

CURRICULUM VITAE  
STEPHEN W. HOAG

**PERSONAL DATA**

Business Address:

School of Pharmacy  
University of Maryland at Baltimore  
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**EDUCATION**

Ph.D. in Pharmaceutics (August 1990)  
University of Minnesota-Twin Cities  
Advisor: Edward G. Rippie, Ph.D.  
Major: Pharmaceutics

Bachelor of Science (May 1982)  
University of Wisconsin-Madison  
Major: Biochemistry

**EXPERIENCE**

- 4/95-Present     **Professor - School of Pharmacy, University of Maryland - Baltimore**  
Research areas include (1) sustained release tablet formulation, dissolution testing, mathematical modeling of tablet compaction, design of tablet machine instrumentation, PC-based data acquisition systems, computer-aided manufacture and formulation, testing of nutritional supplements and PAT. (2) Use of mass transport theories to mathematically model calcium alginate gel formation and diffusion of bioactive molecules from alginate gels. (3) Prenatal vitamin formulation. (4) Thermal analysis of polymers used in film coating. (Promoted to Associate July 1, 2001, Full July 1, 2009)
- 9/08 - Present     **Director - University of Maryland, School of Pharmacy GMP Facility**  
The facility's mission is to provide services such as the design of dosage forms and the production of clinical supplies for small scale Phase I studies needed by academic clinicians and small companies who are performing translational research. Duties include providing scientific oversight, managing day-to-day operations of facility, head of quality assurance and writing regulator documents such as the CMC sections of INDs. Provide development guidance to take ideas from academic clinicians and small companies to the next stage.
- 5/95 - 6/97     **Full Graduate Faculty - Department of Physics, Oregon State University**  
Doctoral thesis advisor for Shawna K. Inoue a Ph.D. in physics at OSU. She used mass transport theories to mathematically model calcium alginate gel formation and diffusion of bioactive molecules from alginate gels.

## STEPHEN W. HOAG

### Page 2

- 9/90 - 4/95      **Assistant Professor - College of Pharmacy, Oregon State University**  
Research areas included sustained release tablet formulation, fluid-bed coating, dissolution testing, mathematical modeling of tablet compaction, design of tablet press instrumentation, PC-based data acquisition systems, and computer-aided manufacture.
- 9/94 - 12/94      **Visiting Professor - Solids Group, Abbott Laboratories, North Chicago, IL**  
Worked on the formulation of a sustained release fluoroquinolone; did wet and dry granulation of waxy materials in GMP facilities and studied the interrelationships between drug solubility, manufacturing conditions, HLB of waxy materials, and drug release rate. Assisted in the development of a semisolid formulation for an HIV protease inhibitor.
- 11/92 - 12/92      **Visiting Professor - Aerosol Group, 3M Pharmaceuticals, St. Paul, Minnesota**  
Conducted a study to investigate the relationship between Kauri-Butanol numbers, solubility parameters, elastomer swelling, and elastomer leak rate for alternative HFC propellants.
- 5/90 - 9/90      Formulated and tested aerosols, worked with cold and pressure filling equipment. Tested particle size using cascade impactor, laser light scattering, and optical microscopy. Used Kauri-Butanol test to investigate the solvent power of alternative propellants (HFC's) and cosolvent blends.
- 1/86 - 5/90      **Research Assistant - Department of Pharmaceutics, University of Minnesota**  
Ph.D. Thesis title: "Physics of Tablet Compaction: Viscoelastic and Thermodynamic Analysis of Internal Tablet Structure." Instrumented a rotary tablet machine and set up a computer data acquisition system. Programmed in BASIC, Pascal, FORTRAN and C.
- 9/87 - 12/87      **Teaching Assistant - Department of Pharmaceutics, University of Minnesota**  
Full responsibility for the teaching of Pharmaceutical Calculations, Phar 5603.
- 9/83 - 1/86      **Research Assistant - Department of Pharmaceutics, University of Minnesota and the World Health Organization**  
Conducted preformulation studies of the different polymorphs and the transitions between polymorphic forms of steroid crystals for use in long-acting contraceptives. Formulated aqueous microcrystalline steroid suspensions, and did quality control analysis of particle size using a Coulter Counter. Characterization of the physical properties of steroids using IR, powder X-ray diffraction, SEM, photo-optical microscopy, DSC, Coulter Counter, dissolution rate, and solubility in isoctane.
- 10/82 - 6/83      **Teaching Assistant - Department of Pharmaceutics, University of Minnesota**  
Gave lectures in physical pharmacy and worked in teaching laboratories.
- 4/81 - 9/82      **Lab Technician - Department of Bacteriology, University of Wisconsin**  
Characterized polygalacturonic acid hydrolase enzyme kinetics from the thermophilic anaerobe *Clostridium thermosulfurogenes*. Found culture conditions that optimized

## STEPHEN W. HOAG

Page 3

consistent cell growth and enzyme production in large anaerobic fermenters and chemostats.

Summers 80 - 81 **Lab Technician - Department of Meat and Animal Science, University of Wisconsin**  
Assisted in a study that tested a new low-temperature method of making summer sausage. Analyzed meat samples for nitrite, percent protein, fat, pH, moisture, and ash content.

### PROFESSIONAL ACTIVITIES & ASSOCIATIONS

Elected USP Council of Experts for 2010 to 2015

Elected USP Council of Experts for 2005 to 2010

Elected USP Council of Experts for 2000 to 2005

Editorial Board for APhA Handbook of Pharmaceutical Excipients 5<sup>th</sup> and 6<sup>th</sup> editions

Editorial Advisory Board for the journal of *Pharmaceutical Development and Technology*

Member of NIPTE (National Institute of Pharmaceutical Technology and Education) Executive Committee (2005 – present)

Manuscript reviewer: *Drug Development and Industrial Pharmacy*  
*International Journal of Pharmaceutics*  
*Journal Pharmaceutical Sciences*  
*Pharmaceutical Development and Technology*  
*Pharmaceutical Research*  
*PharmSciTech*

Reviewed grants for Natural Sciences and Engineering Research Council of Canada (NSERC: Canadian version of NSF) January 1993

Member of:

American Association of Pharmaceutical Sciences  
American Association for the Advancement of Science  
American Chemical Society  
American Institute of Chemical Engineers  
Controlled Release Society  
Society for Applied Spectroscopy

### HONORS AND FELLOWSHIPS

2012 USP Award for an Outstanding Contribution to the Standards-setting Process

Ralph Shangraw Memorial Award 2011

Outstanding Contributed Paper Award, Regulatory Science Section. Pharmaceutical Sciences World Congress (PSWC) /AAPS Annual Meeting held in New Orleans LA, 2010

Elected AAPS Fellow 2009

Elected AACP Delegate 2001-2002

Eli Lilly Young Investigator Award 1993 -1994  
Rho Chi Honor Society (March 1987)  
T. H. Rowell Graduate Fellowship (1987-88)  
T. H. Rowell Graduate Fellowship (1983-84)  
Melendy Graduate Fellowship (Summer 1983)  
Deans Honor List, University of Wisconsin, Four Semesters

## **PUBLICATIONS**

Harris Howland, Raafat M. Fahmy and Stephen W. Hoag, "Analysis of Curing of a Sustained Release Coating Formulation by Application of NIR Spectroscopy to Monitor Changes Associated with Glyceryl Monostearate", *Drug Dev. Ind. Pharm.*, submitted (2013)

Hanpin Lim and Stephen W. Hoag, "Plasticizer effects on physical-mechanical properties of solvent cast Soluplus® films", *AAPS PharmSciTech*, accepted (2013)

Harris Howland and Stephen W. Hoag, "Analysis of Curing of a Sustained Release Coating Formulation by Application of NIR Spectroscopy to Monitor Changes Physical-Mechanical Properties", *Int. J. Pharm.*, **452**(1-2):82-91(2013) DOI: 10.1016/j.ijpharm.2013.04.035

Ravikanth Kona, Haibin Qu, Robert Mattes, Bela Jancsi, Raafat M. Fahmy, Stephen W. Hoag, "Application of in-line near infrared spectroscopy and multivariate batch modeling for process monitoring in fluid bed granulation, *Int. J. Pharm.*, **452**(1-2):63-72(2013). DOI: 10.1016/j.ijpharm.2013.04.039

Vivek S. Dave, Raafat M. Fahmy and Stephen W. Hoag, "Investigation of the physical-mechanical properties of Eudragit® RS PO / RL PO and their mixtures with common pharmaceutical excipients", *Drug Dev. Ind. Pharm.*, **39**(7):1113-25(2013), DOI: 10.3109/03639045.2012.714786

Raafat Fahmy, Ravikanth Kona, Ramesh Dandu, Walter Xie, Gregg Claycamp and Stephen W., Hoag, "Quality by Design I: Application of Failure Mode Effect Analysis (FMEA) and Plackett-Burman Design of Experiments in the Identification of "Main factors" in the Formulation and Process Design Space for Roller-Compacted Ciprofloxacin Hydrochloride Immediate-Release Tablets", *AAPS PharmSciTech*, **13**(4):1243-1254(2012). DOI: 10.1208/s12249-012-9844-x.

Vivek S. Dave, Raafat M. Fahmy, Dennis Bensley and Stephen W. Hoag, "Eudragit® RS PO/RL PO as rate-controlling matrix-formers via roller-compaction: Influence of formulation and process variables on functional attributes of granules and tablets", *Drug Dev. Ind. Pharm.*, **38**(10):1240-1253(2012), DOI:10.3109/03639045.2011.645831

Ikoni Joshua Ogaji and Stephen W. Hoag, "Effect of Grewia Gum as a Suspending Agent on Ibuprofen Pediatric Formulation" *PharmSciTech*, **10**(2):507-13(2011), DOI: 10.1208/s12249-011-9606-1

H. Lim, V. Dave, L. Kidder, N. Lewis, R. Fahmy and S.W. Hoag, "Assessment of the critical factors affecting the porosity of roller compacted ribbons and the feasibility of using NIR chemical imaging to evaluate the porosity distribution", *Int. J. Pharm.*,410:1-8 (2011), doi:10.1016/j.ijpharm.2011.02.028

Stuart Cantor, Stephen W. Hoag, Larry L. Augsburger, Christopher D. Ellison, Mansoor A. Khan and Robbe C. Lyon, "NIR Spectroscopy applications in the development of a compacted multiparticulate system for modified release" *PharmSciTech* (2011), DOI: 10.1208/s12249-010-9580-z

Adam A. Dinerman, Joseph Cappello, Mohamed El-Sayed, Stephen W. Hoag, Hamidreza Ghandehari, "Influence of Solute Charge and Hydrophobicity on Partitioning and Diffusion in a Genetically Engineered Silk-Elastin-Like Protein Polymer Hydrogel", *Macromol. Biosci.*, **10**:1235-47 (2010) online DOI: 10.1002/mabi.201000061

Diane V. Doughty, Lei Diao, Stephen W. Hoag, and Richard N. Dalby, "Use of Flexible Weighted Nasal Spray Dip Tubes to Improve Product Performance", *J Aerosol Med Pulm Drug Deliv.*, **22**(4):1-7 (2009) online DOI: 10.1089/jamp.2008.0727

Simin Hassannejad Tabasi, Vikas Moolchandani, Raafat Fahmy, and Stephen W. Hoag. "Sustained Release Dosage Forms Dissolution Behavior Prediction: A Study of Matrix Tablets Using NIR Spectroscopy" *Int. J. Pharm.***382**(1-2):1-6 (2009).

Sharon Flank, Stephen W. Hoag and James E. Polli, "Near Infrared Spectrophotometric Comparison of Authentic and Suspect Pharmaceuticals" *Pharm. Tech.* **38**(8):46-52 (2009).

Stuart L. Cantor, Stephen W. Hoag, and Larry L. Augsburger, "Evaluation of the mechanical properties of extrusion-spheronized beads and multiparticulate systems", *Drug Dev. Ind. Pharm.*, **35**(6): 683-693 (2009) online DOI: 10.1080/03639040802526797

Stuart L. Cantor, Stephen W. Hoag, and Larry L. Augsburger, "Formulation and characterization of a compacted multiparticulate system for modified release of water-soluble drugs – Part II theophylline and cimetidine" *Drug Dev. Ind. Pharm.* **35**(5):568-582 (2009) online DOI: 10.1080/03639040802459460

Stuart L. Cantor, Stephen W. Hoag, and Larry L. Augsburger, "Formulation and characterization of a compacted multiparticulate system for modified release of watersoluble drugs – Part I Acetaminophen" *Drug Dev. Ind. Pharm.* **35**(3):337-351 (2009) online DOI: 10.1080/03639040802360502

Simin Hassannejad Tabasi, Raafat Fahmy, Dennis Bensley, Charles O'Brien, Stephen W. Hoag. "Quality by Design, Part III: Study of Curing Process of Sustained Release Polymer Products Using NIR Spectroscopy" *J. Pharm. Sci.* **97**(9):4067-4086 (2008).

Simin Hassannejad Tabasi, Raafat Fahmy, Dennis Bensley, Charles O'Brien, Stephen W. Hoag. "Quality by Design, Part II: Application of NIR Spectroscopy to Monitor the Coating Process for a Pharmaceutical Sustained Release Product" *J. Pharm. Sci.* **97**(9):4052-4066 (2008).

Simin Hassannejad Tabasi, Raafat Fahmy, Dennis Bensley, Charles O'Brien, Stephen W. Hoag. "Quality by Design, Part I: Application of NIR Spectroscopy to Monitor Manufacturing Process for Orbifloxacin Tablets" *J. Pharm. Sci.* **97**(9):4040-4051 (2008).

Aditya S Tatavarti, Francis X Muller and Stephen W. Hoag, "Evaluation of the Deformation Behavior of Methacrylic Acid Copolymers and Hydroxypropyl Methylcellulose Using a Compaction Simulator" *Int. J. Pharm.* **348**(1-2): 46-53 (2008).

Lin Xie, Huiquan Wu, Meiyu Shen, Larry L. Augsburger, Robbe C. Lyon, Mansoor A. Khan, Ajaz S. Hussain, Stephen W. Hoag. "Quality-by-Design: Effects of Testing Parameters and Formulation Variables on the Segregation Tendency of Pharmaceutical Powder Measured by the ASTM D 6940-04 Segregation Tester" *J. Pharm. Sci.* **97**(10):4485-4497 (2007).

Pallavi Nithyanandan, Stephen W. Hoag, and Richard N. Dalby. "The Analysis and Prediction of Functional Robustness of Inhaler Devices" *J. Aerosol Med.* **20**(1): 19-37 (2007).

Martinez, Marilyn, Kawalek, Joseph, Howard, Karyn, Ward, Jeffrey, Marroum, Patrick, Marnane, William, Bensley, Dennis, Pelsor, Francis, Hoag, Stephen, Tatavarti, Aditya, Xie, Lin and Raafat Fahmy. "Comparison of Bovine In Vivo Bioavailability of Two Sulfamethazine Oral Boluses Exhibiting Different In Vitro Dissolution Profiles." *J. Vet. Pharmacol. Ther.* **29**(6): 459-467 (2006).

Aditya S Tatavarti and Stephen W. Hoag. "Microenvironmental pH Modulation Based Release Enhancement of a Weakly Basic Drug from Hydrophilic Matrices" *J. Pharm. Sci.* **95**(7): 1459-1468 (2006).

Aditya S. Tatavarti, Raafat Fahmy, Huiquan Wu, Ajaz S. Hussain, William Marnane, Dennis Bensley, Gary Hollenbeck, and Stephen W. Hoag. "Assessment of NIR Spectroscopy for Nondestructive Analysis of Physical and Chemical Attributes of Sulfamethazine Bolus Dosage Forms" *PharmSciTech*: **06**(01):E91-E99 (2005), available from: <http://www.aapspharmscitech.org/>.

Pallavi Nithyanandan, Stephen Hoag, and Richard Dalby. "Analysis of Functional Robustness of Inhaler Devices: Response of pMDIs to Mechanical Stresses" *Respiratory Drug Delivery VIII*, Dalby, R., Byron, P.R., Peart, J., and Farr, S.J., DHI Publishing, Inc., p789-792 (2004).

Aditya S Tatavarti, Ketan A Mehta, Larry L Augsburger and Stephen W Hoag, "Influence of Methacrylic and Acrylic Acid Polymers on the Release Performance of Weakly Basic Drugs from Sustained Release Hydrophilic Matrices" *J. Pharm. Sci.* **93**(9):2319-2331 (2004).

Brian Du and Stephen W. Hoag, "Characterization of Excipient and Tableting Factors that Influence Folic Acid Dissolution, Friability and Breaking Strength from Oil- and Water-Soluble Multivitamin with Mineral Tablets" *Drug. Dev. Ind. Pharm.* **29**(10): 1137-1147 (2003).

Adam A. Dinerman, Joseph Cappello, Hamid Ghandehari, Stephen W. Hoag, "Solute diffusion in genetically engineered silk-elastinlike protein polymer hydrogels" *J. Contro. Rel.* **82**:277-287 (2002).

Adam A. Dinerman, Joseph Cappello, Hamid Ghandehari, Stephen W. Hoag, "Swelling Behavior of a Genetically Engineered Silk-Elastinlike Hydrogel" *Biomaterials* **23**(21): 4203-4210 (2002).

Katharina M. Picker and Stephen W. Hoag, "Characterization of the Thermal Properties of Microcrystalline Cellulose by Modulate Temperature Differential Scanning Calorimetry" *J. Pharm. Sci.* **91**(2):342-349 (2002).

Renuka Nair, S. Gonen and Stephen W. Hoag, "Influence of polyethylene glycol and povidone on the polymorphic transformation and solubility of carbamazepine" *Int. J. Pharm.* **240**(1-2):11-22 (2002).

Nasser N. Nyamweya, Ketan A. Mehta and Stephen W. Hoag, "Film coating with Aqueous Latex Dispersion: General Considerations for Formulating with Pigments" *Pharm. Tech.* **25**(Year Book 2001 Supplement):8-12 (2001).

Nasser N. Nyamweya, Ketan A. Mehta and Stephen W. Hoag, "Characterization of the Interactions Between Polymethacrylate Based Aqueous Polymeric Dispersions and Aluminum Lakes" *J. Pharm. Sci.* **90**(12):1937-1947 (2001).

Rajesh Kuppaswamy, S. R. Anderson, Stephen W. Hoag and Larry L. Augsburger, "Practical Limitation of Tableting Indices" *Pharm. Dev. Tech.* **6**(4):505-520 (2001).

R. Nair, N. Nyamweya, S. Gonen, L.J. Martı´nez-Miranda, S.W. Hoag, "Influence of Various Drugs on the Glass Transition Temperature of Poly(vinylpyrrolidone): A Thermodynamic and Spectroscopic Investigation" *Int. J. Pharm.* **225**(1-2):83-96 (2001).

Stephen W. Hoag and Ajaz Hussain, "Bioavailability of Dietary Supplements: Key Issues in Defining the Research Agenda" *J. Nutr.* **131**(4Suppl.):1389S-1391S (2001), Invited Manuscript.

Rajesh Kuppaswamy, Larry L. Augsburger and Stephen W. Hoag, "Estimation of Capping Incidence by Indentation Fracture Tests" *PharmSci*, : available from: [www.aapspharmaceutica.com/scientificjournals](http://www.aapspharmaceutica.com/scientificjournals) **3**(1):U60-U71 (2001).

Hanu Ramachandrani and Stephen W. Hoag, "Design and Validation of an Annular Shear Cell for Pharmaceutical Powder Testing" *J. Pharm. Sci.* **90**:531-540 (2001).

Brian Du and Stephen W. Hoag, "The Influence of Excipients on the Stability of the Moisture Sensitive Drugs Aspirin and Niacinamide: Comparison of Tablets Containing Lactose Monohydrate with Tablets Containing Anhydrous Lactose" *Pharm. Dev. Tech.* **6**(2):159-166 (2001).

Stephen W. Hoag, Renuka Nair and Fran Muller, "Force Transducer Design Optimization for the Measurement of Die Wall Stress in a Compaction Simulator" *Pharm. Pharmacol. Commum.* **6**:293-298 (2000).

Nasser N. Nyamweya and Stephen W. Hoag, "Assessment of Polymer-Polymer Interactions in Blends of HPMC and Film Forming Polymers by Modulated Temperature Differential Scanning Calorimetry Simulator" *Pharm. Res.* **17**(5):625-631 (2000).

Syed A. Altaf, Stephen W. Hoag and James W. Ayres, "Bead Compacts: II. Evaluation of Rapidly Disintegrating Non-Segregating Compressed Bead Formulations" *Drug. Dev. Ind. Pharm.* **25**(5):637-644 (1999)

Susan K. Lum, Stephen W. Hoag and Wendy C. Duncan-Hewitt, "Powder Densification 2: Viscoelastic Material Properties in Modeling the Uniaxial Compaction of Powders" *J. Pharm. Sci.* **87**:909-916(1998)

Syed A. Altaf, Stephen W. Hoag and Jim Ayres, "Bead Compacts. I. Effect of Compression on Maintenance of Polymer Coat Integrity in Multi-Layered Bead Formulations" *Drug Dev. Ind. Pharm.* **24**(8):737-746 (1998)

Stephen W. Hoag, Hanu Ramachandrani and Ralph Shangraw, "Failure of Prescription Prenatal Vitamin Products to Meet USP Standards for Folic Acid Dissolution" *J. Am. Pharm. Assoc.* **37**:397-400 (1997)

Chuntien Yeh, Syed A. Altaf and Stephen W. Hoag, " Theory of Force Transducer Design Optimization for Die Wall Stress Measurement During Tablet Compaction: Optimization and Validation of Split-Web Die Using Finite Element Analysis" *Pharm. Res.* **14**:1161-1170 (1997).

Syed A. Altaf and Stephen W. Hoag, "Deformation of the Stokes B2 Rotary Tablet Press: Quantitation and Influence on Tablet Compaction" *J. Pharm. Sci.* **84**:337-343 (1995).

Stephen W. Hoag and Edward G. Rippie, "Thermodynamic Analysis of Energy Dissipation by Pharmaceutical Tablets During Stress Unloading" *J. Pharm. Sci.* **83**:903-908 (1994).

Stephen W. Hoag, Ph.D. Thesis, University of Minnesota, August 1990.

#### **PUBLICATIONS – Books and Non-Peer Review**

Ting Wang, Kristine M. Alston, Carl R. Wassgren, Linas Mockus, Ann Christine Catlin, Sudheera R. Fernando, Sumudinie Fernando, Prabir K. Basu, and Stephen W. Hoag, "The Creation of an Excipient Properties Database to Support Quality by Design (QbD) Formulation Development" *Am. Pharm. Rev.* **16**(4):16-25 (2013).

Gary E. Ritchie, Emil W. Ciurczak, Sharon Flank, Stephen W. Hoag and James E. Polli, "Risk and Reputation: A Science and Risk-Based Approach to Brand Protection" *Pharm. Eng.* **32**(3):20-30 (2012).



Tim Freeman, Vikas Moolchandani, Stephen W. Hoag, Xiaowei Fuo, “Capsule Filling “Performance of Powdered Formulations in Relation to Flow”. In *Particulate Materials: Synthesis, Characterization, Processing and Modelling* Chuan-Yu Wu and Wei Ge Editors; Royal Society of Chemistry (RSC) (UK). pp 131-136; 2012. DOI: 10.1039/9781849735148-00131

“Bulk Powder Sampling Procedures” USP General Chapter <1097>; USP 33 NF 28; 2010 wrote most of the chapter with Anthony Okinczyc.

“Pharmaceutical Dosage Forms: Tablets Volume I” 3<sup>rd</sup> Edition, Stephen W. Hoag and Larry L. Augsburger Editors; Informa Healthcare (New York); 2008.

Han-Pin Lim and Stephen W. Hoag, “Particle Size and Shape” In *Pharmaceutical Dosage Forms: Tablets Volume I, 3rd Edition* Stephen W. Hoag and Larry L. Augsburger Editors; Informa Healthcare (New York); 2008.

Stuart Cantor, Larry L. Augsburger, Stephen W. Hoag and Armin H Gerhardt, “Wet Granulation” In *Pharmaceutical Dosage Forms: Tablets Volume I, 3rd Edition* Stephen W. Hoag and Larry L. Augsburger Editors; Informa Healthcare (New York); 2008.

Stephen W. Hoag, Vivek Dave and Vikas Moolchandani, “Compression and Compaction” In *Pharmaceutical Dosage Forms: Tablets Volume I, 3rd Edition* Stephen W. Hoag and Larry L. Augsburger Editors; Informa Healthcare (New York); 2008.

“Pharmaceutical Dosage Forms: Tablets Volume II” 3<sup>rd</sup> Edition, Stephen W. Hoag and Larry L. Augsburger Editors; Informa Healthcare (New York); 2008.

“Pharmaceutical Dosage Forms: Tablets Volume III” 3<sup>rd</sup> Edition, Stephen W. Hoag and Larry L. Augsburger Editors; Informa Healthcare (New York); 2008.

Nasser Nyamweya and Stephen W. Hoag, “Influence of pigments in the properties of polymeric coating systems” In *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms, 3rd Edition* Linda Felton and James McGinity Editors; Informa Healthcare (New York); 2007.

Raafat Fahmy and Stephen W. Hoag, “Excipient Quality Assurance: Handling, Sampling and Regulatory Issues” In *Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems* Ashok Katdare and Mahesh Chaubal Editors; Informa Healthcare (New York); 2006; pp (389-419).

Raafat Fahmy, Simin Hassannejad Tabasi, Stephen W. Hoag, “The Collaborative Research Project between the University of Maryland and Center for Veterinary Medicine at FDA”, *NIR News*, **18**(5):4-5 (2006).

James, E. Polli and Stephen W. Hoag, “Counterfeit Drug Products: Problems and Solutions”, *AAPS News Magazine*, **8**(8):20-22 (2005).

Stephen W. Hoag, "Die-wall Stress Measurement during Pharmaceutical Tablet Compaction." *Eur. Pharm. Rev.* **10**(2):104-111 (2005). (Invited Review)

James, E. Polli and Stephen W. Hoag, "Near-Infrared Technology Detects Counterfeit Drugs", *US Pharmacist*, **29**(2):104 (2004).

Stephen W. Hoag, "Pharmaceutical Process Engineering, Drugs and the Pharmaceutical Sciences Volume 112; Book Review", Anthony J. Hickey and David Ganderton; *Pharm. Res.*, **18**(12):1806 (2001).

Katharina M. Picker, Renuka Nair and Stephen W. Hoag, "Characterization of Pharmaceutical Tablet Elasticity Using a Novel Three-Dimensional Modeling Technique: a Correlation With The Elastic Modulus" *Proceeding of the 3<sup>rd</sup> World Meeting on Pharmaceutics Biopharmaceutics Pharmaceutical Technology* APV Berlin Germany, 141-142 (2000).

Katharina M. Picker, Nasser N Nyamweya and Stephen W. Hoag, "Glass Transition Temperature of MCC by Modulated DSC" *Proceeding of the 2<sup>nd</sup> World Meeting on Pharmaceutics Biopharmaceutics Pharmaceutical Technology* APGI Paris France, 31-32 (1998)

Stephen W. Hoag, Hanu Ramachandrani and Ralph Shangraw, "Problems with Folic Acid Dissolution; letter to the editor" *J. Am. Pharm. Assoc.* **38**:3-4 (1998)

Shawna K. Inoue, Ronald B. Guenther and Stephen W. Hoag, "Algorithm to Determine Diffusion and Mass Transfer Coefficients" *Proceedings of the Conference on Advances in Control Delivery, Controlled Release Society: Deerfield, IL*, 145-146 (1996).

Syed A. Altaf, Stephen W. Hoag and Jim Ayres, "Bead Compacts I: Effect of Multi-layered Beads (MLB) on Maintenance of Polymer Coat Integrity" In *Proc. Int. Symp. Control. Release Bioact. Mater.*, Controlled Release Society: Deerfield, IL, 290-291 (1995).

## **PHARMD & PH.D. STUDENTS, POST DOCTORAL FELLOWS AND VISITING SCIENTISTS**

Stephanie Smisko, PharmD student, did general lab work and helped on the fish oil project Summer 2013

Xiujuan "Sophie" Peng, "Spectroscopic Methods in Process Control" Ph.D. 2011-present

Yong "Andy" Liu, post doctoral fellow worked on the USP spectral Library project "Development of a Spectral Database for Excipients and Drug Products" 2012-present

Haibin Qu Ph.D., visiting professor from the Pharmaceutical Informatics Institute, Department of Chinese Medicine Science & Engineering College of Pharmaceutical Sciences, Zhejiang University worked on several projects but mostly on the "Real Time Release Testing of Pharmaceutical Products Made via Fluid Bed Spray Coating". March to June 2012

## STEPHEN W. HOAG

Page 11

Zhongqiang “Jacky” Lin, “Assessment of Multiparticulate Delivery Made via Fluid Bed Spray Coating” Ph.D. 2010-present

Bhavesh Kothari, “Real Time Release Testing of Pharmaceutical Products Made via Fluid Bed Spray Coating” Ph.D. 2010-present

Seon Hepburn, post doctoral fellow worked on the NIH THP project “Development of I-THP as New Medication for Drug Addiction (DP1)” 2010-Dec 2012

Larisa Wu, post doctoral fellow worked on MIPS project “Development of abuse deterrents and overdose minimizing dosage forms” 2010-2011

Ting Wang, “Developing the Scientific Basis for the Application of Spectroscopic and Chemometric Methods for Excipient Characterization and Quality Testing” Ph.D. expected 2012

Awards: ● AAPS - MSE section travel award to annual meeting in Chicago IL

- IPEC 2012 Travelship award to AAPS annual meeting
- 2011-2012 PSC Graduate Merit award
- USP Research Fellowship Award “Developing the Scientific Basis for Application of Spectroscopic and Chemometric Methods to Excipient Identification and Adulteration Detection” 2012 2013 school year.
- USP Fellowship Award “Developing the Scientific Basis for the Application of Spectroscopic and Chemometric Methods to Excipient Identification and Adulteration Detection” 2011 2012 school year.
- First place student poster completion, Excipient-Fest Americas, Baltimore, MD, April 2011
- Outstanding Contributed Paper Award, Regulatory Science Section. Pharmaceutical Sciences World Congress /AAPS Annual Meeting held in New Orleans LA, 2010
- Travel Award to the FIP Pharmaceutical Sciences World Congress /AAPS Annual Meeting and Exposition, 2010

Ravikanth Kona, “Application of Near-infrared Spectroscopy to Monitor In-process and Product Quality Attributes for Granulation and Immediate Release Tablet Production” Ph.D. December 2012

Awards: ● AstraZeneca Travel award – AAPS/ Pharmaceutical Sciences World Congress (PSWC) 2010, held in New Orleans, LA

Hanpin Lim, “Characterization of a Novel Amphiphilic Polymer - Soluplus<sup>®</sup>” Ph.D. 2012

Awards: ● UMB PSc Department Merit Award for 2010.

- Second place student poster completion, Excipient-Fest Americas, Baltimore, MD 2011

Harris Howland, “Application of NIR Spectroscopy and Fluorescence Spectroscopy for Monitoring of Curing of Sustained Ph.D. 2011

Joshua Ikoni Ogaji, Fulbright fellow worked on excipient characterization, 2009-10 school year.

**STEPHEN W. HOAG**

**Page 12**

Vikas Moolchandani, “Functionality and Performance of Different Lactose Grades in Capsule Filling: Characterization and Evaluation of Formulation and Operating Variables on Dosing Disc Machines” Ph.D. 2010; coadvisor with Larry L Augsburger

Vivek S. Dave, “Physical-Mechanical Characterization of Eudragit<sup>®</sup> Polymers and Their Application in the Extended-Release Matrix Tablets via Roller Compaction” Ph.D. 2009.

Stuart L. Cantor, “Design and Characterization of a Compacted Multiparticulate system for Modified Release” Ph.D. 2008; coadvisor with Larry L Augsburger

Simin Hassannejad Tabasi, “Quality by Design: Application of NIR Spectroscopy for Sustained Release Formulation Development; Study of Tableting, Coating, Dissolution and Curing Process Monitoring” Ph.D. 2006.

Lin Xie, “Quality by design: Application of a segregation tester to identify the critical factors affecting the weight and content uniformity of capsule filled on the two main types of automatic filling machines”, Ph.D. 2006.

Aditya S. Tatavarti, “Microenvironmental pH modulation based release regulation of weakly basic drugs from sustained release hydrophilic matrices” Ph.D. 2004.

Adam A. Dinerman, “An analysis of swelling properties and solute permeability in a genetically engineered silk-elastinlike protein (SELP) polymer (Polymer 47K) hydrogel” Ph.D. 2002.

Renuka Nair, “Drug-Polymer Interactions: Influence on film coating and Tableting” Ph.D. 2001.

Nasser Nyamweya, “Characterization of the Interactions between Aluminum Lake Pigments and Eudragit<sup>®</sup> Film Coating Polymers” Ph.D. 2001

Katharina Piker, Ph.D. visiting professor from Halle University, Worked on thermal characterization of MCC, 1999

Rajesh Kuppaswamy, “Mechanical characterization of pharmaceutical materials to evaluate their suitability for direct compression” Ph.D. 2000.

Jingzhu “Lucy” Wang, a WHO fellow.

Hanu V. Ramachandrani, “Application of shear analysis to predict flow and lubrication properties of consolidated powder beds” Ph.D. 2000.

Doungkamol Leokittikul, “Investigation of Possible Factors Affecting the Dissolution of Folic Acid Tablets” M.S. 1999.

Shawna Inoue, “A Moving Boundary Model of Calcium Alginate Gel Formation and the Estimation of Diffusion and Mass Transfer Coefficients” Ph.D. 1997.

## **STEPHEN W. HOAG**

**Page 13**

Syed A. Altaf, "Tablet Machine Instrumentation to Study Tablet Compaction and Compression of Polymer Coated Beads into Tablets" Ph.D. 1995.

PengJin Xu , Non-thesis Masters 1992.

### **HIGH SCHOOL STUDENTS MENTORED:**

Faith Gray, Summer BioScience Internship Program, High school student from Baltimore, worked on the excipient database project collecting spectra, 2013 summer session

Taeja Dowdy, Baltimore Polytechnic Institute student worked on the excipient database and did general measurements of excipient properties, 2011 – 12 school year

Breonia Harris, Baltimore Polytechnic Institute student worked on the excipient database and did general measurements of excipient properties, 2010 – 11 school year

Carson Holt, Baltimore Polytechnic Institute student worked on measuring material properties, 2009 - 10 school year

Bryan Cothorn Baltimore Polytechnic Institute student: used the shear cell to characterize the flow properties of excipients, ca 2000 – 01 school year.

### **PATENTS**

James E. Polli and Stephen W. Hoag, "Methods to Assure Drug and Drug Product Identity (previously: Method to Evade and Detect Counterfeit Drug Products) Pending

James E. Polli and Stephen W. Hoag, "Drug Authentication" European Patent No. 1671094, Date issued on March 28, 2012.

William McGee James and Stephen W. Hoag, "Method and Composition for Controlling Formaldehyde Fixation by Delayed Quenching" US Patent No. 6,072,086, Date of Patent June 6, 2000.

William McGee James and Stephen W. Hoag, "Method and Composition for Controlling Formaldehyde Fixation by Delayed Quenching" PCT/US97/06196, Filing Date April 14, 1997

James A. Ayres, Syed A. Altaf and Stephen W. Hoag, "Compactable Self-Sealing Drug Delivery Agents" US Patent No. 5,766,623, Date of Patent June 16, 1998.

### **ABSTRACTS**

### **POSTERS:**

Excipient Fest Americas, Baltimore, MD, April 2013; Ting Wang and Stephen W. Hoag; “Elucidating the Variability of Magnesium Stearate with Regards to Different Manufacturers, Grades and Lots and Correlations to Their Spectroscopic Features”

Excipient Fest Americas, Baltimore, MD, April 2013; Ting Wang, Ahmed I. Ashour and Stephen W. Hoag; “Application of Multivariate Analysis to Incorporate Raw Material Variability into Prediction Models for Its Performance”

Excipient Fest Americas, Baltimore, MD, April 2013; Ting Wang, Ahmed I. Ashour and Stephen W. Hoag; “Application of Multivariate Strategies to Classify Excipient Manufacturers Based on NIR Spectra”

Excipient Fest Americas, Baltimore, MD, April 2013; Xiujuan Peng, Yuxiang Zhao, Heather Boyce, Audra Stinchcomb and Stephen W. Hoag; “An Investigation of The Effect of Triacetin on Cold Flow Behavior in Transdermal Systems”

Excipient Fest Americas, Baltimore, MD, April 2013; Zhongqiang Lin, Haibin Qu, Bhavesh Kothari, Rina Chokshi, Brian Carlin, Rafaat Fahmy and Stephen W. Hoag; “Study of Physicomechanical Properties of Aqueous Ethylcellulose Dispersion Films During the Curing Process”

AAPS Annual Meeting and Exposition, Chicago, IL, October 2012; S. Hepburn, Z. Lin, J. Wang, R. Fahmy and S. Hoag. “Development and Validation of a Stability-indicating HPLC Method for the Estimation of L-tetrahydropalmatine in a Capsule Dosage Form” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2012)

AAPS Annual Meeting and Exposition, Chicago, IL, October 2012; S. Hepburn, B. Kothari, R. Fahmy and S. Hoag. “Use of QbD Approach to Develop and Validate a Simple, Sensitive HPLC Method Per ICH Q2A and Q2B Guidelines for the Analysis of Ciprofloxacin HCl Coated Multiparticulate Beads” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2012)

AAPS Annual Meeting and Exposition, Chicago, IL, October 2012; I. Ogaji, I. Okafor and S. Hoag. “Grewia Gum as an Aqueous Film Coating Agent: Some Physicochemical Properties of Theophylline Coated Tablets” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2012)

AAPS Annual Meeting and Exposition, Chicago, IL, October 2012; B. Kothari, B. Jancsik, R. Fahmy and S. Hoag “Effect of Humidity on the Coating Efficiency of Ciprofloxacin HCl Controlled Release Multiparticulate Beads” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2012)

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AAPS Annual Meeting and Exposition, Chicago, IL, October 2012; B. Kothari, A. Ashour, R. Fahmy, C. Moore and S. Hoag. "Effect of Coating Processing Parameters on the Dissolution Profiles of Ciprofloxacin HCl Controlled Release Multiparticulate Beads" *PharmSci*. Available from: <http://www.pharmsci.org/journal> (2012)

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AAPS Annual Meeting and Exposition, Washington, DC, October 2011; I. Ogaji, T. Wang, H. Lim, H. Howard, R. Kona, R. Dandu and S. Hoag. "Particle Size and Particle size Distribution of Potential Polymeric Pharmaceutical Excipient from Natural Sources" *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2011)

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ExcipientFest Americas, Baltimore, MD, May 2010, Bhaveshkumar H. Kothari, Harris Howland, Stephen W. Hoag, "Curing End-Point Determination of Polymer Dispersions Cast Films Using Fluorescence Spectroscopy"

ExcipientFest Americas, Baltimore, MD, May 2010, Ravikanth Kona, Ramesh Dandu, Raafat M. Fahmy, James E. Polli, Stephen W. Hoag, "Hydroxypropyl cellulose (HPC) as dry binder in the formulation development of Ciprofloxacin hydrochloride immediate release tablets: Influence of binder source, lubricant type and their levels on the critical quality attributes (CQA's)"



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between Disintegration and Dissolution Tests for Ciprofloxacin Immediate Release Tablets” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2010)

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37<sup>th</sup> Annual Meeting and Exposition of the Controlled Release Society, Portland, OR, July 2010, Han-Pin Lim, Yidan Lan, Yiping Yao, David Bigio, Stephen W. Hoag, “Dissolution Enhancement of the Poorly Water Soluble Drug by Solid Dispersion with a Novel Polymeric Solubilizer (Soluplus<sup>®</sup>)”

Clinical and Translational Science Award (CTSA) Industry Forum, Bethesda, MD, February 2010; Vadim J. Gurvich, Stephen R. Byrn, Mickey Wells, Stephen W. Hoag, Prabir K. Basu, Robin H. Bogner. “NIPTE: A Multi-University Partnership Supporting Drug Development, Translational Pre-Clinical and Clinical Research in Academia.”

AIChE Annual Meeting: Process Development Division, Nashville, TN, November 2009; Gintaras V. Reklaitis, Hamid Arastoopour, Robin Bogner, James K. Drennen III, Lee E. Kirsch, James Litster, Eric J. Munson, Fernando Muzzio, Raj Suryanarayanan, Stephen W. Hoag and Mansoor A. Khan. “NIPTE-FDA Collaborative Case Study on Model-Based Design Space Development Across Scales and with Stability Considerations.”

AAPS Annual Meeting and Exposition, Los Angeles, CA, November 2009; Dennis Bensley, Ramesh Dandu, Raafat M. Fahmy, Stephen W. Hoag, Ravikanth Kona. “Application of Plackett-Burman design of experiments (DOE) to describe product design space: Identification of critical formulation and process variables.” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2009)

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using hot-melt extrusion technique” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2009)

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non-destructive analytical tool” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2008)

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Parameters, Process Parameters, and Capsule Weight Variation in Capsule Filling on Two Types of Automatic Machines”

Twelfth Annual FDA Science Forum, Washington, DC, May, 2006; S. Hassannejad Tabasi, R. Fahmy, W. Marnane, D. Bensley and S. Hoag, “Application of NIR Spectroscopy for the Monitoring of Tablet Coat Thickness and Prediction of Drug Release from Different Acrylate Copolymers.”

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Hassannejad Tabasi, Simin; Hoag, Stephen; Polli, James. “Application of Near Infrared Spectroscopy to Differentiate Counterfeit and Authentic Drug Products” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Fahmy, Raafat; Hassannejad Tabasi, Simin; Hoag, Stephen, “Application of NIR Spectrometry to Monitor Curing End Point in Coating Formulations Containing Crosslinker Copolymer ” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Bakeev, Katherine; Bensley, Dennis; Fahmy, Raafat; Hassannejad Tabasi, Simin; Hoag, Stephen; Marnane, William, “Calibration Transfer and Direct Prediction of Drug Content for Process Analytical Technology Using Near Infrared Spectroscopy” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Dalby, Richard; Ganguly, Sudipta; Hoag, Stephen; Nithyanandan, Pallavi, “Characterization of Metered Dose Inhaler Robustness: A Stress Analysis and Mechanical Failure Study” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Augsburger, Larry; Hoag, Stephen; Hussain, Ajaz; Wu, Huiquan; Xie, Lin, “Correlation Between Segregation Propensity and Capsule Weight and Content Uniformity for Different Aspirin Formulations” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Hoag, Stephen; Muller, Francis X.; Tatavarti, Aditya S, “Evaluation of the Deformation Behavior of Methacrylic Acid Copolymers Using a Compaction Simulator” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Augsburger, Larry; Hoag, Stephen; Hussain, Ajaz; Khan, Mansoor; Wu, Huiquan; Xie, Lin, “Optimization of Experimental Methodology for ASTM D 6940 Segregation Tester for Pharmaceutical Powder” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Dalby, Richard; Hoag, Stephen; Nithyanandan, Pallavi, “Prediction of Mechanical Failure in Metered Dose Inhalers

(MDIs) using Finite Elements Analysis (FEA)” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Augsburger, Larry; Hoag, Stephen; Hussain, Ajaz; Wu, Huiquan; Xie, Lin, “Use of Dyed Materials to Evaluate Powder Bed Movement in a Capsule Filling Machine” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

AAPS Annual Meeting and Exposition, Memphis TN, November 2005; Dennis; Fahmy, Raafat; Hoag, Stephen; Kidder, Linda; Lee, Eunah; Lewis, Neil; Marnane, William; Xie, Lin, “The Use of Near Infrared Imaging to Understand Dissolution Mechanism” *PharmSci*: Available from: <http://www.pharmsci.org/journal> (2005)

Controlled Release Society 32<sup>nd</sup> Annual Meeting & Exposition, Miami, FL, June 2005, Raafat Fahmy and Stephen W. Hoag, “Potential Applications of Process Analytical Technology for Veterinary Pharmaceuticals.” Poster presentation.

Eleventh Annual FDA Science Forum, Washington, DC, May, 2005; S. Hassannejad Tabasi, k. Bakeev, R. M. Fahmy, W. Marnane, D. Bensley, and S Hoag, “A Comparative Study of Single and Group Assay of Solid Pharmaceutical Dosage Forms to Determine the Potential Sources of Variability Using Near-Infrared Spectroscopy and Chemometric Models”

Eleventh Annual FDA Science Forum, Washington, DC, May, 2005; R. M. Fahmy, W. Marnane, D. Bensley, and S Hoag, “Preprocessing Method Selection Strategies for Chemometric NIR Spectral Analysis”

Eleventh Annual FDA Science Forum, Washington, DC, May, 2005; L. Xie, H. Wu, L.L. Augsburger, A.S. Hussain and S.W. Hoag, “The Segregation Propensity of Formulations with Different Drug to Excipient Particle Size Ratios in Capsule Filling Performance”

AAPS Annual Meeting and Exposition, Baltimore, MD, November 2004; L. Xie, H. Wu, L. Augsburger, A. Hussain, S. Hoag, “Preliminary results on the effect of segregation propensity on capsule filling performance” *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2004)

AAPS Annual Meeting and Exposition, Baltimore, MD, November 2004; A. Tatavarti, R. Fahmy, L. Xie, Y. Zou, W. Steber, G. Hollenbeck, S. Hoag, “NIR Based Nondestructive Determination of Drug Release from Sulfamethazine Boluses Manufactured by Modulation of Formulation and Process Variables” *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2004)

AAPS Annual Meeting and Exposition, Baltimore, MD, November 2004; A. Tatavarti, K. Mehta, L. Augsburger, S. Hoag, “Microenvironmental pH Modulation Based Release Enhancement and Investigation into Solid State Drug Stability” *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2004)

**STEPHEN W. HOAG**

**Page 24**

AAPS Annual Meeting and Exposition, Baltimore, MD, November 2004; P. Nithyanandan, S. Hoag, R. Dalby, "Development of a Rational Test Method for the Analysis of Robustness of Inhaler Devices" *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2004)

AAPS Annual Meeting and Exposition, Baltimore, MD, November 2004; R. Fahmy, A. Tatavarti, W. Marnane, D. Bensley, S. Hoag, "Preprocessing of Data for Chemometric Analysis" *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2004)

Controlled Release Society 31<sup>st</sup> Annual Meeting & Exposition, Honolulu, HI, June 2004, Aditya S. Tatavarti, Ketan A. Mehta, Larry L. Augsburger, Stephen W. Hoag, "Effect of a Methacrylic Acid Polymer on Modulation of Microenvironmental pH and Release of Weakly Basic Drugs From Sustained Release Hydrophilic Matrices" Poster presentation.

Tenth Annual FDA Science Forum, Washington, DC, May, 2004; Raafat Fahmy Aditya S. Tatavarti, Huiquan Wu, Ajaz Hussain, William Marnane, Dennis Bensley, Gary Hollenbeck, and Stephen W. Hoag, "Assessment of NIR Spectroscopy for Process Analytical Testing of Sulfamethazine Boluses Using Different Statistical Models"

Tenth Annual FDA Science Forum, Washington, DC, May, 2004; Aditya Tatavarti, Raafat Fahmy, Lin Xie, Yu Zou, Dennis Bensley, Bill Marnane, Gary Hollenbeck and Stephen W Hoag, "Formulation of Sulfamethazine Boluses with Varying Release Rates and Assessment of the Predictive Potential of NIR On Drug Release"

Respiratory Drug Delivery IX Conference, Palm Desert, California, April 2004; Pallavi Nithyanandan, Stephen Hoag and Richard Dalby "Analysis of Robustness of Inhaler Devices: Response of pMDIs to Mechanical Stresses" Respiratory Drug Delivery IX, DHI Publishing, pp 789-792, 2004.

AAPS Annual Meeting and Exposition, Salt Lake City, UT, October 2003; Aditya Tatavarti, Ketan Mehta, Larry Augsburger and Stephen Hoag, "Release Performance Of Weakly Basic Drugs From Sustained Release Matrix Tablets Incorporated With Acrylic And Methacrylic Acid Polymers" *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2003)

AAPS Annual Meeting and Exposition, Salt Lake City, UT, October 2003; Raafat Fahmy, Aditya Tatavarti, Segmia Tata, Dennis Bensley, William Marnane, Dilara Jappar, Peter Poczatek, Gary Hollenbeck and Stephen Hoag, "Assessment Of The NIR Technique For Process Analytical Testing Of Physicochemical Properties Of Sulfamethazine Boluses" *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2003)

Ninth Annual FDA Science Forum, Washington, DC, April, 2003; Aditya Tatavarti, Segmia K. Tata, Raafat Fahmy, Dennis Bensley, Bill Marnane, Dilara Jappar, Peter Poczatek, Gary Hollenbeck and Stephen W. Hoag, "Assessment of the NIR for Process Analytical Testing of Bolus Dosage Forms"



## STEPHEN W. HOAG

### Page 25

AAPS Annual Meeting and Exposition, Toronto, Ontario, Canada, November 2002; Nasser N. Nyamweya, Ketan A. Mehta and Stephen Hoag, "The effect of Aluminum lakes on film properties" *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2002)

AAPS Annual Meeting and Exposition, Toronto, Ontario, Canada, November 2002; Adam A. Dinerman, Joe Cappello, Hamid Ghandehari, Stephen Hoag, "Influence of Solute Properties on Partitioning and Diffusion in a Genetically Engineered Silk-Elastinlike Protein Polymer Hydrogel" *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2002)

AAPS Annual Meeting and Exposition, Toronto, Ontario, Canada, November 2002; Aditya S. Tataavarti, Hanu Ramachandruni, Jianping Du, Queenie Yin-Liu and Stephen W. Hoag, "Predicting the Behavior of Lubricants During Compaction Using Shear Analysis" *PharmSci* (serial on the internet): Available from: <http://www.pharmsci.org/journal> (2002)

Sixth New Jersey Symposium on Biomaterials Science on "The Next Generation of Biomaterials", New Jersey Center for Biomaterials, Somerset, NJ, October 17-18, 2002; H. Ghandehari, J. Cappello, A. Nagarsekar, A. Dinerman, S. Hoag, and Z. Megeed, "Genetically Engineered Silk-Elastinlike Block Copolymers For Controlled Gene and Drug Delivery"

Fifth International Symposium on Biorelated Polymers, Fall American Chemical Society Meeting, Boston, MA, August 18-22, 2002; H. Ghandehari, J. Cappello, A. Nagarsekar, A. Dinerman, S. Hoag, and Z. Megeed, "Genetic Engineering of Silk-Elastinlike Protein Polymers for Drug Delivery."

AAPS Pharmaceuticals and Drug Delivery Conference, Arlington, VA, April 2002; Aditya S. Tataavarti, Hanu Ramachandruni, Jianping Du, Queenie Yin-Liu, and Stephen W. Hoag, "A Modified Annular shear cell to measure powder lubricity."

Course and Workshop on Cell Culture and Ex-Vivo Models for Drug Absorption and Delivery, Department of Biopharmacy and Pharmaceutical Technology, Saarland University, Saarbrücken, Germany, February, 2002; H. Ghandehari, J. Cappello, A. Nagarsekar, A. Dinerman, S. Hoag, and Z. Megeed, "Controlled Drug Delivery From Genetically Engineered Silk-Elastinlike Copolymers, Fourth Intensive."

AAPS Annual Meeting and Exposition, Denver, CO, October 2001; Adam A. Dinerman, Joe Cappello, Hamid Ghandehari, Stephen Hoag, "Characterization of a Genetically Engineered Silk-Elastinlike Hydrogel for Drug Delivery" *PharmSci* (serial on the internet) **3**(3 supplement): Available from: <http://www.pharmsci.org/journal> (2001)

AAPS Annual Meeting and Exposition, Denver, CO, October 2001; Renuka Nair, Serpil Gonen, Stephen W. Hoag, "Influence of Poly(ethylene glycol) and Ppoly(vinylpyrrolidone) on the Polymorphic Transitions of Carbamazepine" *PharmSci* (serial on the internet) **3**(3 supplement): Available from: <http://www.pharmsci.org/journal> (2001)

## STEPHEN W. HOAG

### Page 26

AAPS Annual Meeting and Exposition, Denver, CO, October 2001; Nasser Nyamweya, Ketan A. Mehta, Stephen W. Hoag, "Interactions in Film Coating Formulations of Aqueous Polymeric Latex Dispersions and Aluminum Lake Pigments" *PharmSci* (serial on the internet) **3**(3 supplement): Available from: <http://www.pharmsci.org/journal> (2001)

AAPS Annual Meeting and Exposition, Denver, CO, October 2001; Jianping Du, Francis X. Muller, Stephen W. Hoag, "The Effect of Porosity on the Three Dimensional Elastic Properties of Tablets Made on a Compaction Simulator" *PharmSci* (serial on the internet) **3**(3 supplement): Available from: <http://www.pharmsci.org/journal> (2001)

AAPS Annual Meeting and Exposition, Denver, CO, October 2001; Renuka Nair, Francis X. Muller, Stephen W. Hoag, "Use of Compaction Simulator to Determine the Mechanical Properties of Solid Dispersions" *PharmSci* (serial on the internet) **3**(3 supplement): Available from: <http://www.pharmsci.org/journal> (2001)

AAPS Annual Meeting and Exposition, Indianapolis, IN, November 2000; N. Nyamweya, K. A. Mehta and S. W. Hoag, "Preformulation of Aluminum Lakes" *PharmSci* (serial on the internet) **2**(4 supplement): Available from: <http://www.pharmsci.org/journal> (2000)

AAPS Annual Meeting and Exposition, Indianapolis, IN, November 2000; J. Du, N. Eddington and S. Hoag, "Development of Glucosamine-Chondroitin Direct Compression Chewable Tablet" *PharmSci* (serial on the internet) **2**(4 supplement): Available from: <http://www.pharmsci.org/journal> (2000)

AAPS Annual Meeting and Exposition, Indianapolis, IN, November 2000; J. Du, F. X. Muller and S. W. Hoag, "The Elastic Modulus of Tablets Made from Mixtures of Pharmaceutical Powders" *PharmSci* (serial on the internet) **2**(4 supplement): Available from: <http://www.pharmsci.org/journal> (2000)

AAPS Annual Meeting and Exposition, Indianapolis, IN, November 2000; R. Nair and S. W. Hoag, "Solid State Characterization of Drug Polymer Interactions" *PharmSci* (serial on the internet) **2**(4 supplement): Available from: <http://www.pharmsci.org/journal> (2000)

AAPS Annual Meeting and Exposition, Indianapolis, IN, November 2000; H. Ramachandrani and S. W. Hoag, "Effect of Consolidation State on the Flow and Lubrication Properties of Powder Beds" *PharmSci* (serial on the internet) **2**(4 supplement): Available from: <http://www.pharmsci.org/journal> (2000)

AAPS Annual Meeting and Exposition, Indianapolis, IN, November 2000; K. M. Picker, R. Nair and S. W. Hoag, "Tablet Elasticity: Correlation of Elastic Modulus and Parameters from Three-Dimensional Modeling" *PharmSci* (serial on the internet) **2**(4 supplement): Available from: <http://www.pharmsci.org/journal> (2000)

The 20<sup>th</sup> Annual GRASP Conference, June 2000; Renuka Nair and Stephen W. Hoag, "Solid State Characterization of Drug Polymer Interactions" Seminar presented by RN.

The 20<sup>th</sup> Annual GRASP Conference, June 2000; N. Nyamweya and S.W. Hoag, "Preformulation of Aluminum Lakes"

Eastern Analytical Society Meeting November 1999; Ronald Rubinovitz, Jianping Du, Myron Duell and Stephen W. Hoag, "Near-Infrared Spectroscopy as a Research Tool: Monitoring of Aspirin Tablet Degradation in a Stability Study."

AAPS Annual Meeting and Exposition, New Orleans, LA, November 1999; J. Du, J. Wang, S.W. Hoag, "Optimization of Folic Acid Dissolution From Multivitamin Tablets With Minerals Using Soluble Excipients" *PharmSci* (serial on the internet) **1**(4 supplement): Available from: <http://www.pharmsci.org/journal> (1999)

AAPS Annual Meeting and Exposition, New Orleans, LA, November 1999; J. Du, M. Duell, S. Tolle, M. Kemper, S.W. Hoag, "Monitoring of Aspirin Degradation Using Near-Infrared Spectroscopy" *PharmSci* (serial on the internet) **1**(4 supplement): Available from: <http://www.pharmsci.org/journal> (1999)

AAPS Annual Meeting and Exposition, New Orleans, LA, November 1999; N.N. Nyamweya, S.W. Hoag, "Polymer-Polymer Interactions in Blends of Film-Forming Polymers by MTDSC" *PharmSci* (serial on the internet) **1**(4 supplement): Available from: <http://www.pharmsci.org/journal> (1999).

AAPS Annual Meeting and Exposition, New Orleans, LA, November 1999; J. Du, S.W. Hoag, "Comparison of Drug Stability in Tablets Containing Lactose Monohydrate With Tablets Containing Anhydrous Lactose" *PharmSci* (serial on the internet) **1**(4 supplement): Available from: <http://www.pharmsci.org/journal> (1999).

AAPS Annual Meeting and Exposition, New Orleans, LA, November 1999; R. Kuppuswamy, S.R. Anderson, R. Shah, S.W. Hoag, L.L. Augsburger, "Indentation Hardness as a Possible Surrogate for Tableting Indices to Predict Tablet Failure" *PharmSci* (serial on the internet) **1**(4 supplement): Available from: <http://www.pharmsci.org/journal> (1999).

AAPS Annual Meeting and Exposition, New Orleans, LA, November 1999; R. Nair, S. Hoag, F. Muller, "An Innovative Approach for the Complete Characterization of Material Properties Using a Compaction Simulator" *PharmSci* (serial on the internet) **1**(4 supplement): Available from: <http://www.pharmsci.org/journal> (1999).

AAPS Annual Meeting and Exposition, New Orleans, LA, November 1999; H.V. Ramachandrani, S.W. Hoag, "Flow Testing of Some Pharmaceutical Excipients Using an Annular Shear Cell" *PharmSci* (serial on the internet) **1**(4 supplement): Available from: <http://www.pharmsci.org/journal> (1999).

Philadelphia Pharmaceutical Forum Student Poster Night, Philadelphia, PA, March 1999; Renuka Nair, Stephen W. Hoag and Francis X. Muller, "A Novel Method for the Determination of Young's Modulus, Shear Modulus, Bulk Modulus and Poisson's Ratio Using a Compaction Simulator."

## STEPHEN W. HOAG

Page 28

Philadelphia Pharmaceutical Forum Student Poster Night, Philadelphia, PA, March 1999; Jianping Du and Stephen W. Hoag, "Comparison of Drug Stability in Tablets Containing Lactose Monohydrate with Tablets Containing Anhydrous Lactose at Different Relative Humidities."

Philadelphia Pharmaceutical Forum Student Poster Night, Philadelphia, PA, March 1999; Hanu Ramachandruni and Stephen W. Hoag, "Application of a Modified Annular Shear Cell in Measuring Lubrication of Pharmaceutical Powders."

AAPS Annual Meeting and Exposition, San Francisco, CA, November 1998; Rajesh Kuppaswamy, Rajen Shah, Stephen R. Anderson, Richard V. Vivilecchia, Stephen W. Hoag and Larry L. Augsburger, "Estimation of Compactibility of Mixtures Using Tableting Indices" *PharmSci.* **1**:S84(1998).

AAPS Annual Meeting and Exposition, San Francisco, CA, November 1998; Katharina M. Picker, Nasser N Nyamweya and Stephen W. Hoag, "The Effect of Glass Transition Temperature of MCC on the Compaction Properties" *PharmSci.* **1**:S174(1998).

AAPS Annual Meeting and Exposition, San Francisco, CA, November 1998; Hanu Ramachandruni and Stephen W. Hoag, "Application of a Modified Annular Shear Cell in Measuring Lubrication of Pharmaceutical Powders" *PharmSci.* **1**:S312(1998).

University of Maryland School of Pharmacy Research Day, Baltimore, MD, April 1998; Nasser N. Nyamweya, Katharina M. Picker and Stephen W. Hoag, "Glass Transition Temperature of MCC by Modulated DSC".

Twelfth Annual AAPS Meeting and Exposition, Boston, MA, November 1997; S Inoue, R Guenther and S Hoag, "Moving Boundary Model of Calcium Alginate Gel Formation" *Pharm. Res.* **14**:S38(1997).

Twelfth Annual AAPS Meeting and Exposition, Boston, MA, November 1997; J. Du, S. Hoag and J. Chen, "Pharmacokinetic Study of  $\gamma$ -Linolenic Acid Administered Via Evening Primrose Oil and a Novel Emulsion Formulation" *Pharm. Res.* **14**:S612(1997).

Philadelphia Pharmaceutical Forum Student Poster Night, Philadelphia, PA, March 1997; Feng Lin, Stephen W. Hoag and Larry L. Augsburger, "Potential Application of New Grades of Microcrystalline Cellulose (Avicel PH-301 and PH-302) To Formulations Intended for Filling Hard Gelatin Capsules".

Eleventh Annual AAPS Meeting and Exposition, Seattle, WA, October 1996; Feng Lin, Stephen Hoag and L.L. Augsburger, "Potential Application of New Grades of Microcrystalline Cellulose (Avicel PH-301 and PH-302) To Formulations Intended for Filling Hard Gelatin Capsules" *Pharm. Res.* **13**:S195(1996).

**STEPHEN W. HOAG**

**Page 29**

Tenth Annual AAPS Meeting and Exposition, Miami, FL, November 1995; Syed A. Altaf, Stephen W. Hoag and James W. Ayres, "Bead Compacts: Development of a Sustained Release Product from Compressed Bead formulations" *Pharm. Res.* **12**:S218(1995).

Tenth Annual AAPS Meeting and Exposition, Miami, FL, November 1995; Shawna K. Inoue and Stephen W. Hoag, "Experimental Measurement of Calcium Alginate Gel Formation" *Pharm. Res.* **12**:S212(1995).

22nd International Symposium on Controlled Release of Bioactive Materials, Seattle, WA, August 1995; Syed A. Altaf, Stephen W. Hoag and James W. Ayres, "Bead Compacts I: Effect of Multi-Layered Beads on Maintenance of Polymer Coat Integrity".

AAPS Western Regional Meeting, San Jose, CA, March 1995; Syed A. Altaf, Stephen W. Hoag and James W. Ayres, "Bead Compacts: Formulation considerations in Development of a Sustained Release Product".

Ninth Annual AAPS Meeting and Exposition, San Diego, CA, November 1994; Syed A. Altaf, Chuntien Yeh and Stephen W. Hoag, "Use of Finite Element Modeling to Validate and Optimize an Improved Instrumented Tablet Die Design for Die Wall Stress Measurement" *Pharm. Res.* **11**:S132(1994).

Ninth Annual AAPS Meeting and Exposition, San Diego, CA, November 1994; Shawna Kondo and Stephen W. Hoag, "Modeling of Mass Transfer Processes in Alginate Gel Formation" *Pharm. Res.* **11**:S285(1994).

AAPS Western Regional Meeting, San Francisco, CA, March 1994; Syed A. Altaf, C. T. Yeh and Stephen W. Hoag, "Optimization of Tablet Die Design for Die Wall Stress Measurement".

Eighth Annual AAPS Meeting and Exposition, Orlando, FL, November 1993; Syed A. Altaf and Stephen W. Hoag, "The Effect of Tablet Machine Elasticity on The Work of Compaction" *Pharm. Res.* **10**:S150(1993).

Eighth Annual AAPS Meeting and Exposition, Orlando, FL, November 1993; David W. Schultz, Stephen W. Hoag, Gary H. Ward and Robert K. Schultz, "The Relationship Between Kauri-Butanol Values and Solubility Parameters to Swell and Leak Rate of Common Rubbers in Non-CFC MDI Formulations" *Pharm. Res.* **10**:S150(1993).

AAPS Western Regional Meeting, San Francisco, CA, March 1993; Syed A. Altaf and Stephen W. Hoag, "Estimation of Work of Compaction Using Elastic Correction Factors for a Rotary Tablet Press."

AAPS Western Regional Meeting, San Francisco, CA, March 1993; Dilip Kaul and Stephen W. Hoag, "Validation of Punch Displacement Equations Using Dial Indicator."

## STEPHEN W. HOAG

Page 30

Seventh Annual AAPS Meeting and Exposition, San Antonio, TX, November 1992; Syed A. Altaf, PengJin Xu and Stephen W. Hoag, "Linear Elastic Analysis of Tablet Machine Deformation" *Pharm. Res.* **9**:S117(1992).

AAPS Western Regional Meeting, Reno, Nevada, March 1992; Syed A. Altaf, Dilip Kaul and Stephen W. Hoag, "Static Measurements of Tablet Machine Deformation Using a Cathetometer."

AAPS Western Regional Meeting, Reno, Nevada, March 1992; PengJin Xu, Syed A. Altaf and Stephen W. Hoag, "Dynamic Characterization of an Instrumented Lower Compression Roller Pin in a Rotary Tablet Press: Influence of Eye-bolt Position."

Sixth Annual AAPS Meeting and Exposition, Washington, DC, November 1991; Stephen W. Hoag and Robert K. Schultz, "The Evaluation of Propellant Blends by Analysis of Kauri-Butanol Values" *Pharm. Res.* **8**:S121(1991).

Sixth Annual AAPS Meeting and Exposition, Washington, DC, November 1991; Syed A. Altaf, PengJin Xu and Stephen W. Hoag, "The Dynamic Characterization of An Instrumented Lower Compression Roller Pin in a Rotary Tablet Press During Tablet Compaction" *Pharm. Res.* **8**:S98(1991).

AAPS Western Regional Meeting, Reno, Nevada, March 1991; Stephen W. Hoag and Syed A. Altaf, "Statistical and Numerical Methods for the Determination of Reversible and Irreversible Energy Dissipated During the Unloading Phase of Tablet Compaction."

Fifth Annual AAPS Meeting and Exposition, Las Vegas, Nevada, November 1990; Stephen W. Hoag and Edward G. Rippie, "The Application of Thermodynamic Principles to Pharmaceutical Tablets" *Pharm. Res.* **7**:S76(1990).

AAPS Midwest Regional Meeting, Chicago, Illinois, May 1988; Stephen W. Hoag and Edward G. Rippie, "Statistical Analysis of Linear Viscoelastic Tableting Data During the Unloading Phase of Manufacture."

## SEMINARS

CRS Annual Meeting, Controlled Release Dosage Forms and Product Development Strategy for Expected New Regulatory Trends Workshop, Honolulu, HI, July 2013, Stephen W. Hoag, "The Use of Spectroscopic Methods for the Examination of the Solid State of Controlled Release Polymers"

Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives Part 15 Public Meeting; Request for Comments, FDA, Silver Spring, MD, June 2013, Stephen W. Hoag, "Quality Challenges and Research Needs in the Generic Pharmaceutical Industry"

Eudragit<sup>®</sup> Advanced Workshop, Piscataway, NJ, June 2013, Stephen W. Hoag, "Developing QbD and PAT Systems for the Monitoring of EUDRAGIT<sup>®</sup> Polymer Coatings" Invited Seminar

## STEPHEN W. HOAG

### Page 31

UMB CERSI Meeting Control Strategies for Pharmaceutical Manufacturing: Real Time Release Testing and Design Space Determination, Baltimore, MD, May 2013, Stephen W. Hoag, “Developing the Control Strategy for Pharmaceutical Manufacturing Across Scales of Manufacturing” Meeting organizer and presenter

GSK Inc., King of Prussia, PA, May 2013, Stephen W. Hoag, “Spectroscopic studies at the University of Maryland” Invited Seminar

NIH/NCATS, Rockville, MD, December 2012, Stephen W. Hoag, “Drug Development Capabilities and Studies at the University of Maryland GMP Facility” Invited Seminar

SCIX 2012, Kansas City, MO, October 2012, Stephen W. Hoag, Ravi Kona, Bhavesh H. Kothari, Raafat Fahmy, “Near Infrared Monitoring of the State of Fluid Bed Processes” Invited Seminar

NIPTE 2012 Research Conference: Understanding Excipient Performance – Key to Successful QbD Formulation, White Oak, Silver Spring, MD, June 2012, Stephen W. Hoag, “NIPTE-FDA Project on Excipients” Conference Chair and meeting organizer

2012 Northeast User Meeting and Technical Seminar, Somerset, NJ, April 2012, Stephen W. Hoag, “The Use of NIR to Monitor the State of Fluid Bed Processes” Invited Seminar

AAPS Workshop on Lipid-based Delivery for Improving Drug Absorption: Mechanistic Understanding and Practical Approaches, Baltimore, MD, April 2012, Stephen W. Hoag, “Hot Melt Extrusion using Lipids” Invited Seminar

Eudragit<sup>®</sup> Advanced Workshop, Malvern, PA, April 2012, Stephen W. Hoag, “Methods for Monitoring of Functional Film Coat Curing: EUDRAGIT<sup>®</sup> Case Studies” Invited Seminar

School of Pharmacy, University of Kentucky, Lexington, KY, February 2012, Stephen W. Hoag, “The Use of Spectroscopic Methods to Monitor Film Coat Formation” Invited Seminar

Merck Inc., West Point, PA, February 2012, Stephen W. Hoag, “NIPTE/FDA Excipient CQAs Database Project” Invited Seminar

IFPAC Annual Meeting, Baltimore MD, February 2012, Stephen W. Hoag, “Examination of Excipient Variability via Spectroscopic Methods: Advantages and Limitations” Invited Seminar and session co-organizer

DFE Pharma Expert Board Meeting, Paris France, December 2011, Stephen W. Hoag, “Current Trends in Excipient Functionality” Invited Seminar

AAPS Annual Meeting and Exposition, Washington, DC, October 2011; Stephen W. Hoag. “Select Topics in Excipient Research” IPEC Shangraw Award speech.

ExActCoat Educational Workshop, Northvale, NJ, September 2011, Stephen W. Hoag, “Immediate Release Color Coatings” Invited Seminar

**STEPHEN W. HOAG**

**Page 32**

FDA Regional Office, Saint Louis, MO, August 2011, Stephen W. Hoag, “The Effect of Excipient Variability on the Identification of Bulk Excipients using NIR and Raman, and the Application of Database Techniques for Calibration Model Transfer to Portable Spectrometers” [Invited Seminar](#)

Roquette® University Educational Courses, Chicago, IL, August 2011, Stephen W. Hoag, “Excipient Variability and Functionality Testing from a QbD Perspective and the Application of Database” [Invited Seminar](#)

Excipient-Fest Americas, Baltimore, MD, May 2011, Stephen W. Hoag, “Excipient Variability and Functionality Testing” Key Note Speaker and panelist

DMV - Fonterra Expert Board Meeting, London England, December 2010, Stephen W. Hoag, “Current Excipient Trends” [Invited Seminar](#)

USP Workshop on: Particle Size Particle Detection and Measurement, USP Headquarters, Rockville, MD, December 2010, Stephen W. Hoag, “Desirable Formulations Properties and Delivery Strategies API for Dry Systems” [Invited Seminar](#)

Bend Research Inc., Bend, Oregon, July 2010, Raafat Fahmy and Stephen W. Hoag, “Risk Analysis in QbD Applications” [Invited Seminar](#)

37<sup>th</sup> Annual Meeting and Exposition of the Controlled Release Society, Portland, OR, July 2010, Stephen W. Hoag, “Tablet and Capsule Manufacturing Roundtable” [Invited Seminar](#)

Republic Polytechnic Hot melt Extrusion Workshop, Singapore, June 2010, Stephen W. Hoag, “The use of polymeric materials to enhance the solubility of poorly soluble drugs: the characterization of the drug in polymeric materials” [Invited Seminar](#)

Eudragit® Workshop for Advanced Users, Cincinnati, OH, May 2010, Stephen W. Hoag, “QbD: Case Study with EUDRAGIT®” [Invited Seminar](#)

Eudragit® Workshop for Advanced Users, Malvern, PA, April 2010, Stephen W. Hoag, “QbD: Case Study with EUDRAGIT®” [Invited Seminar](#)

AHI Quality by Design (QbD) Workshop, Arlington, VA, October 2009, Stephen W. Hoag, “New Technology for In-Process Control, Online Monitoring, and Chemometric Models” [Invited Seminar](#)

51<sup>st</sup> Annual International Industrial Pharmaceutical Research & Development Conference “Bridging Material and Product Quality in Developing Tablet Dosage Forms” Merrimac, WI, June 2009, Stephen W. Hoag, “Excipient and Powder Characterization” [Invited Seminar](#)

AAPS/CRS Workshop on Critical Variables in the In Vitro and In Vivo Performance of Parenteral Sustained Release Products, GA, November 2008, Stephen W. Hoag, “Developing Performance Specifications and Design Space” [Invited Seminar](#)



## STEPHEN W. HOAG

Page 33

First Asian Pharmaceutical Technologies Arden Conference and Annual Meeting of the Pharmaceutics Committee of CPA: Particle and Powder Technologies for Solid Dosage Forms, Beijing, China, October 2008, Stephen W. Hoag, “Mechanistic Understanding of Powder Compaction and Granulation” Invited Seminar and member of organizing committee

College of Notre Dame of Maryland, Department of Chemistry Seminar, Baltimore, MD, October 2008, Stephen Hoag, “The Application of NIR Spectroscopy and Chemometric Modeling Techniques in the Pharmaceutical Industry: New Paradigms for Quality Control in Pharmaceutical Manufacturing” Invited Seminar

FIP 2008 Congress Pre-Satellite Workshop Meeting the Challenges of Pharmaceutical Innovation and Quality by Design in the 21<sup>st</sup> Century: Implementation of PAT, Basel Switzerland, August 2008, Stephen Hoag, “PAT for Animal Products: Applications of NIR Spectroscopy for the Monitoring and Study of Formulation and Process Parameters that Impact Sustained Release Tablet Coat Curing” Invited Seminar

The Council on Pharmaceutical Quality and the Manufacturing Science Work Group FDA, Silver Spring, MD, April 2008, Raafat Fahmy, Stephen Hoag, Marilyn Martinez and Dennis Bensley, “Quality by Design: Application of NIR Spectroscopy for Formulation Development of Sustained Release Dosage Forms” Invited Seminar

Forty-Third Annual Pharmaceutical Technologies Arden Conference: Particle and Powder Technologies for Solid Dosage Forms, West Point, NY, February 2008, Stephen W. Hoag, “Mechanisms of Powder Compaction and Granulation” Member of organizing committee

Third Eudragit<sup>®</sup> Advanced Workshop, New Brunswick, NJ, October 2007, Stephen W. Hoag, “Compaction Properties of Eudragit<sup>®</sup> Polymers” Invited Seminar

EntreMed Inc., Rockville, MD, November 2006; Stephen W. Hoag, “The Compaction Properties of pH Sensitive Eudragit Polymers” Invited Seminar

ISPE Annual Meeting, Orlando Florida, November 2006; Stephen W. Hoag, “Prediction of Curing Endpoint for Sustained Release Polymer Products using NIR Spectroscopy and Multivariate Analysis” Invited Seminar

Second Eudragit<sup>®</sup> Advanced Workshop, New Brunswick, NJ, October 2006, Aditya Tatavarti and Stephen W. Hoag, “Compaction Properties of Eudragit<sup>®</sup> Polymers” Invited Seminar

Garnet E. Peck Symposium In Industrial Pharmacy: Fourth Annual Symposium Advances in Compaction Research in Pharmaceuticals, Lafayette, IN, September 2006, Stephen W. Hoag, “Evaluation of the Deformation Behavior of Methacrylic Acid Copolymers Using a Compaction Simulator” Invited Seminar

Foss 2006 Users Meeting Seminar ” Seminar, Somerset, NJ, September 2006, Simin H. Tabasi Raafat Fahmy and Stephen W. Hoag, “The application of NIR spectroscopy to the study of pharmaceutical tablet film coating and film formation” Invited Seminar

**STEPHEN W. HOAG**

**Page 34**

The MIT Enterprise Forum, Arlington, VA, February 2006; Stephen W. Hoag, “Embedding Covert Anticounterfeit Spectral Features into Formulations to Authenticate Pharmaceutical Products” Invited Presentation

32<sup>nd</sup> FACCS Annual Meeting, Quebec City, Canada, October 2005; Stephen W. Hoag, Simin H. Tabasi, Katherine Bakeev and Raafat Fahmy, “Instrumentation Factors and Sample Presentation Effects on Calibration Transfer and Direct Prediction of Drug Content using Different Near Infrared Spectrometers” Invited Presentation

1<sup>st</sup> Eudragit<sup>®</sup> Advanced Workshop, New Brunswick, NJ, October 2005, Aditya Tatavarti and Stephen W. Hoag, “Compaction Properties of Eudragit<sup>®</sup> Polymers” Invited Seminar

BioAlliance Breakfast Series, Rockville, MD, May 2005; James Polli and Stephen Hoag, “Embedding Covert Anticounterfeit Spectral Features into Formulations to Authenticate Pharmaceutical Products” Invited Presentation

31<sup>st</sup> FACCS Annual Meeting, Portland, OR, October 2004; James Polli and Stephen Hoag, “Embedding Covert Anticounterfeit Spectral Features into Pharmaceutical Formulations to Authenticate Pharmaceutical Products” Invited Presentation

Foss 2004 Users Meeting and Technical “PAT” Seminar, Somerset, NJ, May 2004, James E. Polli and Stephen W. Hoag, “The Application of NIR to Combat Counterfeit Drugs” Invited Seminar

Novartis, East Hanover, NJ, April 2004, Stephen W. Hoag, “The Application of Plasticity Models to the Consolidation of Pharmaceutical Powders: a Work in Progress” Invited Seminar

Fort Dodge Inc., Princeton, NJ, December 2003, Stephen W. Hoag, “Assessment of the NIR Technique for Process Analytical Testing of Bolus Dosage Forms” Invited Seminar

Tablet Tech: Advances in Pharmaceutical Formulation and Processes, Princeton, NJ, November 2003, Stephen W. Hoag, “Physical properties of Avicel and Their Effects on Tablet Formulation Development” Invited Seminar

AAPS Annual Meeting and Exposition, Salt Lake City, UT, October 2003; Stephen Hoag, “Die Wall Stress Measurement: From Transducer Design to Data Collection and Interpretation” *PharmSci* (serial on the internet): Available from: [http://www.pharmsci.org/journal\(2003\)](http://www.pharmsci.org/journal(2003))

Thirty-Fifth Annual Higuchi Research Seminar, Lawrence, KS, May 2002, Stephen W. Hoag, “The Application of Plasticity Models to the Consolidation of Pharmaceutical Powders: a Work in Progress” Invited Seminar

BeneScript Educational Seminar, Orlando, FL, February 2001, Stephen W. Hoag, “Folic Acid Dissolution and Prenatal Nutrition” Invited Seminar

**STEPHEN W. HOAG**

**Page 35**

Inhale of Therapeutic Systems, San Carlos, CA, January 2001, Stephen W. Hoag, "Application of Shear Analysis to the Study of Flow and Lubrication in Consolidated Powder Beds" [Invited Seminar](#)

Pfizer Inc., Groton, CT, August 2000, Stephen W. Hoag, "Elastic Characterization of Pharmaceutical Materials: From Transducer Design to Data Analysis" [Invited Seminar](#)

Martin-Luther-Universität Halle-Wittenberg, Halle, Germany, April 10, 2000; Stephen W. Hoag, "Application of Shear Analysis to the Study of Flow and Lubrication in Consolidated Powder Beds" [Invited Seminar](#)

Office of Dietary Supplements-NIH, Bethesda MD, January 2000; Workshop leader and panel participant for the "Conference/Workshop Bioavailability of Dietary Supplements: Key Issues in Defining the Research Agenda"

Gilead Sciences, Foster City, CA, November 20, 1998; Stephen W. Hoag, "Application of Shear Cell Analysis to Pharmaceutical Formulation Development" [Invited Seminar](#)

Martin-Luther-Universität Halle-Wittenberg, Halle, Germany, June 4, 1998; Stephen W. Hoag, "Education at the University of Maryland and in the United States of America" [Invited Seminar](#)

Martin-Luther-Universität Halle-Wittenberg, Halle, Germany, June 4, 1998; Stephen W. Hoag, "Characterization and Prediction of Calcium Alginate Gel Formation" [Invited Seminar](#)

University of Connecticut, Storrs, CT, April 23, 1998; Stephen W. Hoag "The Integrated Science and Therapeutics Curriculum at the University of Maryland School of Pharmacy" [Invited Seminar](#)

University of Connecticut, Storrs, CT, April 23, 1998; Stephen W. Hoag, "Characterization and Prediction of Calcium Alginate Gel Formation" [Invited Seminar](#)

FMC Corporation, Princeton, NJ, January 22, 1997; Stephen W. Hoag, "Tablet Press Instrumentation Design Using Finite Element Modeling" [Invited Seminar](#)

SmithKline Beecham Pharmaceuticals, King of Prussia, PA, October 22, 1996; Stephen W. Hoag, "Tablet Press Instrumentation Design Using Finite Element Modeling" [Invited Seminar](#)

Scanning Microscopy 1996 Meeting, Bethesda, MD, May 1996; Stephen W. Hoag, and Shawna Inoue "Interfacial Barriers to Mass Transfer in Calcium Alginate Gels" [Invited Seminar](#)

FDA Baltimore District Pre-approval Training Course, Baltimore, MD, January 17, 1996; Stephen W. Hoag, "Tablet Compaction" [Invited Seminar](#)

Eli Lilly and Co., Indianapolis, IN, November 17, 1995; Stephen W. Hoag, "Finite Element Modeling in Tablet Press Instrumentation Design" [Invited Seminar](#)

## STEPHEN W. HOAG

Page 36

Scanning Microscopy 1995 Meeting, Houston, TX, May 1995; Stephen W. Hoag, and Shawna Inoue "Characterizing Heterogeneity in Calcium Alginate Gels: Measurement of Gel Formation Rate." Invited Seminar

Eli Lilly and Co., Indianapolis, IN, June 20, 1994; Stephen W. Hoag, "Deformation of the Stokes B2 Rotary Tablet Press: Quantitation and Influence on Tablet Compaction" Invited Seminar

24th Annual Meeting of the Fine Particle Society, Chicago, IL, August 1993; Stephen W. Hoag, "Characterizing Drug Release from Calcium Alginate Hydrogels." Invited Seminar

Third Annual AAPS Meeting and Exposition, Orlando, Florida, November 1988; Stephen W. Hoag and Edward G. Rippie, "Evolution of Viscoelastic Tablet Structure During Compaction" *Pharm. Res.* 5:S236(1988).

19th Annual Pharmaceutical Graduate Student Research Meeting, University of Michigan, Ann Arbor, Michigan, June 1987; Stephen W. Hoag and Edward G. Rippie, "Evolution of Viscoelastic Tablet Structure During Compression."

17th Annual Pharmaceutics Graduate Student Research Meeting, University of Kentucky, Lexington, Kentucky, June 1985, Stephen W. Hoag and Edward G. Rippie, "Acquisition of Stress/Strain Data in Tableting."

### SHORT COURSES TAUGHT

Amgen Inc., Thousand Oaks CA, December 2010, "Tablet Production & Formulation Short Course" Gave 7 hrs of lecture.

Office of Generic Drugs (OGD), FDA, Rockville MD, March - May 2010, "Excipients and Excipient Functionality" Gave 22 hrs of lecture with Larry Augsburger.

University of Wisconsin, Department of Engineering Professional Development, Las Vegas NV, April 2010, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 6 hrs of lecture.

Center for Veterinary Medicine FDA, Rockville MD, November 2009, "Excipients and Excipient Functionality" Gave 3 hrs of lecture.

Center for Veterinary Medicine FDA, Rockville MD, June 2009, "Tablet Production: Granulation, Compression & Dissolution" Gave 6 hr demonstration.

Bristol-Meyers Squib, New Brunswick, NJ, June 2008, "Tablet Production & Formulation Short Course" Gave 6 hrs of lecture.

Center for Veterinary Medicine FDA, Rockville MD, May 2008, "Emerging Technology Series - Overview of Spectroscopic Chemistry" Gave 3 hrs of lecture.

**STEPHEN W. HOAG**

**Page 37**

University of Wisconsin, Department of Engineering Professional Development, Las Vegas NV, April 2008, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

Center for Veterinary Medicine FDA, Rockville MD, March 2007, "Emerging Technology Series - Chemometrics" Gave 5 hrs of lecture.

University of Wisconsin, Department of Engineering Professional Development, Las Vegas NV, March 2007, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

University of Wisconsin, Department of Engineering Professional Development, Las Vegas NV, March 2006, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

University of Maryland, Department of Pharmaceutical Sciences, Atlanta, GA, August 2005, "Solvay / University of Maryland School of Pharmacy Tablet and Capsule Formulation Workshop" Gave 8 hrs of lecture.

Center for Veterinary Medicine FDA, Rockville MD, April 2005, "Drug Development and Manufacturing Series" Gave 4 hrs of lecture.

University of Wisconsin, Department of Engineering Professional Development, Las Vegas NV, January 2005, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

University of Maryland, Department of Pharmaceutical Sciences, Richmond, VA, January 2005, "Wyeth / University of Maryland School of Pharmacy Tablet and Capsule Formulation Workshop" Gave 8 hrs of lecture.

University of Maryland, Department of Pharmaceutical Sciences, New Brunswick, NJ, August 2004, "BMS / University of Maryland School of Pharmacy Tablet and Capsule Formulation Workshop" Gave 4 hrs of lecture.

Center for Veterinary Medicine FDA, Rockville MD, May 2004, "Drug Development and Manufacturing Series" Gave 4 hrs of lecture.

University of Wisconsin, Department of Engineering Professional Development, Las Vegas NV, February 2004, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

University of Maryland, Department of Pharmaceutical Sciences, New Brunswick, NJ, March 2003, "BMS / University of Maryland School of Pharmacy Tablet and Capsule Formulation Workshop" Gave 4 hrs of lecture.

## **STEPHEN W. HOAG**

**Page 38**

University of Wisconsin, Department of Engineering Professional Development, Philadelphia PA, February 2003, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

University of Wisconsin, Department of Engineering Professional Development, Philadelphia PA, February 2002, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

Silpakorn University, School of Pharmacy, Nakhonpathom Thailand, June 2001, Gave lectures on Drug Development, Drug Product Testing & Regulation in the USA, Gave 12 hrs of lecture.

University of Wisconsin, Department of Engineering Professional Development, San Francisco, CA, January 2001, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

University of Wisconsin, Department of Engineering Professional Development, Philadelphia PA, January 2000, "Tableting and Capsule Manufacturing: Introduction and Update for Competitive Organizations" Gave 5 hrs of lecture.

### **CONSULTING ACTIVITIES**

March 2011, Trial testimony as an expert witness in King Pharmaceuticals Inc. and Elan Corp. v. Actavis, Inc. (Civil Action No. 07-5041 (GEB) (MCA))

January 2011, Deposition testimony as an expert witness in King Pharmaceuticals Inc. and Elan Corp. v. Actavis, Inc. (Civil Action No. 07-5041 (GEB) (MCA))

June 2010, Deposition testimony as an expert witness in Takeda v. Teva (Civil Action No. 09 CV 4655 S.D. New York)

December 2006, Trial testimony as an expert witness in Pfizer v. Mylan(W.D. Pa.)

April 2006, Trial testimony as an expert witness in Pfizer v. Synthron

January 2006, Trial testimony as an expert witness in Pfizer v. Apotex (N.D., Ill.)

January 2005, Deposition testimony as expert witness in Pfizer v. Mylan (W.D. Pa.)

January 2005, Deposition testimony as expert witness in Pfizer v. Apotex (N.D., Ill.)

June 2005, Deposition testimony as an expert witness Cephalon v. Mylan, Teva, Barr and Ranbaxy Laboratories (D.C. NJ.)

July 2000, Deposition testimony as an expert witness Ethex Corp. v. Warner Chilcott (E.D. Mo.)