim Team Spirit Award 2005 (Atrovent® HFA Project Team)
Boehringer Ingelheim President's Award 2007 (Regulatory initiatives for inhalation products)
 Appointed Lifetime Member of Cambridge Who's Who, Registry of Executives, Professionals and Entrepreneurs 2008-2009 Edition
 Certificate of Achievement in Leadership; American Management Association; May 20, 2008.
Product Quality Research Institute Excellence in Research Award (2009; outstanding research in the area of leachables and extractables)
2013 USP Award for an Innovative Response to Public Health Challenges (co-recipient)

Other Professional Activities

1. **Adjunct Assistant Professor (1986-2001);** Department of Environmental Sciences and Engineering, School of Public Health, University of North Carolina, Chapel Hill, North Carolina 27514. Taught graduate level course *Organic Materials in Natural Waters* (1 year), advised several graduate students, presented guest lectures in analytical instrumentation (mass spectrometry, NMR).
2. Dahlem Conference on Humic Substances and Their Role in the Environment; West Berlin; Federal Republic of Germany; invited participant, 1987.
3. Triangle Area Mass Spectrometry Discussion Group; Secretary-Treasurer, 1988-90; Co-chair, 1994-1995.
4. **Technical Team Leader, CFC (Chlorofluorocarbon) Consortium,** 1/2000-8/2006. Member CFC Consortium QA/QC Team 8/2006-4/2007.
5. Co-organizer and Workshop Leader; “Exploring Analytical Methods for Detecting, Identifying and Quantitating Impurities”, Presented by the *Institute for International Research, Pharmaceutical and Biotechnology Division*, Park Hyatt Philadelphia at the Bellevue, Philadelphia, PA, October 16, 2000.
6. Co-organizer and Workshop Leader; “Identify and Quantify Impurities in Excipient Manufacture” (talk entitled: “Identification Strategies for Trace Level Excipient Related Impurities in Drug Product Matrices”), Presented by *The Center for Business Intelligence*, Adam’s Mark Philadelphia, Philadelphia, PA, April 19, 2001.
7. Organizer and Workshop Leader; “A Systematic Approach for the Identification of Small Molecule Impurities in Drug Product Matrices”, Presented by *The Institute for Validation Technology*, The Jurys Washington Hotel, Washington, DC, August 6-7, 2001.
8. Breakout Session Moderator, AAPS Workshop (co-sponsored with FDA): Drug Substance and Drug Product Specifications, Crystal Gateway Marriott Hotel, Arlington, VA, March 18-20, 2002.
9. Member of IPAC-RS (International Pharmaceutical Aerosol Consortium on Regulation and Science) technical teams on Supplier Quality Control and Leachables and Extractables, 2000-2001.
10. **Chair, PQRI Leachables and Extractables Working Group,** Product Quality Research Institute, 2001-present.
11. Scientific Advisory Board, 2nd Annual Forced Degradation Studies – Best Practices for the Pharmaceutical Industry, by the *Institute for International Research*, Capital Hilton, Washington, DC, February 15-17, 2005.
12. Program Planning Committee, *2005 Extractables/Leachables Forum, The Extractables Puzzle: An Integrated Team Approach*, Parenteral Drug Association, Marriott Bethesda North Hotel, North Bethesda, MD, May 23-25, 2005.

13. Program Planning Committee and session moderator, *2007 Extractables/Leachables Forum, Confronting Extractables and Leachables in an Evolving Industry*, Parenteral Drug Association, Hyatt Regency Bethesda, Bethesda, MD, November 6-8, 2007.
14. Member of IPAC-RS OINDP Materials Working Group, 2006-Jan. 2009.
15. Member, PQRI PODP Leachables and Extractables Working Group, Product Quality Research Institute, 2007-present.
16. **Founding member of the Board of Directors, Extractables and Leachables Safety Information Exchange Consortium**, 2007-present.
17. **Co-chair IPAC-RS Leachables and Extractables QbD Feasibility Group**, 2007-February 2008.
18. **Co-chair, IPAC-RS Leachables and Extractables Development Paradigm Working Group**, 2008. Member 2008-2010.
19. **Governing Board Member, Eastern Analytical Symposium (EAS)**, May 2008-2015.

Vice-chair for Short Courses, 2012.
Chair for Short Courses, 2013.
Vice-chair for Programs, 2014.
Chair for Programs, 2015.
20. Member, PhRMA Limited Duration Key Issue Team (LDKIT) on Genotoxic Impurities, 2009-2010.
21. **Member, United States Pharmacopeia (USP) General Chapters--Packaging, Storage, and Distribution Expert Committee**, term 1 2010-2015; term 2 2015-2020.

Chair - Subcommittee on Extractables and Leachables.
Chair - Leachables Threshold and Best Practices Expert Panel.
Chair - Biocompatibility of Materials Used in Packaging Systems, Medical Devices and Implants Expert Panel.
Member - Subcommittee on <661> Containers - Plastic.
Member - <661.3> Plastic Systems Used for Manufacturing Pharmaceutical Products Expert Panel.
Member - <381> Elastomeric Closures for Injection Expert Panel.
22. Program Planning Committee and session moderator, *2010 PDA/FDA Joint Regulatory Conference; Post-Conference Extractables and Leachables Workshop*, Parenteral Drug Association, Renaissance Hotel, Washington, DC, September 15-16, 2010.
23. Program Planning Committee and session moderator, *PQRI Workshop on Safety Thresholds and Best Practices for Parenteral and Ophthalmic Drug Products*, Bethesda, MD, February 22-23, 2011.
24. Program Planning Committee, 2011 IPAC-RS Conference, *Bringing Value to the Patient in a Changing World*, Workshop: *Leachables and Extractables (Experience to Date with PQRI Recommendations (Qualification and Analytical Evaluation Thresholds))*, Bethesda, Maryland, USA, March 29-31, 2011.

25. CoSMoS 2011 Organizing Committee (Conference on Small Molecule Science), August 1-3, The Carolina Inn, Chapel Hill, NC.
26. Member, IPAC-RS Emerging Markets Workshop preparation team; participated in content creation for a United States Pharmacopeia Course: *"Extractables and Leachables: Material Considerations for Medical Devices and Pharmaceutical Products"*, presented in Brazil: April 2012, Sao Paulo; India: 18-19 June 2012, Hyderabad; 21-22 June 2012, Mumbai; China: 10-11 Sep. 2012, Shanghai; 13-14 Sep. 2012, Beijing.
27. Invited participant and speaker, *Forum for Infusion Packaging Development 2014* sponsored by the China National Pharmaceutical Packaging Association, Qingdao, People's Republic of China, September 17-19, 2014.
28. Member of the Advisory Board, *E&L 2016 (and 2017, 2018)*, Smithers Rapra.
29. Invited participant and speaker, *Forum for Injection and Packaging Development 2016* sponsored by the China National Pharmaceutical Packaging Association, Qingdao, People's Republic of China, September 7-9, 2016.
30. **Vimta Invited Lecture Tour of India**, *"Extractables, Leachables, Elemental Impurities & Safety Assessment – 2017"*, 9th October Ahmedabad, 10th October Mumbai, 11th October Hyderabad.
31. Editorial Advisory Board Member:
 - American Pharmaceutical Review*, 2009-present
 - Pharmaceutical Formulation and Quality*, 2011-present
 - Pharmaceutical Outsourcing*, 2011-present
 - Austin Chromatography – Open Access Journal*, 2014-present
32. Journal reviewer:
 - Environmental Science and Technology*
 - PDA Journal of Pharmaceutical Science and Technology*
 - American Pharmaceutical Review*
 - Journal of Pharmaceutical Sciences*
 - Analytical Letters*
 - Journal of Pharmaceutical and Biomedical Analysis*
 - Current Opinion in Drug Discovery and Development*
 - Journal of Chromatographic Science*
 - Regulatory Toxicology and Pharmacology*
 - Pharmaceutical Outsourcing*
 - Pharmaceutical Formulation and Quality*
 - Austin Chromatography*
 - Analytical Chemistry*

Peer Reviewed Publications

(h-index: 29 via Google Scholar on 3-14-24)

1. "Reactions of Chlorine with Selected Aromatic Models of Aquatic Humic Material", D.L. Norwood, J.D. Johnson, R.F. Christman, J.R. Hass, M.J. Bobenrieth, *Environmental Science and Technology*, **14**, 186-190 (1980).
2. "Reaction Products of Aquatic Humic Substances with Chlorine", D.L. Norwood, J.D. Johnson, R.F. Christman, D.S. Millington, *Environmental Health Perspectives*, **46**, 63-71 (1982).
3. "Identity and Yields of Major Halogenated Products of Aquatic Fulvic Acid Chlorination", R.F. Christman, D.L. Norwood, D.S. Millington, J.D. Johnson, A.A. Stevens, *Environmental Science and Technology*, **17**, 625-628 (1983).
4. "Determination of Aqueous Trichloroacetic Acid Using Isotope Dilution Mass Spectrometry", D.L. Norwood, R.F. Christman, J.D. Johnson, J.R. Hass, *Journal of the American Water Works Association*, **78**, 175-180 (1986).
5. "Structural Characterization of Aquatic Humic Material. II. Phenolic Content and its Relationship to Chlorination Mechanism in an Isolated Aquatic Fulvic Acid", D.L. Norwood R.F. Christman, P.G. Hatcher, *Environmental Science and Technology*, **21**, 791-798 (1987).
6. "Application of Continuous-Flow Liquid Chromatography/Fast Atom Bombardment Mass Spectrometry to the Analysis of Diagnostic Acylcarnitines in Human Urine", D.L. Norwood, N. Kodo, D.S. Millington, *Rapid Communications in Mass Spectrometry*, **2**(12), 269-272 (1988).
7. "Application of Fast Atom Bombardment with Tandem Mass Spectrometry and Liquid Chromatography/Mass Spectrometry to the Analysis of Acylcarnitines in Human Urine, Blood, and Tissue", D.S. Millington, D.L. Norwood, C.R. Roe, F. Inoue, *Analytical Biochemistry*, **180**, 331-339 (1989).
8. "A New Method for Quantitative Analysis of Free and Total Carnitine Using Tandem Mass Spectrometry", N. Kodo, D.S. Millington, D.L. Norwood, C.R. Roe, *Clinica Chimica Acta*, **186**, 383-390 (1989).
9. "Combined High Performance Liquid Chromatography/Continuous Flow Fast Atom Bombardment Mass Spectrometric Analysis of Acylcoenzyme A Compounds", D.L. Norwood, C.A. Bus, D.S. Millington, *Journal of Chromatography (Biomedical Applications)*, **527**, 1-13 (1990).
10. "Tandem Mass Spectrometry: A New Method for Acylcarnitine Profiling with Potential for Neonatal Screening for Inborn Errors of Metabolism", D.S. Millington, N. Kodo, D.L. Norwood, C.R. Roe, *Journal of Inherited Metabolic Disease*, **13**(3), 321-324 (1990).
11. "Identification of Phenylpropionyl Carnitine, A New Metabolite of Phenylpropionic Acid, in a Patient with Medium Chain Acyl-CoA Dehydrogenase Deficiency", R. Moore, D.S. Millington, D. Norwood, N. Kodo, P. Robinson, J.F.T. Glasgow, *Journal of Inherited Metabolic Disease*, **13**(3), 325-329 (1990).
12. "2,4-Dienoyl-Coenzyme A Reductase Deficiency: A New Disorder of Fatty Acid Oxidation", C.R. Roe, D.S. Millington, D.L. Norwood, N. Kodo, H. Sprecher, B.S. Mohammed, M. Nada, H.

- Schulz, R. McVie, *Journal of Clinical Investigation*, **85**, 1703-1717 (1990).
13. "Mass Spectrometry", A.L. Burlingame, D.S. Millington, D.L. Norwood, D.H. Russell, *Analytical Chemistry*, **62**, 268R-202R (1990).
 14. "Dipyridamole-Cisplatin Potentiation: Enhanced in vivo Cytotoxicity in Xenograft Models of Human Testicular and Bladder Cancers", T.E. Keane, G. Rosner, J.T. Donaldson, D.L. Norwood, S.H. Poulton, P.J. Walther, *Journal of Urology*, **144**(4), 1004-1009 (1990).
 15. "Mitochondrial Metabolism of Valproic Acid", J. Li, D.L. Norwood, L.- F. Mao, H. Schulz, *Biochemistry*, **30**, 388-394 (1990).
 16. "Biomedical Applications of High-Performance Liquid Chromatography/Mass Spectrometry with Continuous-Flow FAB," D.S. Millington, D.L. Norwood, N. Kodo, R. Moore, M. Green, J. Berman, *Journal of Chromatography (Biomedical Applications)* , **562**, 47-58 (1991).
 - 17.* "Application of the Master Analytical Scheme to the Determination of Volatile Organics in Wastewater Influent and Effluents", L.C. Michael, E.D. Pellizzari, D.L. Norwood, *Environmental Science and Technology*, **25**, 150-155 (1991).
 18. "Rapid Optimization of Enzyme Substrates Using Defined Substrate Mixtures", J. Berman, M. Green, E. Sugg, R. Anderegg, D. Millington, D. Norwood, J. McGeehan, J. Wiseman, *Journal of Biological Chemistry*, **267**(3), 1434-1437 (1992).
 19. "Impact of Extractable Testing on MDI Development Programs", S.K. Sethi, D.L. Norwood, P.A. Haywood, D. Prime, *Journal of Biopharmaceutical Sciences*, **3**(1/2), 63-68 (1992).
 20. "Recognition of Quaternary Ammonium Compounds Using Mass Spectrometry", D.L. Fisher, M. A. Moseley, J. O. Mullis, D. L. Norwood, *Rapid Communications in Mass Spectrometry*, **8**, 65-70 (1994).
 21. "Analysis of Polycyclic Aromatic Hydrocarbons in Metered Dose Inhaler Drug Formulations by Isotope Dilution Gas Chromatography/Mass Spectrometry", D.L. Norwood, D. Prime, B.P. Downey, J. Creasey, S.K. Sethi, P. Haywood, *Journal of Pharmaceutical and Biomedical Analysis*, **13**(3), 293-304 (1995).
 22. "Structure Elucidation and Total Synthesis of a Unique Group of Trace Impurities in Tipranavir® Drug Product", C. A. Busacca, S. Campbell, A. Saha, J. C. Lorenz, K. Grozinger, P. Jones, N. Grinberg, S. Shen, H. Lee, F. Qiu, A. Granger, Z. Yuabova, D. Norwood and C. H. Senanayake, *Magnetic Resonance in Chemistry*, **43**(12), 1032-1039 (2005).
 23. "Identification of Pharmaceutical Impurities", F. Qiu and D. L. Norwood, *Journal of Liquid Chromatography and Related Technologies*, **30**(5-7), 877-935 (2007).
 24. "Development of Safety Qualification Thresholds and Their use in Orally Inhaled and Nasal Drug Product Evaluation", D. Ball, J. Blanchard, D. Jacobson-Kram, R. McClellan, T. McGovern, D. L. Norwood, M. Vogel, R. Wolff, L. Nagao, *Toxicological Sciences*, **97**(2), 226-236 (2007).
 25. "Best Practices for Extractables and Leachables in Orally Inhaled and Nasal Drug Products: An Overview of the PQRI Recommendations", D. L. Norwood, D. Paskiet, M. Ruberto, T. Feinberg, A. Schroeder, G. Poochikian, Q. Wang, T. J. Deng, F. DeGrazio, M. K. Munos,

- and L. M. Nagao, *Pharmaceutical Research*, **25**(4), 727-739 (2008).
26. “Recent Advances in Headspace Gas Chromatography”, Y. Wang, J. McCaffrey and D. L. Norwood, *Journal of Liquid Chromatography and Related Technologies*, **31**, 1823-1851 (2008).
 27. “Development of a Pilot Plant Process for a Nevirapine Analogue HIV NNRT Inhibitor”, Busacca, C. A., Cerreta, M., Dong, Y., Eriksson, M. C., Farina, V., Feng, X., Kim, Ji-Y., Lorenz, J. C., Sarvestani, M., Simpson, R., Varsolona, R., Vitous, J., Campbell, S. J., Davis, M. S., Jones, P., Norwood, D., Qiu, F., Beaulieu, P. L.; Duceppe, J., Hache, B., Brong, J., Chiu, F., Curtis, T., Kelley, J., Lo, Y. S., Powner, T. H., *Organic Process Research and Development*, **12**(4), 603-613 (2008).
 28. “Effects of Perchloric Acid on High Temperature Liquid Chromatography”, Y. Wang, N. Grinberg, J. McCaffrey, and D. L. Norwood, *Journal of Liquid Chromatography and Related Technologies*, **31**(15), 2305-2317 (2008).
 29. “Identification of Drug Meglumine Interaction Products Using LC/MS and Forced Degradation Studies”, F. Qiu, D. Cobice, S. Pennino, M. Becher, and D. L. Norwood, *Journal of Liquid Chromatography and Related Technologies*, **31**(15), 2331-2336 (2008).
 30. “Studies of the Interactions of Amino Alcohols Using High Performance Liquid Chromatography with Crown Ether Stationary Phases”, C. Manolescu, M. Grinberg, C. Field, S. Ma, S. Shen, H. Lee, Y. Wang, A. Granger, Q. Chen, J. McCaffrey, D. Norwood, and N. Grinberg, *Journal of Liquid Chromatography and Related Technologies*, **31**(15), 2219-2234 (2008).
 31. “Genotoxic Impurities: A Quantitative Approach”, Z. Y. Yuabova, D. R. Holschlag, S. A. Rodriguez, C. Qin, V. V. Papov, F. Qiu, J. F. McCaffrey, and D. L. Norwood, *Journal of Liquid Chromatography and Related Technologies*, **31**(15), 2318-2330 (2008).
 32. “HPLC and LC/MS Analysis of Pharmaceutical Container Closure System Leachables and Extractables”, D. L. Norwood, D. Jenke, C. Manolescu, S. Pennino and N. Grinberg, *Journal of Liquid Chromatography and Related Technologies*, **32**, 1768-1827 (2009).
 33. “³¹P Solid State NMR Study of Structure and Chemical Stability of Dichlorotriphenylphosphorane”, N. C. Gonnella, C. Busacca, S. Campbell, M. Eriksson, N. Grinberg, T. Bartholomeyzik, S. Ma and D. L. Norwood, *Magnetic Resonance in Chemistry*, **47**, 461-464 (2009).
 34. “Identification of a Process Impurity Formed During Synthesis of a Nevirapine Analogue HIV NNRT Inhibitor Using LC/MS and Forced Degradation Studies”, F. Qiu, S. Pennino, C. A. Busacca, D. L. Norwood, *Journal of Pharmaceutical and Biomedical Analysis*, **49**(3), 733-738 (2009).
 35. “N-nitrosamines as “Special Case” Leachables in a Metered Dose Inhaler Drug Product”, D. L. Norwood, J. O. Mullis, T. N. Feinberg, L. K. Davis, *PDA Journal of Pharmaceutical Science and Technology*, **63**(4), 307-321, July-August (2009).
 36. “Quantitative Determination of Residual Active Pharmaceutical Ingredients and Intermediates on Equipment Surfaces by Ion Mobility Spectrometry”, C. Qin, A. Granger, V. Papov, J. McCaffrey, and D. L. Norwood, *Journal of Pharmaceutical and Biomedical Analysis*, **51**(1), 107-113 (2009).

37. “Study and characterization of crystalline hydrate/polymorph forms of 5,11-dihydro-11-ethyl-5-methyl-8-(2-(1-oxido-4-quinolinyl)ethyl)-6H-dipyrido(3,2-B:2',3'-E)(1,4)diazepin-6-one by solid state NMR and solution NMR”, N.C. Gonnella, J. Smoliga, S. Campbell, C. Busacca, M. Cerreta, R. Varsolona, and D. L. Norwood, *Journal of Pharmaceutical and Biomedical Analysis*, **51**, 1047-1053 (2010).
38. “Recent Developments in the Application of Comprehensive Two-Dimensional Gas Chromatography”, Y. Wang, Q. Chen, D. L. Norwood and J. McCaffrey, *Journal of Liquid Chromatography and Related Techniques*, **33**(9-12), 1082-1115 (2010).
39. “Automated Solid Phase Extraction (SPE) LC/NMR Applied to the Structural Analysis of Extractable Compounds from a Pharmaceutical Packaging Material of Construction”, D. L. Norwood, J. O. Mullis, M. Davis, S. Pennino, T. Egert, N. C. Gonnella, *PDA Journal of Pharmaceutical Science and Technology*, **67**(3), 267-287, May-June (2013).
40. “The Product Quality Research Institute (PQRI) Leachables and Extractables Working Group Initiatives for Parenteral and Ophthalmic Drug Product (PODP)”, D. Paskiet, D. Jenke, D. Ball, C. Houston, D. L. Norwood, I. Markovic, *PDA Journal of Pharmaceutical Science and Technology*, **67**(5), 430-447, September/October 2013.
41. “Perspectives on the PQRI Extractables and Leachables “Safety Thresholds and Best Practices” Recommendations for Inhalation Drug Products”, D. L. Norwood, L. M. Nagao, C. L. M. Stults, *PDA Journal of Pharmaceutical Science and Technology*, **67**(5), 413-429, September/October 2013.
42. “Extractables Characterization for Five Materials of Construction Representative of Packaging Systems Used for Parenteral and Ophthalmic Drug Products”, D. Jenke, J. Castner, T. Egert, T. Feinberg, A. Hendricker, C. Houston, D. G. Hunt, M. Lynch, A. Shaw, K. Nicholas, D. L. Norwood, D. Paskiet, M. Ruberto, E. J. Smith, F. Holcomb, *PDA Journal of Pharmaceutical Science and Technology*, **67**(5), 448-511, September/October 2013.
43. “Structure Elucidation of a Complex Faldaprevir-(+)- α -Tocopherol Addition Product Reveals Reactivity of Common Excipient Vitamin E TPGS”, N. C. Gonnella, S. A. Rodriguez, S. Pennino, D. Norwood., *Journal of Heterocyclic Chemistry*, 10.1002/jhet.2502 (2015).
44. “Simulated Leaching (Migration) Study for a Model Container-closure System Applicable to Parenteral and Ophthalmic Drug Products (PODPs)”, D. Jenke, T. Egert, A. Hendricker, J. Castner, T. Feinberg, C. Houston, D. Hunt, M. Lynch, K. Nicholas, D. L. Norwood, D. Paskiet, M. Ruberto, E. J. Smith, F. Holcomb, *PDA Journal of Pharmaceutical Science and Technology*, pdajpst. 2016.007229, December 2016.
45. “Impact of the GC-MS Injection Solvent and the Analyte Concentration on Relative Responses for Common Extractables”, D. Norwood, A. Michelson, N. Dunn, J. Duett, L. Fleck, G. Vas, *Reviews in Separation Science*, **4**(1), e22002 (2022).
46. “Evaluation of Extraction Conditions for Volatile Extractables from Polypropylene, PBT Resins, and Chlorobutyl Rubber Elastomers Using a Variety of Solvents and Extraction Techniques”, D. Norwood, L. Fleck, E. Seyyal, A. Michelson, G. Vas, *Reviews in Separation Science*, **4**(1), e22003 (2022).

Books and Book Chapters

1. "Natural and Model Aquatic Humics: Reactions with Chlorine", R.F. Christman, J.D. Johnson, J.R. Hass, F.K. Pfaender, W.T. Liao, D.L. Norwood, H.J. Alexander, in *Water Chlorination: Environmental Impact and Health Effects*, **2**, 15-28, Ann Arbor Science Publishers, Ann Arbor, MI (1978).
2. "Chemical Identification of Aquatic Humic Chlorination Products", R.F. Christman, J.D. Johnson, F.K. Pfaender, D.L. Norwood, M.R. Webb, J.R. Hass, M.J. Bobenrieth, in *Water Chlorination: Environmental Impact and Health Effects*, **3**, 75-83, Ann Arbor Science Publishers, Ann Arbor, MI (1980).
3. "Chlorination Products of Aquatic Humic Material at Neutral pH", D.L. Norwood, J.D. Johnson, R.F. Christman, D.S. Millington, in *Water Chlorination: Environmental Impact and Health Effects*, **4**, 191-200, Ann Arbor Science Publishers, Ann Arbor, MI (1983).
4. "Organic Mass Spectrometry and its Application to Water Analysis", J.R. Hass, D.L. Norwood, in *Treatise on Water Analysis*, **3**, 253-316, Academic Press, New York (1984).
5. "By-Products of Chlorination: Specific Compounds and Their Relationship to Total Organic Halogen", D.L. Norwood, G.P. Thompson, J.J. St. Aubin, D.S. Millington, R.F. Christman, J.D. Johnson, in *Safe Drinking Water: The Impact of Chemicals on a Limited Resource*, Lewis Publishers, Ann Arbor, MI (1985).
6. "Application of Combined Gas Chromatography/Mass Spectrometry for the Identification and Quantitative Analysis of Trace Organic Contaminants", D.S. Millington, D.L. Norwood, in *Organic Carcinogens in Drinking Water: Detection, Treatment and Risk Assessment*, John Wiley and Sons, New York (1985).
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Coauthored Chapters:

21. "Overview of Leachables and Extractables in Orally Inhaled and Nasal Drug Products", Douglas J. Ball, Daniel L. Norwood, Lee M. Nagao; Chapter 1, pp. 3-19.
22. "The Analytical Evaluation Threshold (AET) and its Relationship to Safety Thresholds", Daniel L. Norwood, James O. Mullis, Scott Pennino; Chapter 5, pp. 59-78.
23. "Analytical Best Practices for the Evaluation and Management of Extractables and Leachables in Orally Inhaled and Nasal Drug Products", Daniel L. Norwood, Cheryl L. M. Stults, Lee M. Nagao; Chapter 10, 155-183.
24. "Analytical Techniques for Identification of Extractables and Leachables", Daniel L. Norwood, Scott Pennino, James O. Mullis, Tomas N. Feinberg; Chapter 13, pp. 241-287.

25. “Extractables – The Controlled Extraction Study”, Dennis Jenke, Daniel L. Norwood, Thomas N. Feinberg; Chapter 14, pp. 289-329.
26. “Extractables – Case Study of a Sulfur-cured Elastomer”, Daniel L. Norwood, Fenghe Qiu, James Coleman, James O. Mullis, Alice T. Granger, Keith McKellop, Michelle Raikes, John Robson; Chapter 15, pp. 331-386.
27. “Extractables and Leachables in Drugs and Packaging”, D.L. Norwood, A. T. Granger, D. M. Paskiet, *In Encyclopedia of Pharmaceutical Science and Technology*, Fourth Edition. Taylor and Francis: New York, Published online: 23 Aug 2013; 1548-1566.
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3. "An Application of the 'Master Analytical Scheme' to Influent and Effluent Wastewaters", D.L. Norwood, L.C. Michael, S.D. Cooper, T.W. Pack, M.E. Montgomery, and E.D. Pellizzari, *Proceedings – Water Quality Technology Conference*, Volume Date 1986, 14(Adv. Water Anal. Treat.), 365-386 (1987).

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4. "Strategies for the Analysis of Pharmaceutical Excipients and Their Trace Level Impurities", D.L. Norwood and F. Qiu, *American Pharmaceutical Review*, 7(5), 92-99 (2004).
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6. "Safety Thresholds and Best Practices For Extractables and Leachables in Orally Inhaled and Nasal Drug Products", Submitted to the PQRI Drug Product Technical Committee, PQRI Steering Committee, and U.S. Food and Drug Administration by the PQRI Leachables and Extractables Working Group, Daniel L. Norwood (Chair), Product Quality Research Institute, September 2006, http://pqri.org/pdfs/LE_Recommendations_to_FDA_09-29-06.pdf (accessed 11/15/2006).
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10. "PQRI: Safety Thresholds and Best Practices for Extractables and Leachables in Orally Inhaled and Nasal Drug Products", D. J. Ball, D. L. Norwood, and L. Nagao, *Leachables and Extractables Conference Proceedings*, Dublin, Ireland, March 5-6, 2008, Smithers Rapra Technology, Ltd., 3/1-3/8.
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1. "Application of Capillary Column GC/MS with Low Resolution Accurate Mass Measurement to the Analysis of Humic Acid Degradation Products", D.S. Millington, D.L. Norwood, *Proceedings of the 29th ASMS Conference on Mass Spectrometry and Allied Topics*, Minneapolis, MI, May 24-29, 1981.
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3. "Correlation of Degradation Product Profiles from Aquatic Humic Substances as Determined by GC/MS with C-13 NMR Spectral Characteristics", D.L. Norwood, R.F. Christman, P.G. Hatcher, *Proceedings of the 34th ASMS Conference on Mass Spectrometry and Allied Topics*, Cincinnati, OH, June 8-13, 1986.
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5. "Continuous-Flow FAB LC/MS Analysis of Acylcarnitines and Acyl-CoA Compounds Using Microbore HPLC Columns", D.S. Millington, D.L. Norwood, *Proceedings of the 36th ASMS Conference on Mass Spectrometry and Allied Topics*, San Francisco, CA, June 5-10, 1988.
6. "Biomedical Applications of Dynamic Fast Atom Bombardment", D.S. Millington, D.L. Norwood, presented at the 11th Conference of the Australian and New Zealand Society for Mass Spectrometry, St. Lucia, May 15-19, 1988.
7. "Recent Advances in the Application of Mass Spectrometry to the Diagnosis and Treatment of Inherited Metabolic Disease", D.S. Millington, F. Inoue, D. Gale, D.L. Norwood, C.R. Roe, presented at the Seventh International Symposium on Mass Spectrometry in the Life Sciences, Ghent, Belgium, August 23-26, 1988.
8. "Developments in Continuous Flow FAB LC/MS", C.C. Stacey, D.L. Norwood, D.S. Millington, T.A. Dourdeville, M.D. Balogh, E.G. Cassis, presented at the 40th Pittsburgh Conference, Atlanta, GA, March 6-10, 1989.
9. "Clinical Applications of Tandem Mass Spectrometry", D.L. Norwood, N. Kodo, D.S. Millington, presented at the 103rd N.C. Sectional Conference, American Chemical Society, Chapel Hill, NC, April 15, 1989.
10. "Enhanced Detection of Diagnostic Acylcarnitines in Plasma and Tissue Utilizing FAB Coupled with Tandem Mass Spectrometry", D.S. Millington, D.L. Norwood, N. Kodo, *Proceedings of the 37th ASMS Conference on Mass Spectrometry and Allied Topics*, Miami Beach, FL, May 21-26, 1989.
11. "Comparison of Thermospray and Continuous Flow FAB LC/MS Methods for the Analysis of Acyl-CoA Compounds", D.L. Norwood C.A. Bus, D.S. Millington, *Proceedings of the 37th ASMS Conference on Mass Spectrometry and Allied Topics*, Miami Beach, FL, May 21-26, 1989.
12. "Rapid Screening of Neonatal Whole Blood for Various Metabolic Disorders by FAB/MS/MS", N. Kodo, D.L. Norwood, D.S. Millington, *Proceedings of the 37th ASMS Conference on Mass*

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13. "Use of Tandem Mass Spectrometry for Quantitative Analysis and in vitro Isotope Enrichment Measurements of Free Carnitine and Acylcarnitines", N. Kodo, D.L. Norwood, D.S. Millington, presented at the Second International Symposium on Mass Spectrometry in the Health and Life Sciences", San Francisco, CA, August 27-31, 1989.
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15. High Performance Liquid Chromatography/Continuous Flow Fast Atom Bombardment Mass Spectrometry: Application to Inherited Metabolic Disease", D.L. Norwood, N. Kodo, D.S. Millington, presented at the 41st Southeast Regional Meeting, American Chemical Society, Winston-Salem, NC, October 9-11, 1989.
16. "A New Method of Acylcarnitine Analysis Using Tandem Mass Spectrometry", presented at the American Society of Human Genetics Meeting, Baltimore, MD, November 13-17, 1989.
17. "Liquid Chromatography/Continuous-Flow Fast Atom Bombardment Mass Spectrometric Studies of Novel Acylcarnitines Associated with Suspected Metabolic Disease", D.L. Norwood, D.S. Millington, N. Kodo, J.W. Childers, *Proceedings of the 38th ASMS Conference on Mass Spectrometry and Allied Topics*, Tucson, AZ, June 3-8, 1990.
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20. "Intraoperative Carbon Monoxide Toxicity", R.E. Moon, A.F. Meyer, D.L. Scott, E. Fox, D.S. Millington, D.L. Norwood, *ASA Abstracts, Anesthesiology*, **73**(3A), (1990).
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23. "Applications of the HP GC/IRD/MSD in the Trace Organic Analysis Laboratory", B.P. Downey, D.L. Norwood, presented at the HP User's Meeting preceding the 39th ASMS Conference on Mass Spectrometry and Allied Topics, Nashville, TN, May 18, 1991.
24. "Analysis of Rubber Extractives by Mass Spectrometry", S.K. Sethi, D.L. Norwood, presented at the Symposium on *Regulatory Issues in Aerosol Drug Development*, Arlington, VA, June 14, 1991.

25. "Applications of Combined HPLC/MS in Drug Development", D.L. Norwood, invited presentation at the 1991 Chromatography Symposium organized by Baxter Scientific Products, Durham, NC, October 8, 1991.
26. "Impact of Extractable Testing on MDI Development Programs", S.K. Sethi, D.L. Norwood, presented at *Respiratory Drug Delivery III*, Williamsburg, VA, May 18, 1992.
27. "Particle-Beam LC/MS: The Missing "LINC" in Pharmaceutical Development", D.L. Norwood, B.P. Downey, presented at the VG User's Meeting preceding the 40th ASMS Conference on Mass Spectrometry and Allied Topics, Washington, DC, May 30, 1992.
28. "An MS/MS Method for Distinguishing the Regioisomeric Phenolic Metabolites of GR38032", D.L. Norwood, J.S. Walsh, S.K. Sethi, D.L. Fisher, *Proceedings of the 40th ASMS Conference on Mass Spectrometry and Allied Topics*, Washington, DC, June 1-5, 1992.
29. "Particle-Beam HPLC/MS and the Use of Stable Isotope Labeled Internal Standards for Quantitative Analysis", D.L. Norwood, B.P. Downey, *Proceedings of the 40th ASMS Conference on Mass Spectrometry and Allied Topics*, Washington, DC, June 1-5, 1992.
30. "Rapid Optimization of Enzyme Substrates Using Defined Substrate Mixtures", M. Green, J. Berman, R. Anderegg, D. Kassel, D.S. Millington, D.L. Norwood, J. McGeehan, J. Wiseman, D.M. Bickett, presented at the National Medicinal Chemistry Symposium, SUNY Buffalo, Buffalo, NY, June 14-18, 1992; also presented at *Rapid Functional Screening for Drug Development*, San Diego, CA, September 21-22, 1992.
31. "The Application of Analytical Biochemistry to the Diagnosis, Understanding, and Treatment of Inherited Metabolic Disease", D.L. Norwood, invited seminar at the Department of Biochemistry and Nutrition, Virginia Polytechnic Institute and State University, Blacksburg, VA, October 5, 1992.
32. "Demonstration of the Permeability of Low Density Polyethylene (LDPE) Containers to an Environmental Contaminant", K. Wilbourne, K. Everhart, K. Dunn, D. Fisher, D. Norwood, J. Spadie, presented at the American Association of Pharmaceutical Scientists National Meeting, San Antonio, Texas, November 16-20, 1992.
33. "Recognition of Quaternary Amines and Ammonium Salts Using Tandem Mass Spectrometry", D.L. Norwood, D.L. Fisher, J.O. Mullis, M.A. Moseley, *Proceedings of the 41st ASMS Conference on Mass Spectrometry and Allied Topics*, San Francisco, CA, May 31 - June 4, 1993.
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35. "Evaluation and Application of High Flowrate Electrospray LC/MS", D.L. Norwood, D.L. Fisher, presented at the British Mass Spectrometry Society LC/MS Symposium, London, UK, December 15-16, 1993.
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39. "Analytical Application of Negative Ion Attachment Liquid Chromatography/Mass Spectrometry (LC/MS)", D.L. Norwood, D.L. Fisher, J.O. Mullis, presented at the 109th N.C. Sectional Conference, American Chemical Society, Chapel Hill, NC, April 22, 1995.
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42. "ESI and APCI LC/MS Application to Extractables from Drug Delivery Devices and Container Systems", D.L. Norwood, T.N. Feinberg, J.O. Mullis, *Proceedings of the 44th ASMS Conference on Mass Spectrometry and Allied Topics*, Portland, OR, May 12 - 16, 1996.
43. "Directly Coupled Packed Column SFC with APCI/MS", D.G. Morgan, D.L. Norwood, D.L. Fisher, M.A. Moseley, III., *Proceedings of the 44th ASMS Conference on Mass Spectrometry and Allied Topics*, Portland, OR, May 12 - 16, 1996.
44. "LC/MS Analysis of Packaging Impurities in Drug Product Formulations", T.N. Feinberg and D.L. Norwood, presented at the 110th North Carolina American Chemical Society Local Section Conference Symposium: *Frontiers in Mass Spectrometry*, April 13, 1996.
45. "Applications of Chloride Ion Attachment LC/MS in Pharmaceutical Development", D.L. Norwood, T.N. Feinberg, T.C. Cain, J.D. Lennon, presented at the 50th Southeastern Regional Meeting of the American Chemical Society, Research Triangle Park, NC, November 4-7, 1998.
46. Co-organizer and Workshop Leader (with Dr. Thomas Schuster), "Exploring Analytical Methods for Detecting, Identifying and Quantitating Impurities", Presented by the *Institute for International Research, Pharmaceutical and Biotechnology Division*, Park Hyatt Philadelphia at the Bellevue, Philadelphia, PA, October 16, 2000.
47. Co-organizer and Workshop Leader (with Dr. Thomas N. Feinberg), "Identify and Quantify Impurities in Excipient Manufacture" (talk entitled: "Identification Strategies for Trace Level Excipient Related Impurities in Drug Product Matrices"), Presented by *The Center for Business Intelligence*, Adam's Mark Philadelphia, Philadelphia, PA, April 19, 2001.
48. Organizer and Workshop Leader, "A Systematic Approach for the Identification of Small Molecule Impurities in Drug Product Matrices", Presented by *The Institute for Validation Technology*, The Jurys Washington Hotel, Washington, DC, August 6-7, 2001.

49. “Setting Impurity Specifications Using Forced Degradation Studies”, D.L. Norwood, invited presentation at the 41st Annual Conference on Pharmaceutical Analysis, *Analytical Contributions to Drug Quality*, Extension Services in Pharmacy, School of Pharmacy, Center for Health Sciences, University of Wisconsin – Madison, Merrimac, WI, July 30-August 3, 2001.
50. “Reviewing Novel Strategies for the Analysis of Pharmaceutical Excipients and Their Impurities”, D.L. Norwood, invited presentation at the conference *Pharmaceutical Excipients: Strategies for Harmonization and Reduced Testing to Achieve Worldwide Compliance*, Philadelphia, PA, June 27-28, 2002.
51. “Leachables in Orally Inhaled and Nasal Drug Products: Scientific and Regulatory Perspectives”, D.L. Norwood, invited presentation at the Institute for International Research conference *Impurities and Leachables: Isolation, Identification and Quantification*, Philadelphia, PA, December 11-13, 2002.
52. Workshop Leader, “A Systematic Approach for the Identification of Small Molecule Impurities in Drug Product Matrices”, presented at the United States Food and Drug Administration, Rockville, MD, June 9, 2003.
53. “Application of Modern Analytical Technologies to the Identification of Extractables and Leachables”, D.L. Norwood, invited presentation at the Barnett International conference *Extractables and Leachables in Pharmaceutical Products*, Philadelphia, PA, September 15-16, 2003 (represented at duplicate conferences: Philadelphia, PA, December 9-10, 2003; Washington, DC, October 27-28, 2004; and Boston, MA, July 11-15, 2005).
54. “Extractives Testing for Nasal and Pulmonary Products”, D.L. Norwood, invited presentation at the Valois conference *Practical Approaches to Nasal and Pulmonary Drug Delivery II*, Delray Beach, FL, February 9-11, 2004.
55. “Studies on Extractables Profiling of Elastomers and Polymers”, D.L. Norwood on behalf of the PQRI Leachables and Extractables Working Group, presented at *Respiratory Drug Delivery IX*, Palm Desert, CA, April 25-29, 2004.
56. “Using Accurate Mass Measurement for Trace Level Impurity Identification in Pharmaceutical Development Applications”, D.L. Norwood, invited presentation at the Agilent Technologies 2004 ASMS Saturday Night Technology Forum, Gaylord Opryland Hotel, Nashville, TN, May 22, 2004.
57. “NMR from the View of a Mass Spectrometrists”, D.L. Norwood, invited presentation to the NMR Spectroscopy Group, North Jersey Section of the American Chemical Society, Woodbridge Hilton Hotel, Woodbridge, New Jersey, June 23, 2004.
58. “Application of Modern Analytical Technologies to the Identification of Extractables and Leachables”, D.L. Norwood, invited presentation at the 44th Annual Conference on Pharmaceutical Analysis, *Pharmaceutical Analysis – Advances in Assuring Data and Product Integrity*, Extension Services in Pharmacy, School of Pharmacy, Center for Health Sciences, University of Wisconsin – Madison, Merrimac, WI, August 2-6, 2004.
59. “Identification of Pharmaceutical Impurities by Accurate Mass Measured LC/MS and GC/MS”, D.L. Norwood, invited presentation at the Barnett International conference *Impurities, Degradation and Solvents*, Philadelphia, PA, September 29-30, 2004.

60. “Accurate Mass Measurements: A Rediscovered Resource for Qualitative Trace Organic Analysis in Pharmaceutical Development”, D.L. Norwood, K. McKellop, A. Granger, J. Mullis, invited presentation at Pittcon 2005, March 2, 2005.
61. “PQRI Extractables and Leachables Initiatives”, D. L. Norwood, invited presentation at the *2005 Extractables/Leachables Forum, The Extractables Puzzle: An Integrated Team Approach*, Parenteral Drug Association, Bethesda, MD, May 23-25, 2005.
62. “Unknown Identification vs. Molecular Weight Confirmation – How Much Mass Accuracy is Enough”, D. L. Norwood, invited presentation at the *Conference on Small Molecule Science*, Roger Williams University, Bristol, RI, August 8-11, 2005.
63. “Modern Analytical Techniques for Identification of Degradation Products in APIs and Drug Products”, D. L. Norwood, invited presentation for the Short Course: *Degradation and Stability in Small Molecules (API)/Stability Testing for Global Filings*, 2005 AAPS Annual Meeting and Exposition, Nashville, TN, November 6, 2005.
64. “Best Practices for Leachables and Extractables Testing”, D. L. Norwood, invited presentation for the *PQRI Leachables and Extractables Workshop*, Bethesda, MD, December 5-6, 2005.
65. “Development and Application of the Analytical Evaluation Threshold”, D. L. Norwood, invited presentation for the *PQRI Leachables and Extractables Workshop*, Bethesda, MD, December 5-6, 2005.
66. “Controlled Extraction Study - Sulfur Cured Elastomer”, K. McKellop, J. O. Mullis, A. Granger, D. L. Norwood, invited poster presentation for the *PQRI Leachables and Extractables Workshop*, Bethesda, MD, December 5-6, 2005.
67. “Controlled Extraction Study - “Unknown” Elastomer”, A. Granger, K. McKellop, D. L. Norwood, invited poster presentation for the *PQRI Leachables and Extractables Workshop*, Bethesda, MD, December 5-6, 2005.
68. “The Analytical Evaluation Threshold (AET)”, D. L. Norwood and L. M. Nagao, invited poster presentation for the *PQRI Leachables and Extractables Workshop*, Bethesda, MD, December 5-6, 2005.
69. “Summary of the PQRI Leachables and Extractables Recommendations”, D. Ball, J. Blanchard, L. Celado, F. DeGrazio, B. Doub, T. Feinberg, J. Hrkach, R. McClellan, T. McGovern, D. Norwood, D. Paskiet, D. Porter, A. Schroeder, M. Vogel, Q. Wang, R. Wolff, L. Nagao, M. Munos, T. Deng, M. Ruberto, and A. Hendriker, invited poster presentation for the *PQRI Leachables and Extractables Workshop*, Bethesda, MD, December 5-6, 2005.
70. “Extractables and Leachables in the Pharmaceutical Development Process”, D. L. Norwood, invited presentation for the Symposium Session: *Development of Safety Qualification Thresholds and Their use in Drug Product Evaluation*, 45th Annual Meeting of the Society of Toxicology, San Diego, CA, March 5-9, 2006.
71. “Leachables & Extractables in a GMP and QbD Environment: PAT and its Potential Application” D. L. Norwood, Day 1 Keynote Address at the *16th Annual GMP Roundtable for Clinical Supplies*, Mohonk Mountain House at Lake Mohonk, New Paltz, New York, October 3, 2006.
72. “PQRI Training Course: Leachables and Extractables Best Practices”, D.L. Norwood (organizer

and faculty member), presented at the offices of the IPAC-RS Secretariat, 1301 K St. NW, Washington, DC, September 20-21, 2006.

Note: Second training course presented at the Chicago offices of the IPAC-RS Secretariat, April 12-13, 2007. Third training course presented in Basel, Switzerland, September 26-27, 2007. Fourth training course presented in La Jolla, CA, November 15-16, 2007.

73. “Understanding the Challenges of Extractables and Leachables for the Pharmaceutical Industry – Safety and Regulatory Environment for Pharmaceuticals”, D. L. Norwood, invited presentation at the Intertech Pira conference: *Extractables and Leachables*, Hilton Alexandria Mark Center Hotel, Washington, DC, October 17-18, 2006. (Note that due to illness this presentation was delivered by Mr. James O. Mullis.)
74. “Considerations for Leachables and Extractables in a Quality by Design Environment”, D.L. Norwood, invited presentation at the IPAC-RS Conference: *Inhalation and Nasal Drugs: The Regulatory Landscape*, Bethesda North Marriott Hotel and Conference Center, Bethesda, MD, November 6-8, 2006.

Reproduced in: “The Gold Sheet”, 41(2), pp. 16-18, February 2007.

75. “Hyphenated Techniques (LC/MS and LC/NMR): Implications for HPLC Method Development”, D. L. Norwood, Invited presentation at the *2006 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 13-16, 2006.
76. “Application of Chloride Ion Attachment for Quantitation of Neutral Molecules Using Atmospheric Pressure Chemical Ionization Mass Spectrometry”, C. Qin, Z. Yuabova, J. McCaffrey, T. Feinberg, D. Norwood, presentation at the *2006 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 13-16, 2006.
77. “Effects of Mobile Phase Additives on High Temperature HPLC”, Y. Wang, N. Grinberg, J. McCaffrey, D. Norwood, presentation at the *2006 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 13-16, 2006.
78. “Scientific and Regulatory Perspectives on Leachables and Extractables in Pharmaceutical Products”, D. L. Norwood, Invited presentation at the *2006 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 13-16, 2006.
79. “Routine Control of Extractables”, D. L. Norwood and J. O. Mullis, Invited presentation at the *IPAC-RS Symposium: Extractables in Materials for OINDP*, presented at the offices of the IPAC-RS Secretariat, Chicago, IL, February 13, 2007.
80. “Extractables – Characterization and Control”, D.L. Norwood, Invited presentation at the *IPAC-RS Supplier QC Workshop: OINDP Supplier GMP*, presented at the offices of the IPAC-RS Secretariat, Chicago, IL, February 14, 2007.
81. “Considerations for Leachables and Extractables in a Quality by Design Environment: Contributions of IPAC-RS and PQRI”, D. L. Norwood, Invited presentation at the *2007 Annual Meeting of the Parenteral Drug Association* (Packaging Science Interest Group), Las Vegas, NV, March 20, 2007.
82. “Genotoxic Impurities: A Quantitative Approach”, Z. Yuabova, D. Holschlag, S. Rodriguez, V. Papov, F. Qiu, J. McCaffrey, D. Norwood, presented at the *7th Annual Csaba Horvath Medal*

- Award Symposium*, Connecticut Separation Science Council, Hartford Convention Center, Hartford, CT, April 19-20, 2007.
83. “Identification of Drug-Excipient Interaction Products”, F. Qiu, S. Pennino, D. Cobice, M. Becher, D. L. Norwood, presented at the *7th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council, Hartford Convention Center, Hartford, CT, April 19-20, 2007.
 84. “Identification of Unknown Impurities in a Delayed Release Tablet using SPE, LC/MS and NMR”, C. Qin, F. Qiu, P. Jones, J. McCaffrey, D. L. Norwood, presented at the *7th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council, Hartford Convention Center, Hartford, CT, April 19-20, 2007.
 85. “Mechanism Studies of the Interaction of Aminoalcohols with Crown Ether Columns”, C. Manolescu, N. Grinberg, M. Grinberg, Y. Wang, A. Granger, Q. Chen, J. McCaffrey, D. Norwood, presented at the *7th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council, Hartford Convention Center, Hartford, CT, April 19-20, 2007.
 86. “Effect of Mobile Phase Chaotropic Additives on High Temperature HPLC”, Y. Wang, N. Grinberg, J. McCaffrey, D. Norwood, presented at the *7th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council, Hartford Convention Center, Hartford, CT, April 19-20, 2007.
 87. “Best Practices for Leachables and Extractables Testing”, D. L. Norwood, invited presentation as part of a PQRI workshop at Health Canada, Ottawa, Ontario, Canada, July 26, 2007.
 88. “Control of Extractables/Leachables in a QbD Environment”, D. L. Norwood, invited presentation at the *47th Annual Conference on Pharmaceutical Analysis, Quality by Design: A New Frontier for the Analytical Chemist*, Extension Services in Pharmacy, School of Pharmacy, Center for Health Sciences, University of Wisconsin – Madison, Merrimac, WI, July 30 – August 3, 2007.
 89. “Extractables During Development and Routine Control”, D. L. Norwood and J. O. Mullis, invited presentation at the *IPAC-RS Workshop on Extractables and GMP for Components of Inhalation and Nasal Drug Products*, presented at the Aparentas Ausbildungszentrum, Muttentz, Basel, Switzerland, September 24, 2007.
 90. “Quality by Design (QbD) and the Issue of Leachables and Extractables”, D. L. Norwood, invited presentation at the Intertech Pira conference: *Extractables and Leachables*, Doubletree Hotel, Washington, DC, October 15-17, 2007.
 91. “Best Practices and Chemistry Evaluation for Leachables and Extractables in OINDP”, D. L. Norwood, invited presentation at the *2007 PDA Extractables/Leachables Forum, Confronting Extractables and Leachables Issues in an Evolving Industry*, Parenteral Drug Association, Bethesda, MD, November 6-8, 2007.
 92. “IPAC-RS OINDP Materials Working Group: Working with Suppliers to Address Extractables Challenges”, C. L. M. Stults, B. Falco, J. Creasey, M. Pollard, S. Kaar, X-M. Zeng, D. L. Norwood, G. Reckzuegel, J. Mullis, A. Feilden, A. Rignall, A. Shaw, D. Dohmeier, and B. Redler, poster presentation at the *2007 PDA Extractables/Leachables Forum, Confronting Extractables and Leachables Issues in an Evolving Industry*, Parenteral Drug Association, Bethesda, MD, November 6-8, 2007.

93. “Quantitative Determination of a Potentially Genotoxic Impurity in a New Drug Substance Using LC-MS/MS”, C. Qin, F. Qiu, S. Pennino, Y. Hu, J. McCaffrey, and D. Norwood, presentation at the *2007 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 12-15, 2007.
94. “Lewis Acid Coordination Complex Formation for the Enhancement of Trace GC-MS Analyses of Genotoxic Synthesis Impurities”, K. McKellop, A. Birch, F. Qiu, and D. Norwood, presentation at the *2007 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 12-15, 2007.
95. “Studies of the Interactions of Amino Alcohols with Crown Ether Columns”, C. Manolescu, N. Grinberg, Y. Wang, M. Grinberg, A. Granger, J. McCaffrey, D. Norwood, and Q. Chen, presentation at the *2007 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 12-15, 2007.
96. “Effects of Diluent Solvents on the Separation of Polar Compounds in GC”, Y. Wang, Q. Chen, C. Manolescu, A. Granger, J. McCaffrey, N. Grinberg, and D. Norwood, presentation at the *2007 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 12-15, 2007.
97. “Hyphenated Analytical Techniques: The Central Theme of an Integrated Impurity Identification Strategy”, D. L. Norwood, presented at the 2007 AAPS Annual Meeting in the short-course *Monitoring Impurities in Pharmaceuticals*, San Diego, CA, November 11, 2007. (Note that due to illness this presentation was delivered by Dr. Fenghe Qiu.)
98. “Comparison of UV, ELSD, CAD and MS/MS Detection Techniques for the Quantitation of Genotoxic Impurities”, Z. Y. Yuabova, D. R. Holschlag, S. A. Rodriguez, V. V. Papov, F. Qiu, J. F. McClafferty, and D. L. Norwood, presented at the 2007 AAPS Annual Meeting, San Diego, CA, November 12-16, 2007.
99. “The Analytical Evaluation Threshold (AET) Concept: Sensitivity and Analytical Uncertainty”, J. O. Mullis, A. Granger, C. Qin and D. L. Norwood, presented at the RAPRA International Conference: *Leachables and Extractables 2008*, Dublin, Ireland, March 5-6, 2008. (Also see *Leachables and Extractables 2008 Conference Proceedings*, Paper 4)
100. “PQRI: Safety Thresholds and Best Practices for Extractables and Leachables in Orally Inhaled and Nasal Drug Products”, D. J. Ball, D. L. Norwood, and L. Nagao, presented at the RAPRA International Conference: *Leachables and Extractables 2008*, Dublin, Ireland, March 5-6, 2008. (Also see *Leachables and Extractables 2008 Conference Proceedings*, Paper 3)
101. “Enantiomeric Separation of a Hydroxy Acid and its Methyl Ester Using an A1-Acidic Glycoprotein Column”, C. Manolescu, N. Grinberg, J. Reeves, A. Granger, Y. Wang, Q. Chen, S. Ma, S. Shen, H. Lee, J. McCaffrey, and D. Norwood, presented at the *8th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council and The Horvath Laboratory of Bioseparation Sciences, University of Innsbruck, Innsbruck, Austria, April 14-15, 2008.
102. “Diluent Solvent, A Key Role in the Separation of Polar Compounds in GC in Pharmaceutical Industry”, Y. Wang, Q. Chen, C. Manolescu, S. Shen, N. Grinberg, J. McCaffrey, and D. Norwood, presented at the *8th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council and The Horvath Laboratory of Bioseparation Sciences, University

of Innsbruck, Innsbruck, Austria, April 14-15, 2008.

103. “Influence of the Hofmeister Series on High Temperature Liquid Chromatography”, Y. Wang, N. Grinberg, C. Manolescu, Q. Chen, J. McCaffrey, and D. L. Norwood, presented at the 32nd International Symposium on High Performance Liquid Phase Separations and Related Techniques (HPLC 2008), Baltimore, MD, May 10-16, 2008.
104. “How Low can we Go? Sensitivity and the Analytical Evaluation Threshold for Leachables”, J. Mullis, S. Pennino, and D. Norwood, presented at the IPAC-RS Conference: *“Doing the Right Thing” in the Changing Culture of Design and Development of Inhalation and Nasal Drug Products: Science, Quality, and Patient-Focus*, Bethesda North Marriott Hotel and Conference Center, Bethesda, MD, September 22-24, 2008.
105. “Investigating Paradigms for Extractables and Leachables Management in Orally Inhaled and Nasal Drug Products”, D. L. Norwood, C. L. M. Stults, T. Chesworth, D. Christopher, A. Medina, L. Nagao, A. Purrington, A. Shaw, C. Snodgrass-Pilla, T. Tougas, and B. Walter, presented at the IPAC-RS Conference: *“Doing the Right Thing” in the Changing Culture of Design and Development of Inhalation and Nasal Drug Products: Science, Quality, and Patient-Focus*, Bethesda North Marriott Hotel and Conference Center, Bethesda, MD, September 22-24, 2008.
106. “Tackling the Extractables and Leachables Challenge: Phase Appropriate, Risk-based Extractables/Leachables Management”, C. Stults, B. Falco, M. Coates, J. Creasey, D. Dohmeier, A. Feilden, S. Kaar, J. Mullis, L. Nagao, D. Norwood, G. Reckzuegel, B. Redler, A. Rignall, C. Snodgrass-Pilla, and X-M. Zeng, presented at the IPAC-RS Conference: *“Doing the Right Thing” in the Changing Culture of Design and Development of Inhalation and Nasal Drug Products: Science, Quality, and Patient-Focus*, Bethesda North Marriott Hotel and Conference Center, Bethesda, MD, September 22-24, 2008.
107. “Considerations for Outsourcing of Leachables and Extractables Pharmaceutical Development Programs”, D. L. Norwood, invited presentation at the Intertech Pira conference: *Extractables and Leachables*, Bethesda North Marriott Hotel and Conference Center, Bethesda, MD, September 24-26, 2008.
108. “Extractables and Leachables in Orally Inhaled and Nasal Drug Products”, D. L. Norwood, invited presentation at the *Rubber Mini Expo, 174th Technical Meeting* of the American Chemical Society Rubber Division, Louisville, KY, October 14-16, 2008.
109. “Leachables and Extractables in Solid Dosage Forms”, D. L. Norwood, invited presentation at the Monday Afternoon Roundtable *Leachables and Extractables in Solid Dosage Forms*, 2008 AAPS Annual Meeting and Exposition, Atlanta, GA, November 17, 2008.
110. “Leachables and Extractables in Pharmaceutical Development”, D. L. Norwood and J. O. Mullis (course leaders), Short Course presented at the *2008 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 19, 2008.
111. “Challenges in the Determination of Water Content by Karl Fischer Titration during In-process Control”, Q. Chen, Y. Wang, C. Manolescu, J. McCaffrey, and D. Norwood, presented at the *2008 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 19, 2008.
112. “Ion Mobility Spectrometry – Developing and Validating a Cleaning Verification Method for a High Molecular Weight Analyte,” A. T. Granger, C. Qin, J. McCaffrey, and D. L. Norwood,

- presented at the *2008 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 19, 2008.
113. "Evaluation of Ionic Liquid as Stationary Phase in Supercritical Fluid Chromatography", Y. Wang, N. Grinberg, Q. Chen, C. Manolescu, J. McCaffrey, and D. L. Norwood, presented at the *2008 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 19, 2008.
 114. "Versatility of the BI-rich Extraction for the Trace Analyses of Genotoxic Impurities", A. Birch, K. B. McKellop, J. Ubben, F. Qiu, and D. L. Norwood, presented at the *2008 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 19, 2008.
 115. "Quantitation of a Potentially Genotoxic Impurity in a New Drug Substance Using ESI LC-MS/MS", C. Qin, F. Qiu, J. McCaffrey, and D. L. Norwood, presented at the *2008 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 19, 2008.
 116. "Identification of an Unknown Impurity in a Drug Substance by SPE, HPLC/MS and NMR", A. T. Granger, C. Qin, F. Qiu, P. –J. Jones, S. Campbell, and D. L. Norwood, presented at the *2008 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 19, 2008.
 117. "Identification of a Class of Interaction Products in Tipranavir Drug Product", F. Qiu, A. Granger, C. Busacca, S. Campbell, A. Saha, Z. Yuabova, D. Norwood, and P. –J. Jones, presented at the *2008 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 19, 2008.
 118. "Ion Mobility Spectrometry - Applications in Cleaning Verification and Potential for Pharmaceutical Analysis", C. Qin, A. Granger, J. McCaffrey, and D.L. Norwood, presented at the *9th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council, Hartford Convention Center, Hartford, CT, April 28-29, 2009.
 119. "Investigation of Chiral Separation by GC using Chirasil-Val as Stationary Phase", Q. Chen, N. Grinberg, S. Ma, J. Lorenz, S. Kapadia, Y. Wang, C. Manolescu, H. Lee, S. Shen, J. McCaffrey, and D. Norwood, presented at the *9th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council, Hartford Convention Center, Hartford, CT, April 28-29, 2009.
 120. "Effect of Ionic Liquid Anions on the Retention of Naphthalene Derivatives in SFC", Y. Wang, N. Grinberg, Q. Chen, C. Manolescu, J. McCaffrey, and D. L. Norwood, presented at the *9th Annual Csaba Horvath Medal Award Symposium*, Connecticut Separation Science Council, Hartford Convention Center, Hartford, CT, April 28-29, 2009.
 121. "Study and Characterization of Crystalline Hydrate and Polymorph Forms of a Reverse Transcriptase Inhibitor by Solid-State NMR Spectroscopy", N.C. Gonnella, J. Smoliga, S. Campbell, C. Busacca, D. L. Norwood, M. Cerreta, Genentech and R. Varsolona, presented at the *51st Rocky Mountain Conference on Analytical Chemistry*, Snowmass Conference Center, Snowmass, Colorado, July 19–23, 2009.
 122. "³¹P Solid-State NMR Study of Structure and Chemical Stability of Dichlorotriphenylphosphorane", N. C. Gonnella, C. Busacca, S. Campbell, M. Eriksson, N. Grinberg, T. Bartholomeyzik, S. Ma and D. L. Norwood, presented at the *51st Rocky Mountain Conference on Analytical Chemistry*, Snowmass Conference Center, Snowmass, Colorado, July

19–23, 2009.

123. “The Evolving Regulatory Landscape for Extractables and Leachables”, D. L. Norwood, presented at the *41st Manufacturing Controls Seminar: Taking a Deeper Look*, Consumer Healthcare Products Association, The Westin Governor Morris, Morristown, New Jersey, October 6-7, 2009.
124. “Best Practices for Extractables and Leachables Pharmaceutical Development Studies: PQRI and Beyond”, D. L. Norwood, presented at *Extractables and Leachables 2009 – Strategies to Ensure Safety and Compliance in the Packaging and Processing of Drugs and Biologics*, PharmaEd Resources, Inc., Radisson-Plaza Warwick, Philadelphia, Pennsylvania, October 26-27, 2009.
125. “Leachables and Extractables in Pharmaceutical Development”, D. L. Norwood and J. O. Mullis (course leaders), Short Course presented at the *2009 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 16, 2009.
126. “Effect of Ionic Liquid Ions on the Retention of Naphthalene Derivatives in SFC”, Y. Wang, N. Grinberg, Q. Chen, C. Manolescu, J. McCaffrey and D. L. Norwood, presented at the *2009 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 16, 2009.
127. “Comparison of Various Techniques for use in Cleaning Verification Analysis”, A. T. Granger, C. Qin, J. McCaffrey and D. L. Norwood, presented at the *2009 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 16, 2009.
128. “Safety Thresholds and Best Practices for Extractables and Leachables in OINDP: A PQRI Success Story”, D. L. Norwood and L. M. Nagao, presented at the *PQRI Conference on Advancing Drug Product Quality and Development*, Hilton Executive Meeting Center, Rockville, Maryland, December 15-16, 2009.
129. “Best Practices for Extractables and Leachables Pharmaceutical Development Studies: PQRI and Beyond”, D. L. Norwood, presented at *Extractables and Leachables 2010 – Strategies to Ensure Safety and Compliance in the Packaging and Processing of Drugs and Biologics*, PharmaEd Resources, Inc., Radisson Hotel Fisherman’s Warf, San Francisco, California, May 3-4, 2010.
130. “The Regulatory Environment for Extractables and Leachables – implications for packaging technology”, D. L. Norwood, presented at the *2nd Annual Pharma Packaging and Labeling USA* conference, VIBpharma, Hilton Philadelphia City Avenue, Philadelphia, Pennsylvania, May 18-19, 2010.
131. “Strategies for Minimizing Risk in Selecting a Container Closure System”, D. L. Norwood, presented at *2010 PDA/FDA Joint Regulatory Conference; Post-Conference Extractables and Leachables Workshop*, Parenteral Drug Association, Renaissance Hotel, Washington, DC, September 15-16, 2010.
132. “Study and Characterization of Crystalline Hydrate and Polymorph Forms of a Reverse Transcriptase Inhibitor by Solid State NMR Spectroscopy”, N. C. Gonnella, S. Campbell, J. A. Smoliga, D. L. Norwood, C. A. Busacca, M. Cerreta and R. Varsolona, presented at the *240th ACS National Meeting*, Boston, MA, August 22-26, 2010.

133. “Leachables and Extractables: A History Lesson”, D.L. Norwood, presented at the 31st Annual Meeting of the American College of Toxicology, Continuing Education Course No. 10, *Leachables and Extractables: Best Practices to Identify and Qualify Leachables in Drug Products*, Baltimore, MA, November 7, 2010.
134. “Leachables and Extractables in Pharmaceutical Development”, D. L. Norwood and J. O. Mullis (course leaders), Short Course presented at the *2010 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 17, 2010.
135. “Unique Degradation Chemistry in Complex Formulations of Self-Emulsifying Drug Delivery Systems (SEDDS)”, F. Qiu, S. Pennino, and D. L. Norwood, presented at the *2010 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 18, 2010.
136. “Integrative Toxicology/AET Concept”, D. L. Norwood, presented at the *PQRI Workshop on Safety Thresholds and Best Practices for Parenteral and Ophthalmic Drug Products*, Bethesda, MD, February 22-23, 2011.
137. “Controlled Extraction Study on Cyclic Olefin Copolymer (COC)”, prepared by S. Pennino and D. L. Norwood on behalf of the PQRI PODP Working Group, presented at the *PQRI Workshop on Safety Thresholds and Best Practices for Parenteral and Ophthalmic Drug Products*, Bethesda, MD, February 22-23, 2011.
138. “Brief Overview of PQRI Recommendations: Challenges and Successes”, D. L. Norwood, presented at the 2011 IPAC-RS Conference, *Bringing Value to the Patient in a Changing World*, Workshop: *Leachables and Extractables (Experience to Date with PQRI Recommendations (Qualification and Analytical Evaluation Thresholds))*, Bethesda, Maryland, USA, March 29-31, 2011.
139. “Trace Organic Analysis: Cutting Edge Applications”, D. L. Norwood (session organizer and chair), presented at *CoSMoS 2011* (Conference on Small Molecule Science), The Carolina Inn, Chapel Hill, NC, August 1-3, 2011.
140. “The Future of Trace Organic Analysis”, D. L. Norwood (workshop organizer and chair), presented at *CoSMoS 2011* (Conference on Small Molecule Science), The Carolina Inn, Chapel Hill, NC, August 1-3, 2011.
141. “Managing Materials, Component and Drug Product Quality”, D. L. Norwood, presented as a part of the *ELSIE Symposium: Practical Solutions to Address the Impact of Extractables and Leachables on Materials, Manufacturing Processes and Packaging*, ISPE Boston Area Chapter: *20th Annual Product Show*, Gillette Stadium Clubhouse, Foxborough, MA, October 5, 2011.
142. “The Union Between Drugs and Packaging – Managing Leachables and Extractables”, D. L. Norwood, presented at the *2nd Annual Pharmaceutical/Medical Packaging Leadership Summit*, sponsored by Opal Events, Baltimore Marriott Inner Harbor at Camden Yards, Baltimore, MD, November 7-8, 2011.
143. “Chemistry Considerations in Selection and Qualification of Materials for Parenteral Drug Products”, D. L. Norwood, presented at *Parenteral Packaging Strategies for Drug Developers*, sponsored by HansonWade, Hilton Garden Inn Philadelphia Hotel, Philadelphia, PA, January 31-February 2, 2012.

144. “The Pharmaceutical Packaging Supply-chain: Dealing with Security”, D. L. Norwood, presented at *4th Annual Pharma Packaging and Labelling USA Conference*, sponsored by Arena International Events Group, Hilton Philadelphia City Avenue, Philadelphia, PA, February 28-29, 2012.
145. “Application of Automated Solid Phase Extraction (SPE) LC/NMR and Solid State NMR (SSNMR) to Extractables Profiling”, D. L. Norwood, J. O. Mullis, M. Davis, T. Egert and N. C. Gonnella, presented at the Smithers Rapra Conference: *Extractables and Leachables USA 2012*, Baltimore, MD, May 15-17, 2012. (Also see *Extractables and Leachables USA 2012 Conference Proceedings*, Paper 11).
146. “Structure Elucidation of a Process Impurity in a P38 Map Kinase Inhibitor Drug Substance Using LC/MS and NMR”, S. Campbell, F. Qiu, A. Granger, D. L. Norwood, Z. Tan and J. Song, presented at the *2012 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 12, 2012.
147. “Application of LC-NMR and Solid-State NMR to the Problem of Container Closure Extractables”, J. O. Mullis, M. Davis, T. Egert, N. C. Gonnella, S. Rodriguez and D. L. Norwood, presented at the *2012 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 12, 2012.
148. “Extractables and Leachables Studies for Biologicals and Other ‘High Risk’ Dosage Forms”, D. L. Norwood and T. N. Feinberg (course leaders), Short Course presented at the *2012 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 12, 2012.
149. “Selection and Characterization of Packaging Components and Materials of Construction to Reduce the Potential for Extractables/Leachables Problems in Marketed Drugs”, D. L. Norwood, presented at *Pharma Packaging and Labelling USA*, sponsored by Arena International Events Group, Hilton Philadelphia City Avenue, Philadelphia, PA, February 26-27, 2013.
150. “The United States Pharmacopeia and the Issue of Leachables and Extractables: Past, Present and Future”, D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables USA 2013*, Providence, RI, May 8-9, 2013.
151. “The United States Pharmacopeia and the Issue of Leachables and Extractables: Past, Present and Future”, D. L. Norwood, presented at the Satorius Stedim: *Extractables/Leachables Forum*, San Diego, CA, May 22-23, 2013.
152. “The Materials Supply-Chain for Pre-Filled Syringes: Learnings from the World of Inhalation Drug Products”, D. L. Norwood, presented at the HansonWade: *3rd Annual Pre-Filled Syringes Summit*, Arlington, VA, September 24-26, 2013.
153. “Selectivity of Chloride Ion Attachment in Negative-Ion Atmospheric-Pressure Chemical Ionization LC-MS with Applications to Pharmaceutical Development”, K. B. McKellop, S. Pennino, S. A. Rodriguez and D. L. Norwood, presented at the *2013 Eastern Analytical Symposium*, Garden State Exposition Center, Summerset, NJ, November 18, 2013.
154. “Goals and Objectives, <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems”, D. L. Norwood, presented at the *USP-PQRI Co-Sponsored Workshop on Suitability and Compatibility for Packaging and Delivery Systems*, USP Meeting Center, Rockville, MD, December 9, 2013.

155. “<1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems”, D. L. Norwood, presented at the *USP-PQRI Co-Sponsored Workshop on Suitability and Compatibility for Packaging and Delivery Systems*, USP Meeting Center, Rockville, MD, December 9, 2013.
156. “AET Models for Parenteral and Ophthalmic Drug Products”, D. L. Norwood, S. Pennino and M. Ruberto, presented at the *USP-PQRI Co-Sponsored Workshop on Suitability and Compatibility for Packaging and Delivery Systems*, USP Meeting Center, Rockville, MD, December 9, 2013.
157. “United States Pharmacopeia: USP Packaging Standards: Update”, D. L. Norwood, presented at *Pharma Packaging and Labelling USA*, sponsored by Arena International Events Group, Hilton Philadelphia City Avenue, Philadelphia, PA, February 26-27, 2014.
158. “Analysis of Extractables and Leachables: Past, Present and Future Trends”, D. L. Norwood, presented at *Extractables, Leachables, & Elemental Impurities 2014 Ensuring Quality, Safety, and Regulatory Compliance for Drugs & Biologics* sponsored by PharmaEd Resources, Racquet Club of Philadelphia, PA, March 24-25, 2014.
159. “A Knowledge Based Approach to Extraction Studies”, D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables USA 2014*, Silver Spring, MD, May 7-9, 2014.
160. “USP Update on Extractables and Leachables”, D. L. Norwood, presented at the *2014 PDA Packaging Conference*, Washington Marriott Wardman Park, Washington, DC, May 20-21, 2014.
161. “Leachables Evaluation and USP Guidance”, D. L. Norwood, presented at the HansonWade: *4th Annual Pre-Filled Syringes Summit*, Arlington, VA, September 2-4, 2014.
162. “Analysis of Extractables and Leachables: Past, Present and Future Trends”, D. L. Norwood, presented at *Extractables, Leachables, & Elemental Impurities 2014 Ensuring Quality, Safety, and Regulatory Compliance for Drugs & Biologics* sponsored by PharmaEd Resources, Sheraton La Jolla, CA, September 15-16, 2014.
163. “Extractables and Leachables Assessment: Consensus Scientific Best Practices”, D. L. Norwood, presented at the *Forum for Infusion Packaging Development 2014* sponsored by the China National Pharmaceutical Packaging Association, Qingdao, People’s Republic of China, September 17-19, 2014.
164. “Current Regulatory Initiatives Related to Packaging and Packaging Related Drug Product Impurities”, D. L. Norwood, presented at *Barrier Pharma Packaging 2014* sponsored by AMI, Princeton, NJ, October 14-15, 2014.
165. “The United States Pharmacopeia Strategic Plan for Leachables and Extractables”, D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables USA 2015*, Bethesda, MD, May 12-14, 2015.
166. “What is the Future of Extractables and Leachables Assessment”, D. L. Norwood, presented at *CoSMoS 2015* (Conference on Small Molecule Science), San Diego, CA, August 17-19, 2015.
167. “Report on the Revision Process for USP Biocompatibility General Chapters <87>, <88>, and <1031>”. D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and*

Leachables USA 2016, Bethesda, MD, May 9-11, 2016.

168. “Expectations and Goals for the <87> and <88> Workshop”, presented at the *USP Sponsored Workshop on Revision of Chapters <87>/<88> Biological Reactivity and Establishing a Standardized Extractable Procedure for Plastic Manufacturing Components and Systems*, USP Meeting Center, Rockville, MD, June 20-21, 2016.
169. “Revision Process for USP Biocompatibility General Chapters <87>, <88> and <1031>”, D. L. Norwood, presented at the *Forum for Injection and Packaging Development 2016* sponsored by the China National Pharmaceutical Packaging Association, Qingdao, People’s Republic of China, September 7-9, 2016.
170. “Extractables Assessments for Infusion Drug Products”, D. L. Norwood, presented at the *Forum for Injection and Packaging Development 2016* sponsored by the China National Pharmaceutical Packaging Association, Qingdao, People’s Republic of China, September 7-9, 2016.

Note: Also Biological Reactivity Workshop Moderator.

171. “Extractables and Leachables Laboratory Assessments: From Research Project to Commodity”, D. L. Norwood and K. Comstock, presented at the Smithers Rapra Conference: *Extractables and Leachables USA 2017*, Falls Church, VA, May 9-11, 2017.
172. “ENDS Testing: Extending Extractables and Leachables Knowledge from Pharmaceutical Products”, D. L. Norwood, presented at the Smithers Rapra Conference: *ENDS 2017*, London, United Kingdom, June 14-15, 2017.

Note: Also ENDS 2017 Chair.

173. **Vimta Invited Lecture Tour of India**, “*Extractables, Leachables, Elemental Impurities & Safety Assessment – 2017*”, 9th October Ahmedabad, 10th October Mumbai, 11th October Hyderabad.

“Best Practices for the Design and Conduct of Extractables/Leachables Studies (based on USP<1663> and <1664>)”

“USP Guidance & Standards for Packaging Systems”

“Guidance & Standards for Elemental Impurities (USP<232> and ICH Q3D)”
174. “Smithers Essentials: Extractables and Leachables Fundamentals”, *Smithers Rapra training course*, D. L. Norwood, P. Cummings, A. Schweda, Cleveland, OH, October 17-18, 2017.
175. “Testing Components and Parts, E-Liquid Tobacco, Liquid Nicotine, Flavors and Aromas”, D. L. Norwood, presented at the Smithers Rapra Conference: *ENDS US2017*, Alexandria, Virginia, December 5-6, 2017.
176. “Analytical Technologies and Compound Identification”, D. L. Norwood, presented at the *PQRI PODP Extractables and Leachables Workshop*, Rockville, MD, April 18-19, 2018.
177. “Designing an Extractables and Leachables Program for Regulatory Submission”, A. Feilden and D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables USA 2018*, Bethesda, MD, May 7-9, 2018.

178. “Guidance and Standards for Elemental Impurities,” Smithers Rapra Webinar, presented live June 14, 2018.
179. “An Introduction to E&L”, A. Feilden and D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables China 2018*, Beijing, China, September 11-12, 2018.
180. “The Product Quality Research Institute: Almost Two Decades of Progress on Extractables and Leachables”, D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables China 2018*, Beijing, China, September 11-12, 2018.
181. “Update on US Regulations”, C. Stults, D. L. Norwood and D. Jenke, presented at the Smithers Rapra Conference: *Extractables and Leachables China 2018*, Beijing, China, September 11-12, 2018.
182. “Smithers Essentials: Extractables and Leachables Fundamentals”, *Smithers Rapra training course*, D. L. Norwood, P. Cummings, A. Schweda, Akron, OH, October 24-25, 2018.
183. “Elemental Impurities: Not Just a Safety Issue”, D. L. Norwood, presented at the *Extractables, Leachables, & Elemental Impurities 2018—West Coast - Ensuring Quality, Safety, and Regulatory Compliance for Drugs & Biologics*, PharmaEd Resources, Inc., La Jolla, CA, November 13-14, 2018.
184. “Analytical Challenges in Screening Extracts and/or Drug Products for Organic Extractables and Leachables”, D. L. Norwood, presented at the *Pittcon Conference and Expo 2019, Session 780, Extractables and Leachables Analysis*, Philadelphia, PA, March 19, 2019.
185. “Revisiting the PQRI/USP Identification Categories for Leachables and Extractables”, D. L. Norwood, presented at the *Extractables & Leachables Boston 2019 - Ensuring Quality, Safety, Suitability and Regulatory Compliance for Drugs, Biologics and Medical Devices*, PharmaEd Resources, Inc., Boston, MA, April 10-11, 2019.
186. “Chemical Safety Qualification and Biocompatibility of Packaging Systems and Medical Devices “An Analytical Chemistry Perspective”, D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables USA 2019*, Arlington, VA, May 7, 2019.
187. “Commentary on the Past Twelve Years of Implementing the PQRI Leachables and Extractables Recommendations for OINDP”, D. L. Norwood, presented at the *Inhalation Drug Delivery Systems 2019 - Ensuring Quality, Safety and Regulatory Compliance for Inhalation Drug Delivery Systems*, PharmaEd Resources, Inc., Boston, MA, May 28-29, 2019.
188. “Extractables and Leachables” “Master Class”, M. Creese and D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables China 2019*, Shanghai, China, September 23-25, 2019.
189. “Challenges and Examples of Identifying Unknown Extractables/Leachables: What is an Unknown?”, D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables China 2019*, Shanghai, China, September 23-25, 2019.
190. “Revisiting the PQRI/USP Identification Categories for Leachables and Extractables”, D. L. Norwood, presented at the *Extractables & Leachables West Coast Ensuring Quality, Safety, Suitability and Regulatory Compliance for Drugs, Biologics and Medical Devices*, PharmaEd Resources, Inc., La Jolla, CA, November 18, 2019.

191. “Standard Methods for Extractables/Leachables Profiling: What are the Implications?”, D. L. Norwood, *Extractables & Leachables Summit 2020; Ensuring Quality, Safety, Suitability and Regulatory Compliance for Drugs, Biologics and Medical Devices*, **Extractables & Leachables Virtual Summit**, PharmaEd Resources, Inc., July 30-31, 2020.
192. “Challenges in E&L Profiling: Identification”, D. L. Norwood, presented at the Smithers Rapra Conference: *Extractables and Leachables China 2020*, Shanghai, China, December 9-10, 2020.
193. “Evaluation of Optimal Extraction Conditions for Polypropylene, PBT Resins, and Chlorobutyl Rubber Elastomer – Using a Variety of Solvents and Extraction Conditions,” Biopharma Webinars, presented live October 4, 2023.
194. “Solvent Selection for Controlled Extraction Studies of Pharmaceutical Packaging,” Biopharma Webinars, presented live February 7, 2024.