

## Gregory E. Amidon, Ph.D.

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### PROFESSIONAL SUMMARY

Research Professor of Pharmaceutical Sciences at the University of Michigan, College of Pharmacy, and Director of Pharmaceutical Engineering program. Twenty-eight years of industrial experience as a senior scientist with large pharmaceutical companies in pharmaceutical R&D with expertise in oral bioperformance, in vivo predictive dissolution, pharmaceutical materials science, physical and mechanical property characterization, compaction physics, excipients and formulation development. A lifelong contributor to academic, professional and standards-setting organizations.

#### Oral Bioperformance Assessment:

- Recognized expert and invited speaker on drug delivery and in vitro testing of oral dosage forms.
- Established academic and industrial collaborations to develop and characterize novel in vitro drug release testing systems.

#### Pharmaceutical Materials Science:

- Nationally and internationally recognized expert and invited speaker on physical and mechanical property characterization of active pharmaceutical ingredients, excipients, and formulations.
- Long history of applying basic science and fundamental concepts to solve practical development and manufacturing problems.

#### Physicochemical Characterization:

- Early industrial leader in multidisciplinary approach to integrating pharmaceutical development with discovery research and drug candidate selection.
- Extensive experience in physicochemical characterization of new chemical entities.
- Established standards for physical and chemical characterization procedures using small quantities of drug to support candidate selection and identify dosage form options.

#### Product Development:

- Developed methodologies for early stage solid dosage formulation development using material sparing methods and limited resources.
- Developed and optimized solid, liquid, and parenteral formulations for preclinical and clinical trials, scale up, and production.
- Developed rational strategies and requirements for active pharmaceutical ingredient (API) use.
- Contributed to regulatory submissions: INDs, NDAs.

#### Professional Contributions:

- Research professor, Pharmaceutical Sciences, College of Pharmacy, University of Michigan, Ann Arbor, MI (2007-present)
- Adjunct professor and lecturer, University of Michigan, College of Pharmacy (1980-2007).
- Elected Fellow of the American Association of Pharmaceutical Scientists (1997)
- Elected member of USP Council of Experts (1990-present); Chair, Expert Committee on Excipient Test Methods (1995-2005); Chair, Expert Committee on Physical Methods (2010-2015). Provided sustained leadership in the characterization of pharmaceutical ingredients and physical test methods impacting global excipient and pharmaceutical dosage form standards.
- Chair and member, AAPS Fellows Committee (2012-2014); Member AAPS Foundation Advisory Council (2012-present). AAPS President Elect (2014-2015)

**CAREER HISTORY**

UNIVERSITY OF MICHIGAN, Ann Arbor, MI

Sept 2007 - present

**Research Professor of Pharmaceutical Sciences, College of Pharmacy****Director, Pharmaceutical Engineering**

- Technical leader in pharmaceutical material science establishing a research laboratory to support innovative research in characterization of pharmaceutical materials.
- Director of joint program in Pharmaceutical Engineering supported by the College of Pharmacy and the College of Engineering.
- Responsibilities include lectures and other educational opportunities for professional pharmacy (PharmD), pharmaceutical engineering (Masters in Pharmaceutical Engineering) and graduate students (Ph.D.) on physical, chemical, and mechanical properties of pharmaceutical materials, product development, and formulation properties and technologies.

PFIZER, INC., Ann Arbor, MI

2003 – Sept 2007

**Research Fellow, Enabled Solid Dosage Forms, Research Formulations**

(Level 8 of 9 on Scientific Career Ladder)

- Technical leader in the development of a fully functional pharmaceutical materials characterization laboratory integrating physical and mechanical property characterization into dosage form development.
- Defined and implemented new paradigm at Kalamazoo and Ann Arbor sites to develop oral solid dosage formulations using material sparing techniques.
- Worked with merger integration teams for materials assessment, physicochemical characterization, and immediate release dosage forms development strategy.
- Conducted applied research in areas of compaction physics, lubrication, and impact of physical properties on manufacturing processes that improved understanding and changed work practices.
- Mentor to formulation development scientists.

PHARMACIA CORPORATION, Kalamazoo, MI

**Senior Research Advisor, Global Pharmaceutical Sciences**

1999 – 2003

(Level 8 of 9 on Scientific Career Ladder)

- Technical leader in physical, chemical and mechanical property characterization of active pharmaceutical ingredients, excipients, and formulations to troubleshoot manufacturing problems.
- Recognized as expert in corporation on compaction physics and mechanical properties.
- Led team to establish marketed product definition characteristics for determining critical dosage form and packaging attributes for solid, liquid and parenteral dosage forms.
- Acknowledged technical leader in oral solid dosage formulation development.
- Mentor to formulation development scientists.

PHARMACIA &amp; UPJOHN, INC, Kalamazoo, MI, November

1992 - 1999

**Senior Scientist IV, Pharmaceuticals, Pharmaceutical Development**

(Level 4 of 6 on Scientific Career Ladder)

- Provided leadership in physical and chemical characterization of new chemical entities in collaboration with discovery colleagues.
- Established guidelines and commonly accepted practices for physicochemical characterization using small quantities of material to support discovery drug candidate proposals.
- Conducted fundamental research in powder flow and mechanical properties.
- Successfully supported discovery, development and market introduction of an injectable product (Corvert<sup>®</sup>).

THE UPJOHN COMPANY, Kalamazoo, MI

**Senior Research Scientist III, Pharmaceuticals, Drug Delivery R&D**

1986 – 1992

(Level 3 of 5 on Scientific Career Ladder)

**Scientist II, Pharmacy Research, Pharmaceutical R&D** 1983 – 1986

(Level 2 of 5 on Scientific Career Ladder)

**Scientist I, Pharmacy Research, Pharmaceutical R&D** 1979 – 1983

(Level 1 of 5 on Scientific Career Ladder)

- Developed Phase I and Phase II solid, suspension, and parenteral clinical formulations.
- Conducted applied research on powder flow and compaction of active ingredients, excipients and formulations.
- Early advocate and adopter of proactive pharmaceutical science – discovery collaboration on drug candidate characterization and lead selection.

### PROFESSIONAL SOCIETIES AND HONORS

- AAPS, Research Achievement Award in Physical Pharmacy and Biopharmaceutics (PPB), 2014
- USP Award for Outstanding Contribution to the Standards-setting Process: Excipient Performance 2012
- USP Award for Outstanding Contribution to the Standards-setting Process: Good Distribution Practices for Pharmaceutical Excipients 2011
- American Pharmacists Association, Outstanding Reviewer, Journal of Pharmaceutical Sciences, 2010
- Pfizer Global Research & Development Achievement Award 2006.
- Elected Fellow, American Association of Pharmaceutical Scientists (AAPS) 1997.
- Ebert Prize for the most outstanding research paper published in *Journal of Pharmaceutical Sciences*, 1983.
- Rho Chi (Pharmaceutical Honor Society (1978)) and Phi Lambda Upsilon (Honorary Chemical Society (1978)).

### EDUCATION

**Ph.D.** Pharmaceutical Chemistry, University of Michigan, Ann Arbor, MI 1979

Major Professor: William, I. Higuchi, Ph.D.

Thesis Title: Rotating Membrane Diffusion Studies of Micellar and Suspension Systems.

**M.S.** Pharmaceutical Chemistry, University of Michigan, Ann Arbor, MI 1978

**B.S.** Medicinal Chemistry, University of Michigan, Ann Arbor, MI 1974

### COLLEGE/DEPARTMENT ACTIVITIES

Member, Curriculum and Assessment Committee (2012-present)

Member, Pharmacy Investigations Committee (2011-present)

Member, Pharmaceutical Sciences Department Strategic Planning Committee (2009-present)

Member, College of Pharmacy Strategic Planning Committee (2011-2012)

Chair, BS Pharmaceutical Sciences Implementation Committee (2010-present)

College of Pharmacy, USP Council of the Convention Representative (2014-2015)

Teaching

- Course coordinator, Instructor: Pharmaceutical Sciences 508: Drug Delivery and Solutions (2012-present)
- Course coordinator, Instructor: Pharmaceutical Sciences/Chemical Engineering 519: Pharmaceutical Engineering (2009-present)
- Instructor: Pharmaceutical Sciences 701: Pharmaceutical Design, Delivery and Targeting – Physical-Chemical Concepts (2007-present)
- Instructor: Pharmaceutical Sciences 703: Advanced Physicochemical Concepts in Drug Development and Delivery (2007-present)
- Course co-coordinator, Instructor: Pharmacy 597: Regulatory Issues for Pharmacists, Engineers, Scientists and Managers (2014-present)

**PROFESSIONAL ACTIVITIES**American Association of Pharmaceutical Sciences (AAPS):

President, AAPS 2015-2016  
President Elect, AAPS 2014-2015  
Chair: AAPS Fellows Committee 2012-13  
Chair, AAPS Workshop on Oral Bioperformance 2012  
Member, AAPS Foundation Advisory Board, 2013-present  
Member, AAPS Planned Giving Oversight Committee 2011-2013  
Chair: Physical Pharmacy & Biopharmaceutics Fellows Committee 2008-2011  
Member, Physical Pharmacy & Biopharmaceutics Webinar Committee 2008-2012  
Member: Drug Discovery and Design Interface Working Group, 2007  
Member, Fellows Committee, Pharmaceutical Technologies (PT) Committee 2002-2007.  
Member, Pharmaceutics and Drug Delivery (PDD) Section, Nominations Committee, 1995-1996.  
Chair, PDD Section Awards Committee, 1991-1992.  
Chair, PDD Section Nominations Committee, 1991-1992.  
Member, Executive Council of AAPS, 1990  
Chair, PDD Section, 1990  
Director, PDD, Drug Delivery Symposia on "Predictive Drug Delivery" 1989  
Chair, PDD Screening Committee, 1988  
Member, Executive Committee of Pharmaceutics and Drug Delivery (PDD) Section, 1988-89.

United States Pharmacopeia (USP):

*Member, United States Pharmacopeia (USP) Council of Experts 2010-2015.*  
Chair, USP Expert Committee on Physical Analysis, 2010-2015  
Member, USP Council of Experts Nominations Committee (2014-2015)  
Member, USP Council of Experts Steering Committee (2013-2015)  
Member, USP Council of Experts 2010-2015  
Member, USP CEO Search Committee 2013  
Co-Chair, Excipient Performance Advisory Panel 2008-2011  
Co-Chair, Excipient Good Distribution Practices Advisory Panel 2009-2011  
*Member, United States Pharmacopeia (USP) Council of Experts 2005-2010.*  
Member, Executive Committee, 2008-2010  
Chair, USP Expert Working Group on Excipients General Chapters, 2005-2010  
Member, USP Annual Scientific Meeting Organizing Committee, 2005, 2006, 2007, 2008  
Member, USP Conference Organizing Committee on Pharmaceutical Excipients, 2009  
Member, USP Nominating Committee for the Council of Experts, 2006-2010  
Co-Chair, on Excipient Performance Advisory Panel 2008-2010  
Co-Chair, Excipient Good Distribution Practices Advisory Panel 2009-2010  
*Member, United States Pharmacopeia (USP) Council of Experts 2000-2005:*  
Chair, USP Expert Working Group on Excipients - Methods, 2000-2005  
Member, USP Noncomplex Actives and Excipients Executive Committee, 2000-2005.  
Member, USP Nominating Committee for the Council of Experts, 2004  
Member, USP 2004 USP Annual Scientific Meeting Organizing Committee  
Member, USP 2005 Annual Meeting Organizing Committee  
*Member, United States Pharmacopeia (USP) Committee of Revision 1995-2000:*  
Chair, USP Subcommittee on Excipients - Methods, 1995-2000  
Chair, Advisory Panel on Physical Test Methods, 1995-2000  
Member of USP Drug Standards Division Executive Committee, 1995-2000.

Member, Nominations Committee, 1999

*Member, United States Pharmacopeia (USP) Committee of Revision 1990-1995:*

Member, Packaging and Stability Subcommittee

Member, Excipients Subcommittee

Chair, Advisory Panel on Physical Test Methods, 1991-1995

Member, USP Fellowship Review Committee, 1991

Chair, USP Fellowship Review Committee, 1992

#### Other Academic Activities:

Adjunct Professor, College of Pharmacy, University of Michigan, Ann Arbor, MI, 2007

Adjunct Assoc. Professor, College of Pharmacy, University of Michigan, Ann Arbor, MI, 1994-2007

Member Industrial Advisory Board, Masters of Engineering in Pharmaceutical Engineering Program, University of Michigan, Ann Arbor, MI, 1998-2007

Adjunct Assistant Professor, College of Pharmacy, University of Michigan, Ann Arbor, MI, 1991-1994.

#### Academy of Pharmaceutical Sciences (APhA):

Co-Director, Industrial Pharmaceutical Technology Section Symposium on "Particulate Solids Mechanics" 1986

Chairman, Ebert Prize Committee, 1983-84.

Chairman, Basic Pharmaceutics Screening Committee, 1983-84.

Basic Pharmaceutics Screening Committee Member, 1981-83.

#### Other Professional Activities:

Chair, Science Advisory Board, National Science Foundation, Engineering Research Center (ERC) on Structured Organic Particulate Systems, 2010-present

Member, Scientific & Education Advisory Council, National Institute for Pharmaceutical Technology and Education (NIPTE), 2009-present

Member, USA Steering Committee, Handbook of Pharmaceutical Excipients, 1996 –present.

Member, Editorial Advisory Board, Journal of Pharmaceutical Sciences, 1994 –present.

Member, Editorial Advisory Board, Molecular Pharmaceutics, 2015-present

Guest Editor, Journal of Pharmaceutical Sciences, Special Issue honoring Professor William I Higuchi, 2008

Guest Editor, Molecular Pharmaceutics, Special issue on Oral Bioperformance and 21<sup>st</sup> Century Dissolution Testing, Nov 2010.

Member, Editorial Advisory Board, AAPS Journal, 2000-2006.

Manuscript Reviewer: AAPS Journal, AAPS PharmSciTech, Drug Discovery Today, International Journal of Pharmaceutics, Pharmaceutical Research, Molecular Pharmaceutics, Powder Technology, Journal of Pharmaceutical Sciences.

## **PUBLICATIONS**

1. G.E. Amidon, "Rotating Membrane Diffusion Studies of Micellar and Suspension Systems," Ph.D. Thesis, University of Michigan, Ann Arbor, Michigan (1979).
2. G.E. Amidon, N.F.H. Ho, A.B. French, and W.I. Higuchi, "Predicted Absorption Rates with Simultaneous Bulk Fluid Flow in the Intestinal Tract, J. Theoret. Biol., **89**, 195-210 (1981)
3. G.E. Amidon, D.P. Smith, and E.N. Hiestand, "Rotary Press Utilizing a Flexible Die Wall," J. Pharm. Sci., **70** (6), 613-7 (1981).
4. E.N. Hiestand, G.E. Amidon, D.P. Smith, and B.D. Tiffany, "Mechanical Property Changes of Compacts from Variation of Crystallization Rates of the Solid," International Powder and Bulk Solids Handling and

- Processing; Proceedings of the Technical Program, Cahners Exposition Group, Rosemont, IL, 383-7, May 1981.
5. G.E. Amidon, W.I. Higuchi, and N.F.H. Ho, "Theoretical and Experimental Studies of Transport of Micelle-Solubilized Solutes," J. Pharm. Sci., 71 (1), 77-84 (1982).
  6. G.L. Flynn, A.B. French, N.F.H. Ho, W.I. Higuchi, E.A. Ostafin, L.H. Wabbasse, G.E. Amidon, and E. Williams, "Some Hydrodynamic Boundary Layer Influences on Mass Transfer Coefficients," J. Membrane Sci., 19, 289-308 (1984).
  7. G.E. Amidon and M.E. Houghton, "Powder Flow Testing in Preformulation and Formulation Development," Pharmaceutical Manufacturing, 2 (7), 20-31, (1985).
  8. C.F. Dick, R.A. Klassen and G.E. Amidon, "Determination of the Sensitivity of a Tablet Formulation to Variations in Excipient Levels and Processing Conditions Using Optimization Techniques," Int. J. Pharm., 38, 23-31, (1987).
  9. G.E. Amidon and K.R. Middleton, "Accelerated Physical Stability Testing and Long Term Predictions of Changes in the Crushing Strength of Tablets Stored in Blister Packages," Int. J. Pharm., 45, 79-89, (1988).
  10. M.E. Houghton and G.E. Amidon, "Microscopic Characterization of Particle Size and Shape: an Inexpensive and Versatile method," Pharmaceutical Research, 9, 856-859 (1992).
  11. G.E. Amidon, "Report and Recommendation of the USP Advisory Panel on Physical Test Methods - Functionality I. General Chapter on Particle Characterization by Optical Microscopy," Pharmacopeial Forum, 18, 4089-4092 (1992).
  12. L. Augsburger and G.E. Amidon, "Report and Recommendation of the USP Advisory Panel on Physical Test Methods V. General Chapter on Bulk Density and Tapped Density Determinations," Pharmacopeial Forum, 20, 6931-6933 (1994).
  13. G.E. Amidon and M.E. Houghton, "The Effect of Moisture on the Mechanical and Powder Flow Properties of Microcrystalline Cellulose," Pharm. Res., 12(6), 923-929, (1995).
  14. JK Rhie, Y Hayashi, LS Welage, J Frens, RJ Wald, JL Barnett, GE Amidon, L Putcha and GL Amidon, "Drug Marker Absorption in Relation to Pellet Size, Gastric Motility and Viscous Meals in Humans," Pharm. Res., 15(2), 233-238, (1998).
  15. G.L. Flynn, P.A. Caetano, R.S. Pillai, G.E. Amidon, "Profitable Uses of in vitro Release Testing of Semisolids," The International Journal of Chosun University, 1(3) 571-582 (1998).
  16. G.E. Amidon, "Physical test methods for powder flow characterization of pharmaceutical materials: A review of methods," Pharmacopeial Forum, 25 (3), 4089-4092 (1999).
  17. G.E. Amidon, L.L. Augsburger., H.G. Brittain, S.R. Byrn, C.D. Fox, G.E. Peck, D.E. Wurster, Proposed New General Test Chapter: "Tablet Breaking Force," Pharmacopeial Forum, 26, 513-515 (2000).
  18. S.Y. Choe , B.L. Neudeck , L. S. Welage , G. E. Amidon , J. L. Barnett , G. L. Amidon, "Novel method to assess gastric emptying in humans: the Pellet Gastric Emptying Test," European Journal of Pharmaceutical Sciences, 14 347-353, (2001)

19. Harry G. Brittain and Gregory E. Amidon, "Critical Overview of the Proposed Particle Size Analysis Tests," Am. Pharm. Rev. 6(1) 68-72 (2003).
20. MHariharan, LDGanorkar, GEAmidon, ACavallo, PGatti, MJHageman, IChoo, JLMiller, UJShar, "Reducing the time to develop and manufacture formulations for first oral dose in humans," Pharm. Tech., 68-84, Oct 2003.
21. CKTye, CSun, GEAmidon, "Evaluation of the Effects of Tableting Speed on the Relationships between Compaction Pressure, Tablet Tensile Strength, and Tablet Solid Fraction," J.Pharm.Sci. 94(3), 465-472 (2005).
22. RBandyopadhyay, JSelbo, GE Amidon, MHawley, "Application of Powder X-ray Diffraction in Studying the Compaction Behavior of Bulk Pharmaceutical Powders," J. Pharm. Sci., 94(11) 2520-2530 (2005).
23. BRRohrs, GE Amidon, RHMeury, PJSecreast, HMKing, CJSkoug, "Particle Size Limits to meet USP Content Uniformity Criteria for Tablets and Capsules," J.Pharm.Sci., 95(5), 1049-1059 (2006).
24. XHe, PJSecreast, GEAmidon, "Mechanistic Study of the Effect of Roller Compaction and Lubricant on Tablet Mechanical Strength", Special issue dedicated to David J.W. Grant, J.Pharm.Sci., 96(5), 1342-1355, (2007).
25. GEAmidon, GEPeck, LHBlock, RCMoretton, AKatdare, RLafaver, CSheehan., "Proposed New USP General Information Chapter, Excipient Performance <1059>", Pharmacopeial Forum, 33(6), 423-436 (2007).
26. LHHan, JElliot, SBest, RCameron, ACBentham, AMills, GEAmidon, BCHancock, "Numerical Simulation on Pharmaceutical Powder Compaction", Materials Science Forum Vols. 575-578, 560-565 (2008).
27. LHHan, JAElliott, ACBentham, AMills, GEAmidon and BCHancock, "A Modified Drucker-Prager Cap Model for Die Compaction Simulation of Pharmaceutical Powders", International Journal of Solids and Structures, 45(10), 3088-3106, (2008).
28. CMaheshwari, AJayasankar, NAKhan, GEAmidon, and NRodríguez-Hornedo," Factors that influence the spontaneous formation of pharmaceutical cocrystals by simply mixing solid reactants", CrystEngComm, 2009, DOI: 10.1039/B812264D
29. GEAmidon, GEPeck, LHBlock, RCMoretton, AKatdare, RLafaver, CSheehan, "Excipient Performance <1059>", Pharmacopeial Forum, 35(5), 1228 (2009).
30. GEAmidon, PhD, GEPeck, PhD, LHBlock, RCMoretton, AKatdare, RLafaver, CSheehan, "<1059> Excipient Performance", Pharmacopeial Forum 35(5); 1228-50. (2009).
31. Dahan A. Miller JM. Hoffman A. Amidon GE. Amidon GL "The Solubility-Permeability Interplay in Using Cyclodextrins as Pharmaceutical Solubilizers: Mechanistic Modeling and Application to Progesterone", J.Pharm.Sci., 99(6):2739-49 (2010).
32. DMMudie, GLAmidon, GEAmidon, "Physiological Parameters for Oral Delivery and In vitro Testing", Molecular Pharmaceutics, 7(5) 1388-1405 (2010)
33. GEAmidon, MHawley, "Oral Bioperformance and 21st Century Dissolution" Molecular Pharmaceutics, 7(5) 1361 (2010).

34. DSun, GEAmidon, "Physical Chemistry in the Age of Molecular and Cellular Biology", AAPS New Magazine, American Association of Pharmaceutical Scientists, January 2011.
35. JMiller, ABeiq, BJKrieg, RCarr, GEAmidon, GLAmidon, ADahan, "The solubility-permeability interplay: Mechanistic modeling and predictive application of the impact of micellar solubilization on intestinal permeation", *Molecular Pharmaceutics*, 8:1848-1856 (2011).
36. CSheehan and GEAmidon, "Compendial Standards and Excipient Performance in the QbD Era: USP Excipient Performance Chapter <1059>", *American Pharmaceutical Review*, 14(6):10-18 (2011).
37. W.W. Hauck, et al. "Primary and Secondary Reference Materials for Procedures to Test the Quality of Medicines and Foods". *Pharmaceutical Research*. 29:922-931 (2012).
38. D.M. Mudie, Y. Shi, H. Ping, P. Gao, G.L. Amidon, and G.E. Amidon. Mechanistic analysis of solute transport in an in vitro physiological two-phase dissolution apparatus. *BiopharmDrug Dispos*. 33:378-402 (2012).
39. R. Iyer, S. Hegde, Y.-E. Zhang, J. Dinunzio, D. Singhal, A. Malick, and G. Amidon. The Impact of Hot Melt Extrusion and Spray Drying on Mechanical Properties and Tableting Indices of Materials Used in Pharmaceutical Development. *Journal of Pharmaceutical Sciences*. 102:3604-3613 (2013).
40. YTsume, DMMudie, PLangguth, GEAmidon, GLAmidon, "The Biopharmaceutics Classification System: Subclasses for In Vivo Predictive Dissolution (IPD) Methodology and IVIVC", *Eur. J. Pharm. Sci*, 57: 152-63 (2014).
41. LXYu, GEAmidon, MAKhan, SWHoag, JPolli, GK Raju, JWoodcock, Understanding Pharmaceutical Quality by Design, *AAPS Journal*, 16(4), 771-783 (2014).
42. D.M. Mudie, K. Murray, C.L. Hoad, S.E. Pritchard, M.C. Garnett, G.L. Amidon, P.A. Gowland, R.C. Spiller, G.E. Amidon, and L. Marciari. Quantification of Gastrointestinal Liquid Volumes and Distribution Following a 240 mL Dose of Water in the Fasted State. *Molecular Pharmaceutics*. 11:3039-3047 (2014).
43. BJKrieg, SMTaghavi, GLAmidon, and GEAmidon. In Vivo Dissolution: Transport Analysis of the CO<sub>2</sub>, Bicarbonate In Vivo Buffer System. *J Pharm Sci*. 103(11): 3473-3490. (2014).
44. STakeuchi, YTsume, GEAmidon and GLAmidon. "Evaluation of a Three Compartment In Vitro Gastrointestinal Simulator Dissolution Apparatus to Predict In Vivo Dissolution." *Journal of Pharmaceutical Sciences* 103(11): 3416-3422. (2014).

### BOOK CHAPTERS

1. NfH Ho, JY Park, GE Amidon, PF Ni, WI Higuchi, "Methods for interrelating in vitro, in vivo animal and human studies," *Gastrointestinal Absorption of Drugs*, AJ Aguiar, Ed., APhA, Washington, DC.
2. G.E. Amidon, "Physical and Mechanical Property Characterization of Powders," in Physical Characterization of Pharmaceutical Solids, H.G. Brittain, Editor, Marcel Dekker, Inc. (1995).
3. GEAmidon, XHe, MJHageman, Volume 2, Chapter 18: "Physicochemical Characterization and Principles of Oral Dosage Form Selection" in Burger's Medicinal Chemistry and Drug Discovery, Sixth Edition, Donald J. Abraham, Editor, 649 -682, (2004).



4. GEAmidon, PJSecreast, DMudie, "Particle, Powder and Compact Characterization", in Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, Yihong Qiu, Yisheng Chen, Geoff GZ Zhang, Editors, Academic Press, New York, 163-186 (2009).
5. GEAmidon, XHe, MJHageman, "Physicochemical Characterization and Oral Dosage Form Selection Based on the Biopharmaceutics Classification System" in Burger's Medicinal Chemistry and Drug Discovery, Seventh Edition, (2010).
6. GEAmidon, "Chapter 22: Oral Solid Dosage Forms" in Martin's Physical Pharmacy and Pharmaceutical Sciences, Lippincott Williams & Wilkins, 6th Edition, Patrick Sinko, ed. (2010)
7. GEAmidon, RBharadwajh, BCHancock, CSun, "Chapter 11: Mechanical Performance of Pharmaceutical Products" in Pharmaceutical Materials Science: Principles, Characterization Methods, and Applications, John Wiley & Sons, Inc. (In Press).

### **PRESENTATIONS (Posters/Podium)**

1. G.E. Amidon, A.B. French, N.F.H. Ho, and W.I. Higuchi, "Physical Model for the Simultaneous Flow and Passive Absorption of Solutes Along the Intestinal Tract," 23rd American Pharmaceutical Association, Annual Meeting, New Orleans, LA, April 3-8, 1976.
2. G.E. Amidon, W.I. Higuchi, and N.F.H. Ho, "Development and Characterization of a Rotating Membrane Diffusion Cell," 25 Academy of Pharmaceutical Sciences National Meeting, Hollywood, FL, November 12-16, 1978.
3. G.E. Amidon, W.I. Higuchi, N.F.H. Ho, and J.D. Goddard, "Theoretical Productions of Transport for Micelle Forming Solutes," 27 Academy of Pharmaceutical Sciences, National Meeting, Kansas City, MO, November 11-15, 1979.
4. G.E. Amidon, N.F.H. Ho, W.I. Higuchi, and J.L. Fox, "Transport from Suspension Systems," 27 Academy of Pharmaceutical Sciences National Meeting, Kansas City, MO, November 11-15, 1979.
5. E.N. Hiestand, G.E. Amidon, and D.P. Smith, "Variation of Physical Properties with Changes in Crystallization Rate," 29th Academy of Pharmaceutical Sciences National Meeting, San Antonio, TX, Nov. 9-13, 1980.
6. G.E. Amidon, D.P. Smith, and E.N. Hiestand, "A Rotary Press That Utilizes a Flexible Wall Die," 29th Academy of Pharmaceutical Sciences National Meeting, San Antonio, TX, Nov. 9-13, 1980.
7. G.E. Amidon, E.N. Hiestand, and D.P. Smith, "Flowability of Powders Using a Simplified Shear Cell," 31st National Meeting, Academy of Pharmaceutical Sciences, Orlando, FL, Nov. 15-19, 1981.
8. G.E. Amidon, E.N. Hiestand, and D.P. Smith, "Flowability of Powders Using a Simplified Shear Cell," 31st National Meeting, Academy of Pharmaceutical Sciences, Orlando, FL, Nov. 15-19, 1981
9. G.E. Amidon, D.P. Smith, and E.N. Hiestand, "Lot to Lot Variations in the Physical Properties of Bulk Drug and Their Influence on a Granulated Formulation," 31st National Meeting, Academy of Pharmaceutical Sciences, Orlando, FL, Nov. 15-19, 1981.

10. G.E. Amidon, P.J. Meyer, C.B. Peot, and K.R. Middleton, "Effects of Relative Humidity on the Physical Stability of Compressed Tablets in Blister Packages," Third Upjohn Worldwide Pharmacy R&D Conference, Brook Lodge Conference Center, Augusta, MI, March, 1983.
11. G.E. Amidon, K.R. Middleton, C.B. Peot, and P.J. Meyer, "Physical Stability Predictions of Compressed Tablets in Blister Packages I: Physical Model and Accelerated Testing Conditions," 36th Academy of Pharmaceutical Sciences National Meeting, Philadelphia, PA, October 29-November 1, 1984.
12. K.R. Middleton, N.L. Bare, G.E. Amidon, P.J. Meyer, and E.P. Strzelinski, "Physical Stability Predictions of Compressed Tablets in Blister Packages II: Theoretical Predictions and Observations Utilizing Oscillating Relative Humidity Conditions," 36th Academy of Pharmaceutical Sciences National Meeting, Philadelphia, PA, October 29-November 1, 1984.
13. K.R. Middleton, G.E. Amidon, and E.L. Rowe, "Tableting Indices and Tableting Behavior of Losulazine Hydrochloride and Furegrelate Sodium," AAPS National Meeting, Washington DC, November 2-6, 1986.
14. C.F. Dick, R.A. Klassen, and G.E. Amidon, "Determination of the Sensitivity of a Tablet Formulation to Variations in Excipient Levels and Processing Conditions Using Optimization Techniques," AAPS National Meeting, Washington DC, November 2-6, 1986.
15. R.J. Wald, S.L. Saddler, M.E. Houghton and G.E. Amidon, "Diffusion Cell Testing of the Permeation Properties of Aqueous Based Ethylcellulose Dispersions Used For Controlled Release," AAPS National Meeting, Orlando, FL, October 30 - November 4, 1988.
16. R.J. Wald, S.L. Saddler and G.E. Amidon, "Influence Of HPMC/TALC Undercoating And PEG/Surelease Polymer Coating On The Release Of Flurbiprofen From A Multiparticulate Controlled Release System," AAPS, National Meeting, Orlando, FL, October 30 - November 4, 1988.
17. R.J. Wald and G.E. Amidon, "Calculation of Polymer Coating Thickness and Effective Drug Diffusion Area of Sustained Release Coated Drug Beads," AAPS Midwest Regional Meeting, Chicago, IL, May 14, 1990.
18. R.J. Wald and G.E. Amidon, "Calculation of Polymer Coating Thickness and Effective Drug Diffusion Area of Sustained Release Coated Drug Beads," AAPS Midwest Regional Meeting, Chicago, IL, May 14, 1990.
19. E.W. Thomas, M.M. Cudahy, C.H. Spilman, D.M. Dinh, T.L. Watkins, G.E. Amidon, and R.J. Wald, "Cholesterol Lowering Bile Acid Binding Agents: Novel Lipophilic Polyamines," Boston American Chemical Society Meeting, Boston, MA, April 23-27, 1990.
20. C.H. Spilman, E.W. Thomas, D.M. Dinh, M.M. Cudahy, R.J. Wald and G.E. Amidon, "Novel bile Acid Binding Agents to Lower Plasma Cholesterol," 55th Annual Meeting of the European Atherosclerosis Society, Brugge, Belgium, May 16-19, 1990.
21. M.E. Houghton and G.E. Amidon, "Shape Analysis of Pharmaceutical Solids," AAPS Midwest Regional Meeting, Chicago, IL, May 14, 1990.
22. R.J. Wald, G.E. Amidon, and C.H. Spilman, "Influence of Particle Size and Bile Acid Concentration on the Kinetics of Cholate Binding by Colestipol-HCl," AAPS Annual Meeting, Las Vegas, NV, November 1990.
23. D.W. Osborne, G.E. Amidon, P.J. DeMulder, and T.M. Creek, "Effect of Self Association on In vitro Percutaneous Permeation of Ibutilide Fumarate," 1991 Central Regional Meeting, Society for Investigative Dermatology, Chicago, IL, November 1991.

24. G.E. Amidon, M.E. Houghton, D.A. Shrauger, and V.E. McCurdy. "Influence of Moisture on the Mechanical Properties of Microcrystalline Cellulose," Second Annual Symposium on Moisture, University of Wisconsin, Madison WI, September 16-17, 1992.
25. J.K. Rhie, G. DeBrincat, R.J. Wald, G.E. Amidon, L. Putcha, and G.L. Amidon. "Preliminary Development of a Non-invasive Method to Assess Gastric Emptying," AAPS Annual Meeting, Orlando, FL, November 1993.
26. G.E. Amidon, M.E. Houghton, D.A. Shrauger, and V.E. McCurdy. "Influence of Moisture on the Mechanical Properties of Microcrystalline Cellulose," AAPS Annual Meeting, Orlando, FL, November 1993.
27. N.F.H. Ho, R.J. Wald, G.E. Amidon, C.L. Barsuhn and M.V. Mikelsons. "Analysis of the Pharmacodynamics of Bile Salt Binding with Colestid Granules in the GI Tract," AAPS Annual Meeting, San Diego, CA, November 1994.
28. J.K. Rhie, Y. Hayashi, L.S. Welage, J.L. Barnett, R.J. Wald, G.E. Amidon, L. Putcha, G.L. Amidon. "The Effect of Meal Viscosity on the Gastric Emptying of 0.71 mm Caffeine and 3.6 mm Acetaminophen Enteric Coated Pellets in Humans," AAPS Annual Meeting, San Diego, CA, November 1994.
29. R.J. Wald, R.S.Hsi, Ja.A. Easter, L.J. Larion, G.E. Amidon, and R.H. Meury. "Use of a McCrone Micronizing Mill for Small Scale Milling/Micronization of Radioactive Toxic or Potent Drugs," AAPS Annual Meeting, Miami Beach, November 1995.
30. K. Yamamoto, R.J. Wald, S. Narita, T. Yoshizawa, T. Nishihata and G.E. Amidon. "Validation Study of "Wet-Granule Sieving" Method for Endpoint Detection. Part I," AAPS Annual Meeting, Miami Beach, November 1995.
31. R.J. Wald, G.E. Amidon, D.J. Reits, F.J. McGill, K. Yamamoto, H. Emori, and T. Nishihata. "An In-process Method for Determining Wet Granulation Endpoint by Wet-Granule Sieving. Part II," AAPS Annual Meeting, Miami Beach, November 1995.
32. G.E. Amidon and M.E. Houghton. "The Effects of Physical and Mechanical Properties on Powder Flow," AAPS Annual Meeting, Miami Beach, November 1995.
33. J.K. Rhie, Y. Hayashi, L.S. Welage, J.L. Barnett, R.J. Wald, G.E. Amidon, L. Putcha, and Gordon L. Amidon. "Evaluation of a Novel Non-Invasive Method to Assess Size Differentiated Gastric Emptying in Humans," AAPS Annual Meeting, Miami Beach, November 1995.
34. Rohrs, BR, Amidon, GE, Best, DK, Meury, RH. "Development, Validation and Applications of a Model for Powder Dissolution," AAPS Annual Meeting, Seattle Washington, November 1996.
35. Ching Kim Tye, Changquan (Calvin) Sun, Gregory E. Amidon, "Evaluation of the effects of tableting speed on the relationships between compaction pressure, tensile strength and solid fraction," AAPS Annual Meeting, Baltimore MD, Nov 2004.
36. CChang, FAlvarez-Nunez, WYHsieh, AKong, PNarayan, GEAmidon, "Effect of Particle Size on The Flowability and Segregation Potential of Pharmaceutical Blends," AAPS Annual Meeting, Nov 2005.
37. Seceast, PJ, He, X, Amidon, GE, "Mechanistic study of the effect of roller compaction and lubricant on tablet mechanical strength", AAPS Annual Meeting, San Antonio, TX, Oct 31, 2006.

38. Seceast, PJ, He, X, Amidon, GE, “Mechanistic study of the effect of roller compaction and lubricant on tablet mechanical strength”, AAPS Annual Meeting, San Antonio, TX, Oct 31, 2006.
39. LHan, Jelliott, ACBentham, AMills, GEAmidon, BCHancock, “Numerical Simulation on Pharmaceutical Powder Compaction”, submitted to: 25th International Conference on Physical & Numerical Simulation of Materials Processing, Zhengzhou City, China, October 2007.
40. DMouro, GEAmidon, “Comparison of Blend and Granulation Flow Function Coefficients”, AAPS Annual Meeting, San Diego, CA, November 2007.
41. DMouro, GEAmidon, MMullarney, GCarlson, “Understanding the Relationship between Carr Compressibility Index (CI) and Powder Flow: A new Rating System for CI”, AAPS Annual Meeting, San Diego, CA November 2007.
42. CMaheshwari, AJayasankar, JNKhan, GEAmidon, NRodriguez-Hornedo, “Identifying the factors that influence cocrystal formation in the solid state”, AAPS Annual Meeting, Atlanta, GA, November 2008.
43. RLafaver, KMoore, CSheehan, GEAmidon, ESchmitt, RCMoretton “Excipient Performance and Functionality and How They Relate to Quality Control”, ExcipientFest Americas, Puerto Rico, May 2010.
44. BJKrieg, KAlidoost, XOkalibe, MHaas, GEAmidon, “Impact of Cylinder Volume and Particle Size on Bulk and Tapped Density Measurements”, AAPS Annual Meeting, New Orleans, LA, November 2010.
45. RLafaver, GHolloway, KMoore, CSheehan, GEAmidon, ESchmitt, LBlock, RCMoretton, “Excipient Performance, Functional Category and How They Relate to Quality by Design”, NIPTE Research Conference: Understanding Excipient Performance – Key to Successful QbD Formulation Design. FDA Conference Facilities, White Oak, Silver Spring, MD, June 13-14, 2012
46. KDempah, JKim, GEAmidon, EMunson, “Non-destructive method for assessing particle size distributions within solid formulations”, AAPS Annual Meeting, Chicago, IL, October 2012.
47. DMMudie, YShi, PGao, GLAmidon, GEAmidon, “Mechanistic analysis of simultaneous drug dissolution and partitioning in an in vitro physiological two-phase dissolution apparatus”, AAPS Annual Meeting, Chicago, IL, October 2012.
48. BJKrieg, GLAmidon, GEAmidon, “Predictions and Experimental Dissolution Rates for Weakly Acidic Drugs in Phosphate Buffer and Physiologically Relevant Bicarbonate Buffer Concentrations of the Human Intestine”, AAPS Annual Meeting, Chicago, IL, October 2012.
49. DMMudie, KMurray, SEPritchard, CLHoad , MCGarnett, GLAmidon, PAGowland, RCSpiller,GEAmidon, LMarciani, “Quantification of gastrointestinal liquid volumes following a glass of water”, AAPS Annual Meeting, San Antonio, TX, November 2013.
50. STakeuchi, YTsume, DMudie, GEmidon, GLAmidon, “Development of Gastric Intestinal System (GIS: Three Compartments Dissolution Model) and Perform the Dissolution Test for BCS Class II Basic Drug in the GIS”, AAPS Annual Meeting, San Antonio, TX, November 2013.
51. KAMurry, DMMudie, SEPritchard, CLHoad, MCGarnett, GLAmidon, RCSpiller, GEAmidon, PAGowland, LMarciani, “Quantification of gastrointestinal liquid volumes following a 240 mL dose of water”, ISMRM-ESMRMB Meeting, Milan, Italy, May 2014.

52. BJKrieg, SMTaghavi , GLAmidon, GEAmidon, "An In Vivo Relevant Buffer System: Transport Analysis of Dissolution in CO<sub>2</sub> Bicarbonate Buffer", AAPS Annual Meeting, San Diego, CA Nov 2014.
53. BJKrieg, SMTaghavi , GLAmidon, GEAmidon, "Matching Physiologically Relevant Bicarbonate Buffer to Phosphate Buffer through Transport Analysis", AAPS Annual Meeting, San Diego, CA Nov 2014.
54. BJKrieg, SMTaghavi , GLAmidon, GEAmidon, "Using In Vivo Flow Rates in USP Apparatus 4 to Develop a More In Vivo Relevant Hydrodynamic Dissolution Test", AAPS Annual Meeting, San Diego, CA Nov 2014.
55. FJCao, NRodriguez-Hornedo, GEAmidon, "Mechanistic analysis of cocrystal dissolution as a function of pH and micellar solubilization", AAPS Annual Meeting, San Diego, CA Nov 2014.
56. DArthur, NThakral, MNethercott, DEGromek-Woods, EGhaly, GEAmidon, CCSun, RSuryanarayanan, EJMunson, "Monitoring Effects of Compaction Pressure and Storage Conditions on Polymorphic Changes of Chlorpropamide in Tablets", AAPS Annual Meeting, San Diego, CA Nov 2014.
57. NTWinqvist, MJNethercott1, GEAmidon, EJMunson, Characterizing of Variability in Magnesium Stearate in Bulk and in Formulations, AAPS Annual Meeting, San Diego, CA Nov 2014.

### **INVITED PRESENTATIONS**

1. "Powder Flow Studies Utilizing a Simplified Shear Cell Apparatus," University of Michigan, College of Pharmacy Pharmaceutics Seminar, Sept., 1982.
2. "Flowability of Powders," Fourth Annual Update Conference, University of Wisconsin-Extension, Nov., 1984.
3. "Powder Flow Characterization," Fifth Annual Update Conference, University of Wisconsin-Extension, October, 1985.
4. "Characterization of Powder Flow," University of Texas, College of Pharmacy, April, 1986.
5. "Physical and Mechanical Property Effects on Powder Flow," AAPS Pharmaceutical Technology Symposium, AAPS National Meeting, Orlando, FL, November, 1988.
6. "Mechanical Property Characterization of Bulk Drug, Excipients, and Formulations," Wisconsin Update Conference in Pharmaceutics, April, 1989.
7. "Physical and Mechanical Property Effects on Powder Flow," Land O"Lakes Conference, Wisconsin, June, 1989.
8. "Physical and Mechanical Property Characteristics of Pharmaceutical Materials," 1990 Ardon House Conference, Harriman, NY, January 1991.
9. "Compaction Characteristics of Excipients," Land O"Lakes Conference, Wisconsin, June, 1992.
10. "Physical Test Methods," Second Joint Pharmacopeial Open Conference on International Harmonization of Excipient Standards, St. Petersburg Beach, FL Jan 30 - Feb 2, 1994.

11. "Mechanical Properties of Powders: Basic Considerations and Characterization," 1997 Arden House Conference, Harriman, NY, January 1997.
12. "Physical and Mechanical Properties of Powders," Joint AAPS/Royal Pharmaceutical Society of Great Britain Conference, Southampton, England, March 1997.
13. "Powder Characterization and Evaluation of Powdered Materials," 1997 Eighth International Symposium on Pharmaceutical and Biomedical Analysis," Orlando, FL May 4-7, 1997.
14. "Mechanical Properties: Even Formulations Behave Differently Under Stress," College of Pharmacy, Purdue University, West Lafayette, IN, March 25, 1998.
15. "Powder Flow," June Land-O-Lakes Research Conference, University of Wisconsin-Extension, Lake Delton, WI, June 1-5, 1998.
16. "Future Trends in Powder Characterization," June Land-O-Lakes Research Conference, University of Wisconsin- Extension, Lake Delton, WI, June 1-5, 1998
17. "Introduction to the Expert System for Capsule Formulation Development," Expert Working Group, Capsugel Conference, Baltimore, MD, August 19, 1998.
18. "The Role of Excipient Functionality in Today's Environment," WorldPharm 98 Conference, Philadelphia, PA, September 22-23, 1998.
19. "Powder Characterization," Interpharmacoepial Open Conference on International Harmonization, Sevilla, Spain, October 26-27, 1998.
20. "Fundamental Forces and the Mechanics of Solids," University of Iowa, College of Pharmacy, Iowa City, IA, February 1999.
21. "Physical Property Characterization and Beyond," Physical Properties of Pharmaceutical Solids Symposium, AAPS Annual Meeting, Indianapolis, IN, Oct 31, 2000.
22. "Characterization of the Mechanical Properties of Pharmaceutical Solids," College of Engineering, University of Michigan, Ann Arbor, MI, December 7, 2000.
23. "Excipients: Where Are We Heading?" 24th Annual meeting of Puerto Rico Pharmaceutical Quality Association, San Juan, Puerto Rico, January 30-31, 2001.
24. "Excipient Function: Implementation of Performance Tests," USP Open Conference, December 11-14, 2001, Ft. Myers, FL.
25. "Mechanical Property Characterization of API, Excipients and Formulations During Development," AAPS Pharmaceutics and Drug Delivery Conference, Washington DC, April 2002.
26. "Mechanical Property Characterization of API, Excipients and Formulations During Development," University of Minnesota. Minneapolis, MN, September 4, 2002.
27. "Update on Excipient Functionality Tests," AAPS Annual Meeting, Toronto, Canada, November 14, 2002.

28. "Roundtable Discussion: Issues Regarding a Fast to Human Approach," Michael J. Hageman, Gregory E. Amidon, Michael S. Bergren, AAPS Annual Meeting, Toronto, Canada, November 14, 2002.
29. "Excipient Function: Implementation of Performance Tests," Federation of the Brazilian Pharmaceutical Manufacturers (FEBRAFARMA) Conference on Pharmaceutical Excipients, November 18-19, 2002, Brazil.
30. "Fundamental Aspects of Solid Dosage Forms," University of Wisconsin – Extension, Pfizer, Inc., Ann Arbor, MI June 23-25, 2003.
31. "Mechanical Properties of Pharmaceutical Materials," 2<sup>nd</sup> Annual Meeting of Chinese Pharmaceutical Association, Shanghai, China, November 2003.
32. "Process Characterization," 2<sup>nd</sup> Annual Meeting of Chinese Pharmaceutical Association, Shanghai, China, November 2003.
33. "Early Preformulation and Formulation Evaluation of NCEs. Is it Useful, Practical, or Even Necessary to Assure Success in Pharmaceutical Development?," AAPS Annual Meeting Roundtable Discussion, Baltimore MD, November 6, 2004.
34. "Mechanical Properties of Mixtures. 1+1≠2," 2<sup>nd</sup> Annual Garnet Peck Symposium, Purdue University, West Lafayette, IN, November 18, 2004.
35. "Effects of Particle Size, Shape and Texture on Pharmaceutical Processing and Performance," AAPS Arden House Conference, Arden House Conference Center, Harriman, NY, January 2005
36. "Particle Engineering, A Formulator's Perspective," AAPS Arden House Conference, Arden House Conference Center, Harriman, NY, January 2005.
37. "Controlling Excipient Quality," Conference on Challenges in Global Pharmaceutical Product Development, Dublin, Ireland, April 19-20, 2005.
38. "Intrinsic Properties of Drug Substance, Excipients, and Process Selection," FDA Office of Generic Drugs Manufacturing Sciences Workshop on Manufacturing Science and Scale-up Challenges in the Manufacture of Oral Dosage Forms, Gaithersburg, Maryland, May 23, 2005.
39. "Excipient Performance Tests," USP Annual Scientific Meeting 2005, San Diego, CA, September 2005.
40. "Mechanical Property Characterization of Pharmaceutical Mixtures", Department of Materials Science, University of Cambridge, UK, August 2, 2006.
41. "Mechanical Property Characterization of Pharmaceutical Materials, Formulations and Processes Suitable for Combination Products", AAPS Conference: Challenges in developing fixed- dose Combination Oral Solid Dose Products, Crystal City, VA., September 13-14, 2006.
42. "Data Driven Formulation Development Using Material Sparing Methods", Garnet Peck Symposium, Purdue University, West Lafayette, IN, September 20-21, 2006.
43. "Performance Related Tests in Excipients", USP Annual Scientific Meeting 2006, Denver, CO, Sept., 2006.

44. "Compaction Properties of Pharmaceutical Ingredients", College of Pharmacy, Pharmaceutics Conference, University of Michigan, Ann Arbor, MI, October 27, 2006.
45. "Evolving USP Developments in Excipient Technology", AAPS Pharmaceutical Technologies Symposium, AAPS Annual Meeting, San Antonio, TX, November 2, 2006.
46. "Excipient Performance" and "Multi-source Excipients", United States Pharmacopeia & FebrFarm
47. Excipient Conference, San Paulo, Brazil, May 7-8, 2007.
48. "Quality of Manufactured Medicines: General Chapters and Performance Testing", USP Annual Scientific Meeting 2007, Tampa, FL, September 25-27, 2007.
49. "Keynote talk: Challenges in pharmaceutical solids characterization", Arden House Conference, West Point, NY Feb 3-8, 2008.
50. "Compaction Simulation and Applications", Arden House Conference, West Point NY, February 3-8, 2008.
51. "Linking Physical & Chemical Characteristics with Formulation Strategies and "First in Human" Formulations", AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidate Selection, South San Francisco, CA., May 19-21, 2008.
52. "Pharmaceutical Materials Science: Application of Dynamic and Quasi-static Test Methods to Characterize Pharmaceutical Solids", New Jersey Pharmaceutical Association for Science and Technology (NJPhAST), Somerset, NJ, September 18, 2008.
53. "Fundamental Issues of Particles and Powders for Pharmaceutical Applications", 1st Asian Pharmaceutical Technologies Arden Conference and Annual Meeting of the Pharmaceutics Committee of Chinese Pharmaceutical Association, Beijing, China, November 2008.
54. "Powder Compaction and Simulation", 1st Asian Pharmaceutical Technologies Arden Conference and Annual Meeting of the Pharmaceutics Committee of Chinese Pharmaceutical Association, Beijing, China, November 2008.
55. "Understanding the Mechanical Properties of Drug Substance and their Impact on Formulation and Process Development", Joint Symposium, AAPS Annual Meeting, Atlanta, GA, November 2008.
56. "Fundamental Issues of Particles and Powders for Pharmaceutical Applications", Joint Symposium, AAPS Annual Meeting, Atlanta, GA, November 2008.
57. "Pharmaceutical Materials Science: Impact of crystal properties on the mechanical properties of particles, powders, and tablets", New Jersey Institute of Technology, Graduate Seminar Series in Chemical Engineering, Newark, NJ, February 16, 2009.
58. "Pharmaceutical Materials Science: Powder Characterization", Physical Pharmacy and Biopharmaceutics Meeting, AAPS, Baltimore, MD, May 2009.
59. "Excipient QbD As It Relates to Excipient Performance and Functionality: USP Excipient Performance Chapter <1059>", USP Annual Scientific Meeting 2009, Washington D.C., June 2009.
60. AAPS Webinar, "Pharmaceutical Materials Science: Mechanical Property Characterization of Pharmaceutical Solids", June 2009.



61. "Pharmaceutical Materials Science/Mechanical Property Characterization: Industrial Applications and Academic Research", The Mylan School of Pharmacy, Duquesne University, Pittsburgh, PA, October 2009.
62. AAPS Visiting Scientist lecture, "Pharmaceutical Materials Science/Mechanical Property Characterization: Industrial Applications and Academic Research", College of Pharmacy, University of Toledo, Toledo, OH, October 2009.
63. "Excipient Performance <1059>, Critical Material Attributes, QbD and Functionality Related Characteristics", GEAmidon, USP Annual Scientific Meeting, New Orleans, LA 2010.
64. "Powder Compaction Characterization – A Macroscopic View", GEAmidon, Engineering Research Center for Structured Organic Particulate Systems Conference, New Jersey Institute of Technology, Newark, NJ, May 2011.
65. "Oral Bioperformance In vitro Testing and Predictions", GEAmidon, AstraZeneca, Gothenburg, Sweden, May 2011.
66. "Making Sense of Excipient Performance for Quality by Design (QbD). Catherine Sheehan, Ian Robertson, Chris Moreton, Lawrence Block, Gregory E. Amidon. Webinar. ([www.pharmtech.com](http://www.pharmtech.com)). April 19, 2012
67. "Compaction and the Properties of Mixtures", NIPTE Research Conference: Understanding Excipient Performance – Key to Successful QbD Formulation Design. GEAmidon, Junghyun Kim, FDA Conference Facilities, White Oak, Silver Spring, MD, June 13-14, 2012
68. "Introduction to <1059> Excipient Performance: QbD Principles", GEAmidon, USP Workshop on Food Ingredients", Washington DC, June 2012.
69. "Oral Bioperformance and 21<sup>st</sup> Century Dissolution Testing", FDA Advisory Panel Meeting, FDA Conference Facilities, White Oak, Silver Spring, MD, August, 2012
70. "Physiologically Relevant Parameters for In Vitro Testing Including Bicarbonate Buffer and Surface pH", GEAmidon, BJKrieg, GLAmidon, AAPS Workshop on Oral Bioperformance, October 13-14, 2012.
71. "Modeling Two Phase Dissolution System", GEAmidon, DMMudie, GLAmidon, AAPS Workshop on Oral Bioperformance, October 13-14, 2012.
72. "Compaction and the Properties of Mixtures", GEAmidon, Junghyun Kim, Compaction Simulation Forum. Cambridge, MA, Nov 12-13, 2012.
73. "Compaction and the Properties of Mixtures", GEAmidon, RIyer, JKim, AAPS Arden House Conference, Washington DC, March 2013.
74. "Industrial aspects of drug dissolution", GEAmidon, DMMudie, BJKrieg, STakeuchi, GLAmidon, European Federation for Pharmaceutical Sciences (EUFEPS), Drug Absorption, Transport and Delivery: Responding to Challenging Situations", Uppsala, Sweden, June 23-26, 2013.
75. "The future of oral bioperformance evaluation of solid dosage formulations", GEAmidon, Academy of Pharmaceutical Science and Technology, Japan (APSTJ), Kyoto, Japan, August 19-20, 2013.

76. "Discovery to Market: Challenges and Opportunities", GEAmidon, Institute for Supply Management, Western Michigan University, Kalamazoo, MI, February 18, 2014
77. "The Best Buffer (or at least a unique buffer) in the World: CO<sub>2</sub>-Bicarbonate", GEAmidon, BJKrieg, GLAmidon, In Vivo Predictive Dissolution Conference, Ann Arbor, MI, August 2014.