Ann W. Newman, Ph.D. PO Box 251 Kure Beach NC 28449 phone: 765-650-4462 e-mail: ann.newman@seventhstreetdev.com www.SeventhStreetDev.com



Profile	Senior pharmaceutical scientist with demonstrated scientific and leadership expertise in the pharmaceutical industry based on over 20 years of large pharma and contract research experience. Strong knowledge base in pharmaceutical sciences including problem-solving, drug development, solid state chemistry (polymorphs, salts, cocrystals, amorphous, dispersions), crystallization, physical characterization (active pharmaceutical ingredients (API), excipients, and drug products), preformulation studies, process-induced transformations, current Good Manufacturing Practices (cGMP), regulatory, and intellectual property (IP).
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EducationPh.D., Inorganic Chemistry, University of Connecticut, Storrs, CTB.S., Chemistry and Medical Technology, SUNY at Fredonia, Fredonia, NY

### Professional

**Experience** Seventh Street Development Group, Lafayette, IN Pharmaceutical Consultant 2009-present

- Provide consulting, training, and webcast services on solid-state pharmaceutics and pharmaceutical development.
- Projects include solid form characterization and quantitation, screening (polymorphs, salts, cocrystals, amorphous dispersions), crystallization of Phase I materials, process induced transformations, compilation of information for intellectual property documentation

**Crystal Pharmatech**, New Brunswick, NJ Vice President, Scientific Development 2012-2017

Provide scientific and business expertise for internal and external projects

Aptuit, West Lafayette, IN

Vice President, R&D 2007–2008

(Aptuit purchased SSCI in Oct. 2006)

- Developed and implemented new global research and development function within company covering both scientific and clinical operations over six sites.
- Responsible for overseeing system with over 70 R&D projects and over 80 people participating in R&D projects. Scientific areas included API, preclinical (toxicology, safety, pharmacokinetics), formulation, solids, analytical, clinical packaging, and regulatory.
- Chaired the Technical Development Committee consisting of scientific leaders of the company.
- Worked with Scientific Advisory Board and Technical Development Committee to perpetuate innovation within the company.
- Codeveloped initial Aptuit INDiGO<sup>™</sup> fast to IND offering based on internal R&D project.

SSCI, Inc., West Lafayette, IN Vice President, Materials Science 1998–2007
 Played an integral role in the rapid growth of the company, including staffing, systems design and implementation, client development, technical output, and scientific innovation.

- Interfaced with clients on scientific and regulatory issues as well as client problems.
- Planned and supervised scientific projects including solid form screens and selection (polymorphs, salts, cocrystals, amorphous, amorphous solid dispersions), physical characterization, crystallization, crystal form quantitation, and process chemistry.
- Provided short courses and training for employees and client companies.

Bristol-Myers Squibb, New Brunswick, NJ

Principal Scientist	1998
Senior Research Investigator II	1994–1998
Senior Research Investigator I	1990–1994
Research Investigator	1988-1990

- Responsible for physical characterization function in the Bristol-Myers Squibb Pharmaceutical Research Institute, including support of crystal form/salt selection, bulk drug scale-up, and formulation development. Scope included late Drug Discovery through Phase IV, as well as marketed products when needed.
- Provided characterization assistance and expertise to other divisions (Legal, Technical Operations, Apothecon, Bristol-Myers Products, Convatec) when needed.
- Provided written documentation on physical characterization of selected crystal form for IND and NDA filings and summary reports for crystal form/salt selection.
- Represented group and inter and intra-departmental meetings, as well as external conferences.

Academic Experience	<ul> <li>Purdue University, West Lafayette, IN</li> <li>Served on doctoral graduate student com</li> <li>Guest lecturer in undergraduate and grad</li> </ul>	•	2000–present jects
		rm lecturer for IPPH 362 Basic Pharmaceutics: Solution Dosage Forms	
	<ul><li>Rutgers University, New Brunswick, NJ</li><li>Served on doctoral graduate student com</li></ul>	Outside Examiner mittees	1992-1997

# Training

Experience	Seventh Street Development Group, Lafayette, IN		
	<ul> <li>Seventh Street Development Group Live Webcasts</li> </ul>	2009-2017	
	<ul> <li>Seventh Street Development Group On Demand Webcasts</li> </ul>	2009-2017	
	<ul> <li>AAPS On-Demand Webcast Course "Preformulation 101"</li> </ul>	2015-2017	
	<ul> <li>ACS Webcast Series "Polymorphism in Organic/Pharmaceutical Systems"</li> </ul>	2009-2014	
	ACS On Demand Webcast Course "Solid State Characterization of Organic Com	pounds" <i>2011-17</i>	
	On-site Short Course "Solid State Characterization of Pharmaceutical Solids	2010, 2013, 2016	
	<ul> <li>On-site Short Course "Amorphous and Amorphous Dispersions"</li> </ul>	2011, 2013	
	<ul> <li>Web Training Course "Amorphous Pharmaceutical Materials"</li> </ul>	2020, 2021	
	<ul> <li>University of Wisconsin Professional Training Course (2.5 days)</li> </ul>	2014-2018	
	" Understanding, Characterizing, and Developing Amorphous Materials and Amorphous		
	Solid Dispersions"		
	Crystal Pharmatech and Scientific Update Training Course		
	"How to Identify the Optimal Solid-State Form for Pharmaceutical Development	nt <i>2014, 2016</i>	
	SSCI, West Lafayette, IN		
	<ul> <li>"Polymorphs and Solvates of Drugs Short Course"</li> </ul>	1997-2004	
	<ul> <li>"Process Analytical Technology (PAT) Short Course"</li> </ul>	2003	
	<ul> <li>"Particle Formation and Characterization Short Course"</li> </ul>	2000	

**Publications** Author on over 60 technical publications, presenter/collaborator for over 100 presentations, and presenter for over 60 webcasts.

**Affiliations** American Chemical Society (ACS), American Association of Pharmaceutical Scientists (AAPS); Special Editor for Journal Pharmaceutical Sciences Special Issue for Steve Byrn; 2011-2018 Planning Committee for June Land O'Lakes Conference; Cambridge Who's Who.

## Books

"Pharmaceutical Amorphous Solid Dispersions" A. Newman, editor. Wiley and Sons, New York, 2015.

## Publications

"Perspective: What We Need to Know about Solid-State Isothermal Crystallization of Organic Molecules from the Amorphous State below the Glass Transition Temperature" A. Newman, G. Zografi. *Mol Pharm.* **2020**, *17*, 1761-1777.

"Commentary: Considerations in the Measurement of Glass Transition Temperatures of Pharmaceutical Amorphous Solids" A. Newman, G. Zografi. *AAPS PharmSciTech*, **2019**, *21*, 26

"Chapter 6 Hygroscopicity and Hydrates in Pharmaceutical Solids", S.M. Reutzel-Edens, D.E. Braun, A.W. Newman in *Polymorphism in the Pharmaceutical Industry: Solid Form and Drug Development*, Wiley, Weinheim, **2019**, 159-188.

"An Examination of Water Vapor Sorption by Multi-Component Crystalline and Amorphous Solids and Its Effects on their Solid-State Properties" A. Newman, G. Zografi. *J Pharm Sci*, **2019**, *108*, 1061–1080.

"Chapter 3 Solid-state Characterization Techniques" A. Newman, R. Wenslow in *Pharmaceutical Crystals: Science and Engineering*, Wiley, New York, **2018**, 89-121.

"Chapter 10 Salt and Cocrystal Screening" A. Newman, C. Chen, C. Sanrame in *Early Drug Development: Bringing a Preclinical Candidate to the Clinic*, Wiley, New York, **2018**, 229-270.

"Coamorphous Active Pharmaceutical Ingredient–Small Molecule Mixtures: Considerations in the Choice of Coformers for Enhancing Dissolution and Oral Bioavailability" A. Newman, S. Reutzel-Edens, G. Zografi. *J Pharm Sci*, **2018**, *107*(1), 5-17.

"New Directions in Pharmaceutical Amorphous Materials and Amorphous Solid Dispersions, A Tribute to Professor George Zografi- Proceedings of the June 2016 Land O'Lakes Conference" A. Newman, J.E. Hastedt, M Yazdanian. *AAPS Open*, **2017**, *3*(7), 1-14.

"Chapter 18 Rational Design of Amorphous Solid Dispersions" A. Newman in *Developing Solid Oral Dosage* Forms, 2<sup>nd</sup> Edition, Academic Press, London, **2017**, 497-518.

"Interrelationships Between Structure and the Properties of Amorphous Solids of Pharmaceutical Interest" G Zografi, A. Newman. *J Pharm Sci.* **2017**, 106, 5-27.

"Solid Form Changes During Drug Development: Good, Bad, and Ugly Case Studies" A. Newman, R. Wenslow. AAPS Open. **2016**, 2:2 (DOI 10.1186/s41120-016-0003-4).

"Drug Development- Don't Overlook Key Preclinical Research" R. Wenslow, A. Newman. *Drug Dev. Deliv.* **2016**, *16(3)*, 66-72.

"Chapter 1. Introduction to Amorphous Solid Dispersions" G. Zografi, A. Newman in *Pharmaceutical Amorphous Solid Dispersions*, Wiley, New York, 2015, 1-42.

"Chapter 3. Amorphous Solid Dispersion Screening" A. Newman in *Pharmaceutical Amorphous Solid Dispersions*, Wiley, New York, 2015, 85-116.

"Amorphous Solid Dispersions: A Robust Platform to Address Bioavailability Challenges" A. Newman, K. Nagapudi, R. Wenslow. *Therapeutic Delivery*. **2015**, *6*, 247-261.

"Critical Considerations for the Qualitative and Quantitative Determination of Process-Induced Disorder in Crystalline Solids" A. Newman, G. Zografi. *J. Pharm. Sci.* **2014**, *103(9)*, 2595-2604.

"States of Matter Related to Pharmaceutical Formulations" B.J. Sandman, A. Newman, G. T. Knipp. in *Applied Physical Pharmacy*, 2nd Edition, McGraw Hill Education, New York, **2014**, 15-39.

"Specialized Solid Form Screening Techniques" A. Newman. Org. Proc. Res. Dev. 2013, 17, 457-471.

"Characterizing Miscibility in Amorphous Solid Dispersions" A. Newman, E. Munson. Amer. Pharm. Rev. 2012, April, 92-98.

"Commentary: Assessing the Performance of Amorphous Solid Dispersions" A. Newman, G. Knipp, G. Zografi. J. Pharm. Sci. **2012**, 101(4), 1355-1377.

"X-ray Powder Diffraction in Solid Form Screening and Selection" A. Newman. Amer. Pharm. Rev. 2011, Sept/Oct, 44-51.

"A Solid-State Approach to Enable Early Development Compounds: Selection and Animal Bioavailability Studies of an Itraconazole Amorphous Solid Dispersion" D. Engers, J. Teng, J. Jimenez-Novoa, P. Gent, S. Hossack, C. Campbell, J. Thomson, I. Ivanisevic, A. Templeton, S. Byrn, A. Newman. *J. Pharm. Sci.*, **2010**, *99*(*9*), 3901-3922.

"Pharmaceutical Cocrystals and Their Physicochemical Properties" N. Schultheiss, A. Newman. Cryst. Growth Des., 2009, 9(6), 2950-2967.

"Characterization of API:Polymer Mixtures Using X-ray Powder Diffraction" A. Newman, D. Engers, S. Bates, I. Ivanisevic, R. C. Kelly, G. Zografi, *J. Pharm. Sci.*, **2008**, *97*(*11*), 4840-4856.

"Minireview: Characterization of the "Hygroscopic" Properties of Active Pharmaceutical Ingredients" A. W. Newman, S. M. Reutzel-Edens, G. Zografi, *J. Pharm. Sci.*, **2008**, *97(3)*, 1047-1059.

"Salt Cocrystal Form Selection" A. W. Newman, S. L. Childs, B. A. Cowans, in *Preclinical Development Handbook*, John Wiley and Sons, Hoboken, **2008**, 455-481.

"Assessment of Defects and Amorphous Structure Produced in Raffinose Pentahydrate upon Dehydration" S. Bates, R. Kelly, P. Schields, I. Ivanesvic, G. Zografi, A. W. Newman, *J. Pharm. Sci.*, **2007**, *96*(5), 1418-1433.

"Relationship of Triboelectric Charging and Dielectric Properties of Pharmaceutically-Relevant Mixtures" D.A. Engers, M.N. Fricke, A.W. Newman, and K.R. Morris, *J. Electrostat.*, **2007**, *65*, 571-581.

"Thermal Microscopy" I. M. Vitez, A. W. Newman, in *Thermal Analysis of Pharmaceuticals*, CRC Press, Boca Raton, **2007**, 221-264.

"PAT – Process Understanding and Control of Active Pharmaceutical Ingredients" S. R. Byrn, J. K. Liang, S. Bates, Ann W. Newman, *Journal of PAT*, **2006**, *3(6)*, 14-19.

"Analysis of Amorphous and Nanocrystalline Solids from Their X Ray Diffraction Patterns" S. Bates, G. Zografi, D. Engers, K. Morris, K. Crowley, A. Newman, *Pharm. Res.*, **2006**, *23*(*10*), 2333-2349.

"Triboelectrification of Pharmaceutically-Relevant Powders During Low-Shear Tumble Blending" D. A. Engers, M. N. Fricke, R. P. Storey, A. W. Newman, and K. R. Morris, *J. Electrostat.*, **2006**, *64*, 826-835. *AW Newman Seventh Street Development Group page 4 of 15*  "The Physical Characterization of Hygroscopicity in Pharmaceutical Solids" S. M. Reutzel-Edens and A. W. Newman, in *Polymorphism*, Wiley-VCH, Weinheim, **2006**, 235-258.

"Solid-state Analysis of the Active Pharmaceutical Ingredient in Drug Products", A. W. Newman, S. R. Byrn, Drug Discovery Today, 2003, 8(19), 898-905.

"Form Selection of Pharmaceutical Compounds", A. W. Newman and G. P. Stahly, in *Handbook of Pharmaceutical Analysis*, Marcel Dekker, New York, **2002**, *vol. 117*, 1-57.

"Chemical Reactivity in Solid-State Pharmaceutics", S. R. Byrn, W. Xu, A. W. Newman, *Adv. Drug Delivery Rev.*, **2001**, *48*(1), 115-136.

"The Role of Powder X-Ray Diffraction as a Powerful Tool in Characterization of Various Hydrates of a Drug Substance", M. Davidovich, R. Mueller, K. Raghaven, S. Ranadive, I. Vitez, B. Sarsfield, J. DiMarco, J. Gougoutas, A. Newman, *Amer. Pharm. Rev.*, **2001**, *4*(1), 53-60.

"Sorbitol", A. W. Newman, I. M. Vitez, R. L. Mueller, C. Kiesnowski, M. Davidovich, W. P. Findlay, *Analytical Profiles of Drug Substances and Excipients,* Academic Press, New York, **1999**, *vol. 26*, 459-502.

"The Evolution of Hot Stage Microscopy to Aid Solid State Characterizations of Pharmaceutical Solids", I. M. Vitez, A. W. Newman, M. Davidovich, C. Kiesnowski, *Thermochimica Acta*, **1998**, *324*, 187-196.

"Physical Characterization of the Polymorphic Variations of Magnesium Stearate and Magnesium Palmitate Hydrate Species", S. A. Sharpe, M. Celik, A. W. Newman, H. G. Brittain, *Struct. Chem.*, **1997**, *8*, 73-84.

"Quantitation of Pseudopolymorphism in Cefepime.2HCl by Diffuse Reflectance IR and Powder X-ray Diffraction Techniques", D.E. Bugay, A. W. Newman, W. P. Findlay, *J. Pharm. and Biom. Anal.*, **1996**, *15*, 49-61.

"Starches and Starch Derivatives", A. W. Newman, I. M. Vitez, C. Kiesnowski, R. Mueller, in *Encyclopedia of Pharmaceutical Technology*, Marcel Dekker, New York, **1996**, *vol* 14, 223-248.

"Starch", A. W. Newman, I. M. Vitez, C. Kiesnowski, R. Mueller, D. E. Bugay, W. P. Findlay, C. Rodriguez, in *Analytical Profiles of Drug Substances and Excipients,* Academic Press, New York, **1996**, *vol* 24, 523-578.

"Particle Morphology: Optical and Electron Microscopies", A. W. Newman and H. G. Brittain, in *Physical Characterization of Pharmaceutical Solids*, H. G. Brittain, Ed., Marcel Dekker, New York, **1995**, 127-156.

"Micromeritics", A. W. Newman, in *Physical Characterization of Pharmaceutical Solids*, H. G. Brittain, Ed., Marcel Dekker, New York, **1995**, pp. 253-280.

"Talc", A. W. Newman, I. M. Vitez, P. Cortina, G. Young, J. DeVincentis, D. E. Bugay, T. Patel, *Analytical Profiles of Drug Substances and Excipients,* Academic Press, New York, **1994**, *vol 23*, 511-542.

"Characterization of Humidity-Dependent Changes in Crystal Properties of a New HMG-CoA Reductase Inhibitor in Support of its Dosage Form Development", K. R. Morris, D. E. Bugay, A. W. Newman, S. A. Ranadive, A. K. Singh, M. Szyper, S. A. Varia, H. G. Brittain, A. T. M. Serajuddin, *Int. J. Pharm.* **1994**, *108*, 195-206.

"An Integrated Approach to the Selection of Optimal Salt Form for a New Drug Candidate", K. R. Morris, M. G. Fakes, A. B. Thakur, A. W. Newman, A. K. Singh, J. J. Venit, C. J. Spagnuolo, A. T. M. Serajuddin, *Int. J. Pharm.* **1994**, 105, 209-217.

"Factors Affecting Differences in Film Thickness of Beads Coated in Fluidized Bed Units", R. Wesdyk, Y. M. Joshi, J. DeVincentis, A. Newman, N. B. Jain, *Int. J. Pharm*. **1993**, *93*, 101-109.

"Physical Interactions of Magnesium Stearate with Starch-Derived Disintegrants and Their Effects on Capsule and Tablet Dissolution", D. S. Desai, B. A Rubitski, S. A. Varia, A. W. Newman, *Int. J. Pharm.* **1993**, *91*, 217-226.

"Changes in Material Properties Accompanying the NF Identity Test for Microcrystalline Cellulose", H. G. Brittain, G. Lewen, A. W. Newman, K. Fiorelli, S. Bogdanowich, *Pharm. Res.* **1993**, *10*(*1*), 61-67.

"Titanium Dioxide", H. G. Brittain, G. Barbera, J. DeVincentis, A. W. Newman, *Analytical Profiles of Drug Substances and Excipients,* Academic Press, New York, **1992**, *vol 21*, pp. 659-691.

"Physical Characterization of Pharmaceutical Solids", H. G. Brittain, S. J. Bogdanowich, D. E. Bugay, J. DeVincentis, G. Lewen, A. W. Newman, *Pharm. Res.* **1991**, *8*(*8*), 963-973.

"Anhydrous Lactose", H. G. Brittain, S. J. Bogdanowich, D. E. Bugay, J. DeVincentis, G. Lewen, A. W. Newman, *Analytical Profiles of Drug Substances and Excipients,* Academic Press, New York, **1991**, *vol 20*, 369-398.

"The Effect of Size and Mass on Film Thickness of Beads Coated in Fluidized Bed Equipment", R. Wesdyk, N. Jain, Y. M. Yoshi, K. Morris, A. Newman, *Int. J. Pharm*. **1990**, *65*, 69-76.

"Relationship Between the Physical and Mechanical Properties of Wet Granulated Microcrystalline Cellulose Following Drying", M. Chatrath, J. N. Staniforth, A. Winiecki Newman, H. G. Brittain, *J. Pharm. Pharmacology* **1990**, *42*, 80P.

"Electrocatalytic Reactions in Organized Assemblies. 6. Electrochemical and Spectroscopic Studies of Catalytic Clay Micelle Electrodes", C. Shi, J. F. Rusling, Z. Wang, W. S. Willis, A. M. Winiecki, S. L Suib, *Langmuir* **1989**, *5*(*3*), 650-660.

"Chemical Stability of Aluminophosphate Molecular Sieves During Hydrochloric Acid Treatment", A. M. Winiecki, S. L. Suib, *Langmuir* **1989**, *5(2)*, 333-338.

"X-Ray Photoelectron Spectroscopy Investigations of Zeolites", A. M. Winiecki, S. L. Suib, M. L. Occelli, *Langmuir* **1988**, *4*(*3*), 512-518.

"Surface Chemical States of Aluminophosphate and Silicoaluminophosphate Molecular Sieves", S. L. Suib, A. M. Winiecki, A. Kostapapas, *Langmuir* **1987**, *3*(4), 483-488.

"Surface States of Aluminophosphate and Zeolite Molecular Sieves", S. L. Suib, A. M. Winiecki, A. Kostapapas, *Stud. Surf. Sci. Catal. Vol. 28*, Y. Murakawa, A. Iijima, J. W. Ward, Eds., Elsevier, Amsterdam, **1986**, 409-415.

"Photoassisted Catalysis in Organized Media: Olefin Isomerization via Photolysis of Metal Carbonyls in Zeolites", S. L. Suib, A. Kostapapas, K. C. McMahon, J. C. Baxter, A. M. Winiecki, *Inorg. Chem.* **1985**, *24*, 858-863.

# **Invited Presentations**

"Using Thermal Analysis to Characterize Amorphous Pharmaceutical Materials", A. Newman, invited talk at Rigaku Pharmalytical Summit, Virtual Conference, May 2021.

"Coamorphous Materials: What Are They and Are They Developable?" A. Newman, invited talk at Northeast Regional Discussion Group (NERDG), Hartford CT, April 2018. AW Newman Seventh Street Development Group page 6 of 15 "Process Induced Transformations: Why is My Form Changing?" A. Newman, invited talk at June Land O'Lakes Conference, University of Wisconsin Annual International Industrial Pharmaceutical Research and Development Conference on Material Sciences Based Approaches to Improving Drug Delivery Performance: From Discovery Through Manufacturing, Madison WI, June 2017.

"Amorphous Basics and Preparation of Amorphous Solids" A. Newman, invited talk at Amorphous Solids Short Course at Denver X-Ray Conference, Chicago IL, August 2016.

"Amorphous Solid Dispersions: Screening, Selection, and Scale-up" A. Newman, invited talk at University of Wisconsin Professional Development Course on Understanding, Characterizing, and Developing Amorphous Materials and Amorphous Solid Dispersions, Madison WI, May 2016.

"Using Polymorph Screening Information to Develop a Crystallization Process" A. Newman, invited talk at Scientific Update Process Development Conference, Barcelona Spain, September 2015.

"Amorphous Solid Dispersion: Screening, Selection, and Scale-up" A. Newman, invited talk at University of Wisconsin Professional Development Course on Understanding, Characterizing, and Developing Amorphous Materials and Amorphous Solid Dispersions, Madison WI, May 2015.

"XRPD to Characterize Disordered and Amorphous Pharmaceutical Samples" A. Newman, invited talk at IUCr 2014, Montreal, August 2014.

"Amorphous Solid Dispersion: Screening, Selection, and Scale-up" A. Newman, invited talk at University of Wisconsin Professional Development Course on Understanding, Characterizing, and Developing Amorphous Materials and Amorphous Solid Dispersions, Madison WI, April 2014.

"Form Screening and Selection" A. Newman, invited talk at the ACS ProSpectives 2013 International Conference on Pharmaceutical Solid State Research: Form, Function, Formulation, Suzhou China, October 2013.

"Case Studies on Solid Form Changes During Development" A. Newman, invited talk at the Scientific Update Conference on Organic Process Research and Development, Clearwater, FL, March 2013.

"Making Amorphous API" A. Newman, invited talk at the Understanding Pharmaceutical Amorphous Materials Workshop, 11th Pharmaceutical Powder Diffraction X-Ray Diffraction Symposium (PPXRD-11), Fort Myers, FL, May 2012.

"Using Thermal Techniques for Amorphous Materials" A. Newman, invited talk at the Understanding Pharmaceutical Amorphous Materials Workshop, 11th Pharmaceutical Powder Diffraction X-Ray Diffraction Symposium (PPXRD-11), Fort Myers, FL, May 2012.

"Quantifying Low Level Amorphous Content" A. Newman, invited talk at Almac and University of Cork Joint Workshop: Quantitative Analytical Methods for the Solid State, Cork, Ireland, March 2012.

"Amorphous Dispersion Overview: Challenges and Opportunities" A. Newman, invited talk at ExL Pharma Enhancing Drug Bioavailability and Solubility Workshop on Assessing Technologies for Efficient Development of Amorphous Solid Dispersions, Boston, MA, January 2012.

"Solid Form Screening and Selection during Development" A. Newman, invited talk at CrystEngComm Pharmaceutical Polymorphism Symposium, London, UK, November 2011. "Solid State Chemistry of Biopharmaceuticals: Fundamental Issues and Study Approaches" A. Newman, S. Byrn, S. Bogdanowich-Knipp, H. Zhang, R. Von Dreele, invited talk at Asian Arden House, Seoul, South Korea, June 2011.

"An Overview of Solid Form Screening during Drug Development" A. Newman, invited talk at 10th Pharmaceutical Powder X-Ray Diffraction Symposium (PPXRD-10), Lyons France, May 2011.

"Amorphous Basics" A. Newman, invited talk at the Understanding Pharmaceutical Amorphous Materials Workshop, 10th Pharmaceutical Powder Diffraction X-Ray Diffraction Symposium (PPXRD-10), Lyons France, May 2011.

"Making Amorphous API" A. Newman, invited talk at the Understanding Pharmaceutical Amorphous Materials Workshop, 10th Pharmaceutical Powder Diffraction X-Ray Diffraction Symposium (PPXRD-10), Lyons France, May 2011.

"Using Thermal Techniques for Amorphous Materials" A. Newman, invited talk at the Understanding Pharmaceutical Amorphous Materials Workshop, 10th Pharmaceutical Powder Diffraction X-Ray Diffraction Symposium (PPXRD-10), Lyons France, May 2011.

"Case Study: Physical Chemical Properties-Changes During Development" A. Newman, invited talk at June Land O'Lakes Conference, 52<sup>nd</sup> Annual International Industrial Pharmaceutical Research and Development Conference on Science-Driven Drug Product Development Strategies to Achieve Proof of Concept, Merrimac, June 2010.

"Drug Product Characterization: What Form Do I Have?" A. Newman, invited talk at 9th Pharmaceutical Powder Diffraction X-Ray Diffraction Symposium (PPXRD-9), Hilton Head, February 2010.

"Amorphous and Amorphous Dispersion Basics", A. Newman, invited talk at the Understanding Pharmaceutical Amorphous Materials Workshop, 9th Pharmaceutical Powder Diffraction X-Ray Diffraction Symposium (PPXRD-9), Hilton Head, February 2010.

"Role of Solid Forms in Lifecycle Management" A. Newman and J. Hastedt, invited workshop at Pharma IQ's 8<sup>th</sup> Annual Polymorphism and Crystallization Scientific Forum, Philadelphia, October 2009.

"Form Selection to Improve Solubility" A. Newman, invited talk at Pharma IQ's 4<sup>th</sup> Annual Improving Solubility Conference 2008, London, June 2008.

"Comprehensive Approach to Form Screening" A. W. Newman, invited talk at Polymorphism and Crystallization Scientific Forum, Philadelphia, September 2005.

"Amorphous and Disordered Pharmaceutical Materials" S. Bates and A.W. Newman, invited workshop at Polymorphism and Crystallization Scientific Forum, Philadelphia, September 2005.

"Process-Induced Transformations" A. W. Newman, invited presentation at Polymorphism, Crystallization and Salt Selection Conference, Washington, DC, February 2005.

"Cocrystallization as a Feasible Method of Solid Form Screening" S. Childs and A. W. Newman, invited workshop at Polymorphism, Crystallization and Salt Selection Conference, Washington, DC, February 2005.

"Process Analytical Technology (PAT): Achieving Mechanistic Understanding through Solid-State Chemistry" S. R. Byrn and A. W. Newman, invited workshop at Polymorphism, Crystallization and Salt Selection Conference, Washington, DC, February 2005.

"Analysis of Short-range Order in X-ray Amorphous Indomethacin Using X-ray Powder Diffraction and Pair-Wise Distribution Functions" A. W. Newman, S. Bates, G. Zografi, K. Crowley, invited presentation at Preformulation/Formulation Strategies Conference, Philadelphia, February 2005.

"Trouble Shooting Phase Transitions During Processing", A. W. Newman, invited presentation at Polymorphism and Crystallization Forum, Princeton, April 2004.

"An Overview of Form Selection", Form Selection for Pharmaceutical Systems Workshop, A. W. Newman, invited presentation at Polymorphism and Crystallization Forum, Princeton, April 2004.

"A Tiered Approach to Salt and Cocrystal Selection", A. W. Newman, invited presentation at Salt Selection and Formulation /Preformulation Strategies, Philadelphia, March 2004.

"Commonly Used Techniques to Characterize Phase Transitions During Processing", A. W. Newman, invited presentation at AAPS Annual Meeting, Toronto, November 2002.

"SSCI and MSI Joint Venture", A. W. Newman, invited talk at Molecular Simulations Inc. Pharmaceutical Development Consortium Meeting, March 1999.

"The Effect of Particle Size at Various Stages of Pharmaceutical Manufacturing: Using Traditional and Non-Traditional Techniques", A. W. Newman, J. DeVincentis, G. Lewen, D. Bergman, K. Fiorelli, S. J. Bogdanowich invited talk at Fine Particle Society 23rd Annual Meeting, July 1992.

### **Professional Presentations**

"Screening and Animal Bioavailability Studies on Itraconazole Amorphous Dispersions" D. Engers, J. Teng, J. Jimenez-Novoa, P. Gent, S. Hossack, C. Campbell, J. Thomson, I. Ivanisevic, A. Templeton, S. Byrn, A. W. Newman at AAPS, Atlanta, November 2008.

"Computational Studies of API:Polymer Mixtures From X-ray Powder Diffraction Data" S. Bates, I. Ivanisevic, P. Chen, D. Engers, R. Kelly, A. Newman, G. Zografi at 6th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology, Barcelona, Spain, April 2008.

"Characterization of API:Polymer Mixtures using X-ray Powder Diffraction" S. Bates, R. Kelly, D.Engers, G. Zografi, A. Newman at AAPS, San Diego, November 2007.

"Analysis of Process Induced Defects in Pharmaceutical Solids" S. Bates, P. Schields, I. Ivanisevic, R. Kelly, G. Zografi, A. W. Newman at AAPS Annual Meeting, San Antonio, October 2006.

"In-situ Monitoring of a Drying Process for a Complex Hydrate API using Raman Spectroscopy" J. K. Liang, A. W. Newman, J. Stults, V. Smolenskaya at AAPS Annual Meeting, Nashville, November 2005.

"Relationship Between Triboelectric Charge and Dielectric Response in Binary Mixtures Containing Metal Stearates" D. A. Engers, M. W. Nowling, A. W. Newman, and K. R. Morris at Purdue-Michigan Program for the Study of Supramolecular Assemblies and Solid-State Properties, West Lafayette, IN, September 2005.

"Pair-Distribution Functions: Probing the Evolution of Microstructure in Amorphous Pharmaceutical Materials" D. A. Engers, K. R. Morris, G. Zografi, A. W. Newman, S. Bates at Midwest Organic Solid State Chemistry Symposium XVI, West Lafayette, June 2005.

"Polymorph and Crystallization Studies of dOTC", A. W. Newman, M. C. Andres, G. P. Stahly, A. Cimpoia at AAPS Annual Meeting, Toronto, November 2002.

"Quantitation of dOTC Form A in Drug Product Using X-Ray Powder Diffraction", A. W. Newman, M. C. Andres, A. Cimpoia at AAPS Annual Meeting, Toronto, November 2002.

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"Solving Characterization Problems in the Solid State using CERIUS<sup>2</sup>", A. W. Newman, I. M. Vitez, M. Davidovich, R. L. Mueller, K. L. Morris at Molecular Simulations Inc. Materials Characterization Seminar, September 1998.

"The Use of Scanning Electron Microcopy in the Characterization of Pharmaceutical Solids", R. L. Mueller, A. W. Newman, I. M. Vitez, C. Kiesnowski, D. E. Bugay, W. P. Findlay at Fine Particles Society, April 1998.

"Scanning Electron Microscopy as a Problem Solving Tool", R. L. Mueller, A. W. Newman, I. M. Vitez, C. Kiesnowski, D. E. Bugay, W. P. Findlay at Eastern Analytical Symposium and Exposition, November 1997.

"Physical Characterization of BMS-206XXX Precipitates", A. W. Newman, I. M. Vitez, M. Davidovich, R. L. Mueller, J. Z. Gougoutas, J. Dimarco, C. Rodriguez, D. E. Bugay, S. C. Fung, L. E. Schechler, S. A. Ranadive, K. S. Raghaven at BMS-PRI Scientific Poster Session, November 1997.

"BMS-206XXX Solid State Forms", R. G. Corrao, M. Davidovich, J. DiMarco, J. Z. Gougoutas, A. W. Newman, W. L. Parker, K. S. Raghaven, S. A. Ranadive, V. D. Sharma, I. M. Vitez at BMS-PRI Scientific Poster Session, November 1997

"The Use of Hot Stage Photomicroscopy in Crystal Form Characterization", I. M. Vitez, A. W. Newman, M. Davidovich, C. Kiesnowski at BMS-PRI Scientific Poster Session, November 1997.

"Crystal Structures of Solvates of BMS-212XXX", M. F. Malley, J. D. DiMarco, J. Grosso, H. N. Joshi, S. Modi, A. W. Newman, W. L. Parker, Z. Shi, J. Z. Gougoutas at BMS-PRI Scientific Poster Session, November 1997. "The Evolution of Hot Stage Microscopy to Aid Solid State Characterization of Pharmaceutical Systems", I. M. Vitez, A. W. Newman, M. Davidovich, C. Kiesnowski at North American Thermal Analysis Society (NATAS), September 1997.

"Physical Characterization and Preliminary Quantitation of BMS-180048-02 Crystal Forms", A. W. Newman, I. M. Vitez, C. Kiesnowski, R. L. Mueller, J. DiMarco, J. Gougoutas at BMSIARC Conference, June 1997.

"Characterization of BMS-201XXX-04 Crystal Forms", A. W. Newman, R. Mueller, I. M. Vitez, C. Kiesnowski, D. E. Bugay, C. Rodriguez at BMS-PRI Scientific Poster Session, November 1996.

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"Pre-Compaction and Lubrication Properties of PRUV (Sodium Stearyl Fumarate)", A. Ahmed, M. Celik, A. W. Newman, I. M. Vitez, C. Kiesnowski at AAPS Annual Meeting, October 1996.

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"Characterization of BMS-193884 Crystal Forms", A. W. Newman, I. M. Vitez, C. Kiesnowski, D. E. Bugay, W. P. Findlay at BMSIARC Conference, June 1996.

"Starch and Starch Derivatives", A. W. Newman, R. L. Mueller, I. M. Vitez, C. Kiesnowski, D. E. Bugay, W. P. Findlay at BMS-PRI Scientific Poster Session, November 1995.

"The Effect of DSC Pan Configuration on the Thermal Characterization of Pharmaceuticals", I. M. Vitez, A. W. Newman at the AAPS Eastern Regional Meeting, June 1995.

"The Analytical Capabilities of the AR&D Materials Science Group in New Brunswick", I. M. Vitez, A. W. Newman, D. E. Bugay, J. DeVincentis, W. P. Findlay, C. Kiesnowski, R. L. Mueller, F. Rinaldi at BMSIARC Conference, June 1995.

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"Determination of Most Stable BMS-180291-02 Polymorphic Forms", A. W. Newman, I. M. Vitez, P. A. Cortina, D. E. Bugay, W. P. Findlay, G. Young at BMS-PRI Scientific Poster Session, November 1994.

"Evaluation of Pharmaceutical Polymorph Issues using Modulated Differential Scanning Calorimetry", I. M. Vitez, A. W. Newman, P. A. Cortina, G. Young at 23th Conference of the North American Thermal Analysis Society", September 1994.

"Pharmaceutical Solid and Particulate Characterization During Drug Development", A. W. Newman, P. Cortina, J. DeVincentis, I. Vitez, S. A. Ranadive, F. Rinaldi, D. E. Bugay at Fine Particle Society 25th Annual Meeting, July 1994.

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"Characterization of Unknown Particulates in Bulk d-Sotalol HCI: A Collaborative Approach Utilizing FTIR Microscopy, Energy Dispersive X-Ray Analysis, and Polarizing Optical Microscopy", F. Rinaldi, D. Bugay, A. Newman, J. DeVincentis, H. Brittain at BMSIARC Conference, May 1993.

"Characterization of Taxol Crystalline Forms", A. W. Newman, K. R. Morris, D. E. Bugay, W. P. Findlay, G. V. Barbera, J. DeVincentis at BMS-PRI Scientific Session, November 1992.

"The Use of Anhydrous Lactose in Aqueous Granulation Processes", R. Wesdyk, A. W. Newman, N. C. Guma at AAPS 1992 Annual Meeting, November 1992.

"Effects of Lactose Type, Drug Solubility, Capsule Filling Machine Capsule Size, and Lubricant Concentration on Dissolution Stability", D. S. Desai, B. A. Rubitski, J. S. Bergum, A. W. Newman, S. A. Varia at AAPS 1992 Annual Meeting, November 1992.

"The Energetic and Structural Effect of Particle Size on the Characterization of Pharmaceutical Solids", K. R. Morris, A. W. Newman, D. E. Bugay, G. V. Barbera at Fine Particle Society 23rd Annual Meeting, July 1992.

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"Humidity-Dependent Changes in Crystalline Properties of an Organic Hydrate in Bulk Material and in Solid Dosage Forms", K. R. Morris, A. W. Newman, D. E. Bugay, S. A. Ranadive, M. Szyper, S. A. Varia, H. G. Brittain, A. T. M. Serajuddin at AAPS National Meeting, November 1991.

"Physical Interactions of Different Lubricants with Starch-Derived Disintegrants and Their Effects on Capsule Dissolution", D. S. Desai, B. A. Rubitski, S. A. Varia, A. W. Newman, K. R. Morris at AAPS National Meeting, November 1991.

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"Physical Characterization and Dehydration of Amiloride Hydrochloride Dihydrate", H. G. Brittain, A. Winiecki Newman at AAPS National Meeting, November 1990.

"Relationship Between the Physical and Mechanical Properties of Wet Granulated Microcrystalline Cellulose Following Drying", M. Chatrath, J. N. Staniforth, A. Winiecki Newman, H. G. Brittain at British Pharmaceutical Conference, September 1990.

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"Scanning Electron Microscopy, Thermogravimetry, and Luminescence Studies of Uranium Carbonate", D.L. Perry, H. G. Brittain, A. Winiecki at 197th ACS National Meeting, April 1989.

"Clay-Micelle Electrode for Catalytic Reduction of Organo-Halides", J. F. Rusling, C. N. Shi, A. M. Winiecki, S. L. Suib at ACS 195 National Meeting, June 1988.

"XPS Studies of Chemically Treated Aluminophosphate and Silicoaluminophosphate Molecular Sieves", A.M. Winiecki, S. L. Suib at ACS 192 National Meeting, August 1986.

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"X-Ray Photoelectron Spectroscopy Investigations of Silica-Rich Zeolites", A. M. Winiecki, S. L. Suib at University of Connecticut Randolph T. Majors Memorial Lecture Series, October 1985.

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# Webcasts

"Coamorphous Materials: What Are They and Are They Developable?" A. Newman for Seventh Street Development Group, March 14, 2019.

"Process Induced Disorder: How Do I Measure Amorphous Defect Content in Crystalline Materials?" A. Newman for Seventh Street Development Group, November 4, 2014.

"Physical Stability: How Do I Know Which Form is the Most Stable?" A. Newman for Seventh Street Development Group, April 3, 2013.

"Specialized Screening: How Do I Deal with Difficult Compounds?" A. Newman for Seventh Street Development Group, February 27, 2013.

"Cocrystal Screening, Characterization, and Selection" A. Newman for American Association of Pharmaceutical Scientists (AAPS), October 3, 2012.

"Cocrystals: What Does the Latest Regulatory Guidance Say?" A. Newman for Seventh Street Development Group, February 8, 2012.

"Amorphous Dispersions: What Are They and Will They Help?" A. Newman for Seventh Street Development Group, September 28, 2011.

"Form Selection: What Solid Form Should I Choose?" A. Newman for Seventh Street Development Group, August 31, 2011.

"Characterization: How Do I Know if I Have Polymorphs?" A. Newman for Seventh Street Development Group May 25, 2011.

"Polymorph Screening: How Do I Find New Forms?" A. Newman for Seventh Street Development Group, April 27, 2011.

"Hygroscopicity: Is My Form Hygroscopic?" A. Newman for Seventh Street Development Group, November 17, 2010.

"Solubility Improvement: Will Solid Forms Help My Solubility?" A. Newman for Seventh Street Development Group, November 23, 2010.

"Case Studies: What Happens When My Solid Form Changes?" A. Newman for Seventh Street Development Group, November 3, 2010.

"Formulation: Will My Solid Form Change?" A. Newman for Seventh Street Development Group Spring Webcast Series, June 2, 2010.

"Crystallization: How Do I Make the Right Form?" A. Newman for Seventh Street Development Group Spring Webcast Series, May 26, 2010.

"Salt Selection: How Do I Find New Salts?" A. Newman for Seventh Street Development Group Spring Webcast Series, May 19, 2010.

"Amorphous: What Do I Need to Know About Amorphous Materials" A. Newman for Seventh Street Development Group Spring Webcast Series, May 12, 2010.

"From a Beaker to a Bottle: Overview of the Drug Discovery and Development Process for Small Molecule Therapeutics" A. Newman for American Chemical Society Webinars Professional Growth Series, May 6, 2010.

"Solid Amorphous Dispersions: What Are They and Will They Help" A. Newman for Seventh Street Development Group Winter Webcast Series, February 9, 2010.

"Cocrystal Screening: How Do I Find Cocrystals" A. Newman for Seventh Street Development Group Winter Webcast Series, February 2, 2010.

"Drug Product Characterization: What Solid Form Is In My Formulation" A. Newman for Seventh Street Development Group Winter Webcast Series, January 28, 2010.

"Physical Stability: How Do I Know Which Form Is the Most Stable" A. Newman for Seventh Street Development Group Winter Webcast Series, January 19, 2010.

"Form Selection: What Solid Form Should I Choose" A. Newman for Seventh Street Development Group Winter Webcast Series, December 15, 2009 and January 14, 2010.

"Process Induced Transformations: Why Is My Form Changing" A. Newman for Seventh Street Development Group Fall Webcast Series, November 6, 2009.

"Cocrystal Properties: Will Cocrystals Help" A. Newman for Seventh Street Development Group Fall Webcast Series, October 22, 2009.

"Polymorph Screening: How Do I Find New Forms" A. Newman for Seventh Street Development Group Fall Webcast Series, October 16, 2009.

"Characterization: How Do I Know If I Have Polymorphs" A. Newman for Seventh Street Development Group Fall Webcast Series, October 8, 2009.

"What Are Polymorphs and Why Do We Care" A. Newman for Seventh Street Development Group Fall Webcast Series, September 22, 2009.

"Intellectual Property and Regulatory Considerations for Polymorphs" A. Newman for American Chemical Society Webcast Series on Polymorphism in Organic/Pharmaceutical Systems, August 18, 2009, November 10, 2009, November 11, 2010.

"Process Induced Transformations During Compound and Product Manufacture" A. Newman for American Chemical Society Webcast Series on Polymorphism in Organic/Pharmaceutical Systems, August 11, 2009, November 3, 2009, November 4, 2010.

"Developing a Formulation Process" A. Newman for American Chemical Society Webcast Series on Polymorphism in Organic/Pharmaceutical Systems, August 4, 2009, October 27, 2009, October 28, 2010.

"Developing a Crystallization Process" A. Newman for American Chemical Society Webcast Series on Polymorphism in Organic/Pharmaceutical Systems, July 28, 2009, October 20, 2009, October 21, 2010, November 18, 2011, December 1, 2011.

"Thermodynamic Stability of Polymorphs and Choosing the Best Form for Development" A. Newman for American Chemical Society Webcast Series on Polymorphism in Organic/Pharmaceutical Systems, July 21, 2009, October 13, 2009, October 14, 2010, November 17, 2011.

"Polymorph Screening" A. Newman for American Chemical Society Webcast Series on Polymorphism in Organic/Pharmaceutical Systems, July 14, 2009, October 6, 2009, October 7, 2010.

"Solid-State Characterization" A. Newman for American Chemical Society Webcast Series on Polymorphism in Organic/Pharmaceutical Systems, July 7, 2009, September 29, 2009, September 30, 2010, November 11, 2011.

"Introduction to Polymorphism" A. Newman for American Chemical Society Webcast Series on Polymorphism in Organic/Pharmaceutical Systems, June 23, 2009, September 22, 2009, September 23, 2010, November 10, 2011.