

CURRICULUM VITAE  
STEPHEN W. HOAG

**PERSONAL DATA**

Business Address:

School of Pharmacy  
University of Maryland at Baltimore  
20 N. Pine St.  
Baltimore, MD 21201  
Web page address: [www.pharmacy.umaryland.edu/faculty/shoag/](http://www.pharmacy.umaryland.edu/faculty/shoag/)

**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.
- 9/90 - 4/95     **Assistant Professor - College of Pharmacy, Oregon State University**

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

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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**

H. Gregg Claycamp, Raafat Fahmy, Ravi Kona, Stephen W. Hoag, “Quality-by-Design II: Application of Quantitative Risk Analysis to the Formulation of Ciprofloxacin Tablets”, submitted to *AAPS PharmSciTech* (2014).

Ting Wang, Stephen W. Hoag, James Polli, Maria Lin Eng and Neha Umesh Sheth, “Quality of antiretroviral (ARV) and opportunistic infections medications dispensed from developing countries and internet pharmacies”, on line at *J. Clin. Pharm. Ther.* (2014). doi: 10.1111/jcpt.12226

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 Glycerol Monostearate”, In press *Drug Dev. Ind. Pharm.*, (2014)

Vikas Moolchandani, Larry L. Augsburger, Abhay Gupta, Mansoor Khan, John Langridge, and Stephen W. Hoag, “Characterization and selection of suitable grades of lactose as functional fillers for capsule filling: part 1”, *Drug Dev. Ind. Pharm.* In press (2014). DOI: 10.3109/03639045.2014.957703

Ravikanth Kona, Raafat M. Fahmy, Gregg Claycamp, James E. Polli, Marilyn Martinez, Stephen W. Hoag, “Quality-by-Design III: Application of Near-Infrared Spectroscopy to monitor roller compaction in-process and product quality attributes in formulation development of immediate release tablets”, In press *PhamSciTech*,(2014).

Vivek S. Dave, Raafat M. Fahmy and Stephen W. Hoag, “Near-infrared spectroscopic analysis of the breaking force of extended-release matrix tablets prepared by roller-compaction: influence of plasticizer levels and sintering temperature”, in press *Drug Dev. Ind. Pharm.*, (2014)

Qingqing (Maggie) Chen, Russell Martin, Stephen W. Hoag, Robert A. Wood, Hai-Quan Mao and Corinne Keet, “Formulation and Characterization of Orally Dissolving Thin Films Containing the German Cockroach *Blattella germanica* (Blat g 2) Allergen”, *Int. J. Pharma Sci.*, **4**(5):730-35 (2014).

Lawrence X. Yu, Gregory Amidon, Mansoor A. Khan, Stephen W. Hoag, James Polli, G. K. Raju, and Janet Woodcock, “Understanding Pharmaceutical Quality by Design”, *AAPS Journal*, **16**(4):771-783 (2014). DOI: 10.1208/s12248-014-9598-3

William C. Stanley, James W. Cox, Girma Asemu, Kelly A. O’Connell, Erinne R. Dabkowski, Wenhong Xu, Rogerio F. Ribeiro Jr, Kadambari C. Shekar, Stephen W. Hoag, Sharad Rastogi, Hani N. Sabbah, Caroline Daneault, Christine des Rosiers, “Evaluation of Docosahexaenoic Acid in a Dog Model of Hypertension Induced Left Ventricular Hypertrophy”, *J. Cardiovasc. Transl. Res.*,**6**(6):1000-10 (2013). DOI: 10.1007/s12265-013-9511-y,

Hanpin Lim and Stephen W. Hoag, "Plasticizer effects on physical-mechanical properties of solvent cast Soluplus<sup>®</sup> films", *AAPS PharmSciTech*, **14**(3):903- 10 (2013). DOI: 10.1208/s12249-013-9971-z

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<sup>®</sup> 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

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Vivek S. Dave, Raafat M. Fahmy, Dennis Bensley and Stephen W. Hoag, "Eudragit<sup>®</sup> 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

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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/>.

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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).

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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 Kuppuswamy, 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. Martı́nez-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 Kuppuswamy, 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 Ramachandruni 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).

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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).

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#### **PUBLICATIONS – Books, Book Chapters and Non-Peer Review**

Vivek S. Dave, Seon Hepburn and Stephen W. Hoag, "Physical States and Thermodynamics Principles in Pharmaceutics" In *Pharmaceutics: Basic Principles and Application to Pharmacy Practice*, Alekha K. Dash, Somnath Singh and Justin Tolman Editors; Academic Press (San Diego, CA); (2014).

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## **PATENTS**

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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"

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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."

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

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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".

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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).

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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."

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."

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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

Development and Regulation of Abuse-Deterrent Opioid Medications – Public Meeting, Silver Spring, MD, October 2014, Stephen W. Hoag, "Excipient properties affecting the mechanical performance of abuse deterrent formulations" [Invited Seminar](#)

2014 GPhA Fall Technical Conference, North Bethesda, MD, October 2014, Stephen W. Hoag, "The Pharmaceutical Excipients Database Hosted on PharmaHUB" [Invited Seminar](#)

The Cortona Conference: Advances in Pharmaceutical Innovation and Manufacturing Control, Cortona, Italy, September 2014, Stephen W. Hoag, "The Use of NIR Spectroscopy and Process Environmental Data to Monitor the Coating of Multiparticulate Beads in a Fluid Bed" [Invited Seminar](#)

Zhejiang University, Hangzhou, China, Hangzhou, China, June 2014, Stephen W. Hoag, "The Research infrastructure and Education System at American Universities" [Invited Seminar](#)

2014 International Symposium on Trends in Advanced Pharmaceutical Manufacturing, Hangzhou, China, June 2014, Stephen W. Hoag, "The development of control strategies for the fluid bed coating of multiparticulate beads" [Invited Seminar](#)

Generic Drug User Fee Amendments of 2014; Regulatory Science Initiatives Part 15 Public Meeting; Request for Comments, FDA, Silver Spring, MD, May 2014, Stephen W. Hoag, "Raw Material and Manufacturing Factors Affecting the Quality of Generic Pharmaceutical Products"



IFPAC Annual Meeting, Arlington VA, January 2014, [S. Mamedov](#), T. Wang, S. Hoag, "Determination of magnesium concentration in commercial magnesium stearate samples using XRF spectroscopy" [Invited Seminar](#)

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IFPAC Annual Meeting, Arlington VA, January 2014, [Stephen W. Hoag](#) and Raafat Fahmy, “Real Time Release Testing of Ciprofloxacin HCl Modified Release Capsules. Case Study” [Invited Seminar](#)

SCIX Annual 2013, Milwaukee, WI, September 2013, Stephen W. Hoag, “Developing the Control Strategy for Real Time Release Testing of Ciprofloxacin HCl Controlled Release Multiparticulate Beads” [Invited Seminar](#)

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](#)

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 Annual 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](#)

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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

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

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

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

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](#)

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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

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 Aniticounterfeit 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

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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)

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

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

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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

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

University of Maryland, School of Pharmacy, Baltimore MD, October 2014, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

17<sup>th</sup> International Diffuse Reflectance Conference (IDRC), Chambersburg Meeting, Chambersburg PA, August 2014, "Chemometrics for Pharmaceutical Scientists" Organized a 1 day short course 4 hrs lecture.

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University of Maryland, School of Pharmacy, Baltimore MD, June 2014, "Chemometrics for Pharmaceutical Scientists" Organized a 4 day short course 13 lectures 2 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore, October 2013, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

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.

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.

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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.

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.

**RESEARCH GRANTS & CONTRACTS FUNDED**

**Source: NIAID (Grant #: U19-AI109776) (PI)**

Title: Center of Excellence for Translational Research (CETR) Network  
CETR Title: Immunoprophylactic Strategies to Control Emerging Enteric Infections.

Amount: ???

Period: 3/1/14 – 2/28/19

PI: Myron M, Levine // Stephen W. Hoag co-investigator:

**Source: NIPTE-FDA (Request for Quotation: DA-RFQ-1120913)**

Title: Abuse Deterrent Risk Assessment

Amount: \$499,000

Period: October 1, 2013 – September 31, 2015

PI: Stephen W. Hoag and Stephen Byrn

**Source: NIH-NICHD (Grant Number: R21HD073557-01AI)**

Title: Development of a Dissolving Film for Allergen Immunotherapy in Children

Amount: \$64,228

Period: April 1, 2013 – March 31, 2015

PI: Corinne Keet, MD // Stephen W. Hoag co-investigator



**Source: University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI) Exchange Awards**

Title: Conference title: Control Strategies for Pharmaceutical Manufacturing: Real Time Release Testing and Design Space Determination

Amount: \$4,000 towards conference expenses

Period: Conference held May 13, 2013

PI: Stephen W. Hoag



**Source: NIPTE-FDA (Solicitation Number: 1U01FD005275-01)**

Title: Quantitative Detection of Cold Flow in Transdermal Systems

Amount: \$89,999.75

Period: March 1, 2012 – March 1, 2013

PI: Stephen W. Hoag / Co-PI Audra Stinchcomb, A

**Source: FDA (Solicitation Number: FDA-10-1085962)**

Title: Real Time Release Testing

Amount: \$167,878

Period: August 9, 2011 – September 30, 2013

PI: Stephen W. Hoag

**Source: Wyle / NASA**

Title: Subcontract T72096 – Manufacturing of Intranasal Scopolamine Spray Solution and Quality Testing

Amount: \$35,498

Period: March 1, 2011 – June 30, 2011

PI: Stephen W. Hoag

**Source: NIDA (Grant Number: 1DP1DA031401-01)**

Title: Development of I-THP as New Medication for Drug Addiction (DP1)

Amount: Total Costs: \$3,750,000

Period: 09/30/2010 – 07/31/2015

PI's: Jia Bei Wang, MD//Stephen W. Hoag co-investigator

**Source: Hypoxyprobe Inc.**

Title: Capsule Filling

Amount: [REDACTED]

Period: April, 15 2011 – June, 15 2011

PI: Stephen W. Hoag

**Source: NIH grant number P20HL101434**

Title: Docosahexaenoic Acid for Treatment of Heart Failure

Amount: \$42,085

Period: May, 2010 – January, 2012

PI: William C. Stanley, Ph.D. // subcontract Stephen W. Hoag

**Source: MIPS (Grant Number: 4607)**

Title: Development of abuse and overdose minimizing dosage forms

Amount: \$99,999

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Period: 8/1/2010-4/30/2012

PI: Stephen W. Hoag

**Source: NIPTE (Prime Sponsor: FDA HHSF223200910009C)**

Title: Approach to the Understanding and Predicting Excipient Properties and Functionality

Amount: \$134,906

Period: 9/22/09-9/21/11

PI: Stephen W. Hoag

**Source: FDA**

Title: Development of Immediate Release Oral Formulations Using the Concept of Quality by Design and Predicting In Vivo and In Vitro Correlations for Class II (Low Solubility, High Permeable) Drugs in Dogs and Humans

Amount: \$299,726

Period: September 19, 2008 – March 18, 2011

CoPI's: Stephen W. Hoag and James E. Polli

**Source: FDA**

Title: Evaluation of Biopharmaceutics Classification System Class 3 Drugs for Possible Biowaivers

Amount: \$300,000

Period: September 22, 2008 – September 21, 2009

PI: James E. Polli/Stephen W. Hoag co-investigator

**Source: NIPTE (# FDA-SOL-08-000664)**

Title: Influence of the Physics of Tablet Compression

Amount: \$12,155

Period: October 1, 2009-September 30, 2010

PI: Gintaras V. (Rex) Reklaitis, Purdue Univ., Dept of ChemE/Stephen W. Hoag co-investigator

**Source: NIPTE (# FDA-SOL-08-000664)**

Title: Development of Quality by Design (QbD) Guidance Elements on Design Space Specifications Across Scale with Stability Considerations

Amount: \$7,596

Period: September 22, 2008 – September 21, 2009

PI: Gintaras V. (Rex) Reklaitis, Purdue Univ., Dept of ChemE/Stephen W. Hoag co-investigator

a) The objective of this project is to improve pharmaceutical product quality, and maximize process innovation and continuous quality improvements by: a) developing QbD guidance elements on process design space, scale-up, and process validation for three unit operations: mixing, granulation, and drying; b) developing a framework for optimizing design space specification across scales with consideration to stability.

b) The goal of this project is to systematic study the effect of tablet compression on the stability of gabapentin granulations, and examine these effects during granulation scale up.

**Source: University of Maryland, School of Pharmacy Seed Grant Program**

Title: Quality of Antiretroviral (ARV) and Opportunistic Infection Medications Dispensed from Pharmacies and ARV Treatment Sites

Amount: \$50,000

Period: November 1, 2008 – December 31, 2010

Co-PI: Neha Sheth and Maria Lin Eng

**Source: Maryland Psychiatric Research Center (MPRC)**

Title: Assessment of Oxytocin Nasal spray and Placebo for Clinical Studies

Amount: \$10,000

Period: May 1, 2009 – August 20, 2009

PI: Stephen W. Hoag

**Source: FDA / CVM**

Title: The Application of Design Space to a Sequence of Unit Operations: Process Understanding for the Interactions of Tablet Production and Dry Granulation. (Roller Compactor Granulation)

Amount: \$24,999

Period: June 14, 2007 – June 13, 2008

PI: Stephen W. Hoag

Title: The Use of Design Space to Enhance the Process Understanding of Tablet Manufacturing Processes. (Roller Compactor Granulation)

Amount: \$24,999

Period: July 1, 2006 – June 30, 2007

PI: Stephen W. Hoag

Title: PAT Applications for Tablet Film Coating

Amount: \$25,000

Period: January 1, 2005 - May 30, 2006

PI: Stephen W. Hoag

Title: Analysis and Prediction of Tablet Coat Curing: via NIR Spectroscopy and in vitro Dissolution

Amount: \$25,000

Period: January 1, 2005 - December 31, 2005

PI: Stephen W. Hoag

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Title: Integrating Design of Experiment Methodology and Statistical Simulation Approach for Science and Risk-based Assessment on their Regulatory Utility in the Domain of Process Analytical Technology (PAT) Initiative and 21st Century Drug Quality System

Amount: \$25,000

Period: May 15, 2004 - May 14, 2005

PI: Stephen W. Hoag



**Source: FDA / CDER - Office of Pharmaceutical Science**

Title: Integrating Design of Experiment Methodology and Statistical Simulation Approach for Science and Risk-based Assessment on their Regulatory Utility in the Domain of Process Analytical Technology (PAT) Initiative and 21st Century Drug Quality System

Amount: \$20,000

Period: July 1, 2004 – June 30, 2005

PI: Stephen W. Hoag



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Period: May 15, 2000 - May 15, 2001

PI: Stephen W. Hoag

**Source: University of Maryland DRIF & Departmental Funds**

Title: Equipment Grant: Purchase of a Laser Diffraction Particle Sizing System

Amount: \$38,700

Period: June 1, 1999

PI: Stephen W. Hoag

**Source: UMAB DRIF**

Title: Equipment Grant: Purchase of a Modulated Differential Scanning Calorimeter

Amount: \$10,000

Period: June 1, 1996

PI: Stephen W. Hoag

**Source: Abbott Laboratories**

Title: Visiting Professor at Abbott Laboratories

Amount: [REDACTED]

Period: September 1994 - December 1994

PI: Stephen W. Hoag

**Source: American Association of Colleges of Pharmacy (AACP)**

Title: A Thermodynamically Based Fracture Criteria for the Prediction of Capping and Lamination in Pharmaceutical Tablets

Amount: [REDACTED]

Period: November 1991 - November 1993

PI: Stephen W. Hoag

**Source: Oregon State University Research Council**

(NIH Biomedical Research Support Grant RR07079)

Title: The Use of Viscoelastic Models in the Development of Quality Assurance Specifications for the Control of Lot-to-lot Variations in Tableting Excipients

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Amount: \$8,000  
Period: April 30, 1991 - April 29, 1992  
PI: Stephen W. Hoag

### GRANTS AS CO-INVESTIGATOR

**Source: FDA / CVM**

Title: To Correlate Process Analytical Technology (PAT) Methodology Utilizing Near-IR with Common Quality Control Analytical Methods (in vitro/in vitro) and Blood Level Studies (in vitro/in vivo).

Amount: \$20,000  
Period: May 15, 2003 - May 14, 2004  
PI: Gary Hollenbeck

**Source: Maryland Industrial Partnerships (MIPS)**

Title: Chewable Cosequin Tablet  
Amount: \$96,180  
Period: August 1, 1997 - July 31, 1998  
PI: Natalie Eddington

### 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.)