CURRICULUM VITAE

STEPHEN W. HOAG

PERSONAL DATA

Business Address:
School of Pharmacy
University of Maryland at Baltimore
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205 Oak Forest Pl.
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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.

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.

Visiting Professor - Aerosol Group, 3M Pharmaceuticals, St. Paul, Minnesota

11/92 - 12/92 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 isooctane.

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.

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 2015 to 2020
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
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) Elected Chair of Executive Committee (2013-2015)
Appointed to FDA Pharmacy Compounding Advisory Committee (2014-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

Asuka A. Orr, Agbo-oma Uwakweh, Xun Li, Ahmad Kiani Karanji, Stephen W. Hoag, Daniel J. Deredge and Alexande MacKerell "Mapping the Distribution and Affinities of Ligand Interaction Sites on Human Serum Albumin" Biophysical Journal (special issues Challenges in Biomolecular Simulations) Accepted (2025).

Ana L. Coutinho, Asmita Adhikari, Samuel Krug, Maureen Kane, R. Gary Hollenbeck, Stephen W. Hoag and James E. Polli. "In vitro-in vivo correlation of amorphous solid dispersion enabled itraconazole tablets" *Pharm Res.* (2025). DOI: https://doi.org/10.1007/s11095-025-03837-z

Haixi Cui, Yongrong Zhang, Hua Yu, R. Gary Hollenbeck, Lydia Nyasae, Yihan Wang, Yiguang Han, Zhiyong Yang, Hanping Feng, and Stephen W. Hoag. "Rodent Diets Incorporated with Live Biotherapeutic Products (LBPs): An Innovative Dosing Strategy to Support Preclinical Animal Studies on LBP Intervention" *AAPS PharmSciTech*. **26**, 55 (2025). DOI: https://doi.org/10.1208/s12249-025-03050-6

Xun Li, Asuka A. Orr, Mohammad M. Sajadi, Anthony L. DeVico2 Daniel J. Deredge, Alexander D. MacKerell Jr., Stephen W. Hoag. "Investigating the Interaction between Excipients and Monoclonal Antibodies PGT121 and N49P9.6-FR-LS: A Comprehensive Analysis." Molecular Pharmaceutics (2025). DOI: 10.1021/acs.molpharmaceut.4c00973

R. Gary Hollenbeck, Raafat Fahmy, Marilyn Martinez, Ahmed Ibrahim and Stephen W. Hoag. "Design and process considerations for preparation of modified release ivermectin and praziquantel tablets by wet granulation." *PharmSciTech*. **26**, 43(2025). DOI: https://doi.org/10.1208/s12249-024-03030-2

Dongyue Yu, Meng Li, Stephen W. Hoag and Haichen Nie. Understanding Excipient-Induced Crystallization of Spray-Dried Amorphous Solid Dispersion. *J. Pharm Sci.* **114**(1):234-244 (2025). DOI: https://doi.org/10.1016/j.xphs.2024.08.024

Marilyn N. Martinez, Raafat Fahmy, Linge Li, Kithsiri Herath, R. Gary Hollenbeck, Ahmed Ibrahim, Stephen W. Hoag, David Longstaff, Shasha Gao, Michael J. Myers. "The Use of Systemically Absorbed Drugs to Explore An In Vitro Bioequivalence Approach For Comparing Non-Systemically Absorbed Active Pharmaceutical Ingredients in Drug Products For Use in Dogs." *Pharm. Res.* **41**, 1797-1809 (2024). DOI: 10.1007/s11095-024-03766-3

Dongyue Yu, Stephen W Hoag. The Impact of Diluents on the Performance of Amorphous Solid Dispersion Tablets. *Int. J. of Pharm.* (2024). doi: 10.1016/j.ijpharm.2024.123924

Dongyue Yu, Haichen Nie, Stephen W. Hoag "Comprehensive Evaluation of Polymer Types and Ratios in Spray-Dried Dispersions: Compaction, Dissolution, and Physical Stability". *Int. Nat. J. of Pharm.* (in press 2023)

Ahmed Ibrahim, Fang Wang, R. Gary Hollenbeck, Marilyn N. Martinez, Raafat Fahmy, Stephen W. Hoag "Development and Validation of a Stability-indicating UPLC-DAD Method for the Simultaneous Determination of Ivermectin and Praziquantel in Pharmaceutical Tablets and Dissolution Media". *AAPS PharmSciTech* (accepted 2023)

Brianna L. Scotland, Andrea L. Cottingham, Jackline Joy M. Lasola, Stephen W. Hoag, Ryan M. Pearson "Development of protein-polymer conjugate nanoparticles for modulation of dendritic cell phenotype and antigen-specific CD4 T cell responses". *ACS Applied Polymer Materials* **5**(11):8794-8807 (2023)

Amanda B. Kagan, Blake S. Moses, Rena Lapidus, Bryan T. Mott, Ganesha Rai, Nicole M. Anders, Stephen W. Hoag, Michelle A. Rudek, Curt I. Civin "ART714 is a best-in-class antileukemic 2-carbon-linked dimeric artemisinin derivative". *Cancer Chemotherapy and Pharmacology* (submitted 2023)

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Annabelle M. Belcher, Thomas O. Cole, Ebonie Massey, Amy S. Billing, Michael Wagner, William Wooten, David H. Epstein, Stephen W. Hoag, Emerson M. Wickwire, Aaron D. Greenblatt, Luana Colloca, John Rotrosen, Lawrence Magder, Eric Weintraub, Eric D. Wish, Ted J. Kaptchuk. "Effectiveness of Conditioned Open-label Placebo With Methadone in Treatment of Opioid Use Disorder A Randomized Clinical Trial", *JAMA Network Open.* **6**(4) (2023). doi: 10.1001/jamanetworkopen.2023.7099

Luke Schenck, Paresma Patel, Ramesh Sood, Llorente Bonaga, Peter Capella, Olivier Dirat, Deniz Erdemir, Steven Ferguson, Cinzia Gazziola, Lindsey Saunders Gorka, Laurie Graham, Raimundo Ho, Stephen Hoag, Ephrem Hunde, Billie Kline, Sau (Larry) Lee, Rapti Madurawe, Ivan Marziano, Jeremy Miles Merritt, Sharon Page, James Polli, Mahesh Ramanadham, Mohan Sapru, Ben Stevens, Tim Watson, Haitao Zhang. "FDA/M-CERSI Co-Processed API Workshop Proceedings", J. Pharm. Sci. PreProof (2023). doi.org/10.1016/j.xphs.2023.01.006

Dongyue Yu, Frederick Fiddler, Ahmed Ibrahim, Raymond Sanedrin, Heidi Tremblay, Stephen W Hoag. "Surface Characterization as a Tool for Identifying the Factors Affecting the Dissolution Rate of Amorphous Solid Dispersion Tablets", AAPS *PharmSciTech.* **23**(8):282-83(2022). DOI: 10.1208/s12249-022-02413-7

Stephen W. Hoag; Elena V. Mishina; Lauren Viray; Fang Wang; Gary Hollenbeck; Bartosz Koszowski; Wallace B. Pickworth "Formulation of Smokeless Tobacco Products with a Wide Range of pH to Study Nicotine Pharmacokinetics and Pharmacodynamics", in press *Drug Dev. Ind. Pharm.* (2022).

Lee, Hyun, Hollenbeck, Robert, Morgan, Jill, Howard, Amy, Siddiqui, Akhtar, Sayeed, Vilayat, Selen, Arzu, Hoag, Stephen. "A Method for the Tribological Assessment of Oral Pharmaceutical Liquids", *Drug Dev. Ind. Pharm.* **48**(5):198-210(2022). https://doi.org/10.1080/03639045.2022.2092125

Melissa Metry, Samuel A. Krug, "Vijaya Kumari Karra, Sean Ekins, Stephen W. Hoag, Maureen A. Kane, Jeffrey C. Fink and James E. Polli "Lack of an effect of polysorbate 80 on intestinal drug permeability in humans,", *Pharm. Res.*, accepted. (2022). Doi: https://doi.org/10.1007/s11095-022-03312-z. (selected for Pearls of Bioequivalence Award, by Frankfurt Foundation Quality of Medicines and European Federation for Pharmaceutical Sciences)

Fang Wang, Wenbo Yua, Carmen Popescu, Ahmed Ashour Ibrahim, Dongyue Yu, Ryan Pearson, Alexander D. MacKerell Jr and Stephen W. Hoag, "Cholecalciferol complexation with hydroxypropyl-b-cyclodextrin (HPBCD) and its molecular dynamics simulation", *Pharm. Dev. Tech.*,1-10. (2022). doi: https://10.1080/10837450.2022.2064492.

Salma Salema, Stephen R. Byrn, Daniel T. Smitha, Vadim J. Gurvich, Stephen W. Hoag, Feng Zhange, Robert O. Williams III and Kari L. Clase, "Impact assessment of the variables affecting the drug release and extraction of polyethylene oxide based tablets", *J. Drug Del. Sci Tech.*,***71****:103337.* (2022). doi: https://doi.org/10.1016/j.jddst.2022.103337.

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Yuwei Lu, Chenguang Wang, Changquan Calvin Sun and Stephen W. Hoag, "Feasibility of developing oral tablets of biologics the case of intravenous immunoglobulin" *Int. J. Pharm.*, **604**(7):120737(2021). doi: https://doi.org/10.1016/j.ijpharm.2021.120737.

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using Compaction Simulation Studies" *J. Pharm. Sci.*, **10**(7):2789-99 (2021). doi: https://doi.org/10.1016/j.xphs.2021.03.008.

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Liting Wan, Lin Li, Janette M Harro, Stephen W Hoag, Bing Li, Xia Zhang, Mark E Shirtliff, "In Vitro Gastrointestinal Digestion of Palm Olein and Palm Stearin-in-water Emulsions with Different Physical State and Fat Content", accepted *Journal of Agricultural and Food Chemistry*, **68**(26)L7062-7071 (2020). DOI: 10.1021/acs.jafc.0c00212

Olga Ponomareva, Brianne Redman, MacKenzie A. Sayer, Heidi J. Wehring, Gopal Vyas, Charles M. Richardson, James Gold , David A. Gorelick, Daniela Cihakova, Monica V. Talor, Stephen W. Hoag, Robert W. Buchanan, Jiantao Wang, Shuo Chen, Fang Liu, Jia Bei Wang, Deanna L. Kelly, "L-Tetrahydropalmatine, a Novel Dopamine Antagonist, Fails to Show Improvement in Psychiatric Symptoms as Adjunctive Treatment for Schizophrenia", in press *Schiz Bulletin Online (SBO),**1**(1)* (2020). DOI: 10.1093/schizbullopen/sgaa026

Boyce Heather, Vivek Dave, Myke Scoggins, Vadim Gurvich, Daniel Smith, Stephen Byrn and Stephen W. Hoag, "Physical Barrier Type Abuse-Deterrent Formulations: Mechanistic Understanding of Sintering-Induced Microstructural Changes in Polyethylene Oxide Placebo Tablets", *PharmSciTech*, **21**(3):86 (2020). DOI: 10.1208/s12249-019-1594-6

Moshe Honick, Sharmila Das, Stephen W Hoag, Francis X Muller, Alaadin Alayoubi, Xin Feng, Ahmed Zidan, Muhammad Ashraf, James E Polli, "The Effects of Spray Drying, HPMCAS Grade, and Compression Speed on the Compaction Properties of Itraconazole-HPMCAS Spray Dried Dispersions", *Eur J Pharm Sci*, **155**(1):105556, (2020). DOI: 10.1016/j.ejps.2020.105556

Moshe Honick, Kanika Sarpal, Alaadin Alayoubi, Ahmed Zidan, Stephen W. Hoag, Robert G. Hollenbeck, Eric J. Munson, and James E. Polli, "Utility of Films to Anticipate Effect of Drug Load and Polymer on Dissolution Performance from Tablets of Amorphous Itraconazole Spray-Dried Dispersions", *PharmSciTech*, **20**(8):331, (2019). DOI: 10.1208/s12249-019-1541-6

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Bowen Jiang, Amita Jain, Yuwei Lu and Stephen W. Hoag, "Probing Thermal Stability of Proteins with Temperature Scanning Viscometer", Mol. Pharm.,**16**(8):3687-3693 (2019). DOI: 10.1021/acs.molpharmaceut.9b00598

Annabelle M. Belcher, Thomas O. Cole, Aaron D. Greenblatt, Stephen W. Hoag, David H. Epstein, Michael Wagner, Amy S. Billing, Ebonie Massey, Kristen R. Hamilton, Zofia Kozak, Christopher J. Welsh, Eric Weintraub, Emerson M. Wickwire, Eric D. Wish, Ted J. Kaptchuk, Luana Colloca, "Open-Label Dose-Extending Placebos For Opioid Use Disorder: A protocol for a

randomized controlled clinical trial with methadone treatment", *BMJ Open*, (2019). DOI: 0:e026604. doi:10.1136/bmjopen-2018-026604

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Andres Bejarano, Chandima Hewa Nadungodage, Fang Wang, Ann Christine Catlin, Stephen W. Hoag, "Decision Support for Excipient Risk Assessment in Pharmaceutical Manufacturing", *AAPS PhamSciTech*, **20**(6):233 (2019). Invited Manuscript for Theme issue Team Science and Education for Pharmaceuticals: the NIPTE Model, DOI: https://doi.org/10.1208/s12249-019-1440-x

Ting Wang, Alan Potts, and Stephen W. Hoag, "Elucidating the Variability of Magnesium Stearate and the Correlations with Their Spectroscopic Features", *J. Pharm Sci.*, **108**(4):1569-1580 (2019). DOI: https://doi.org/10.1016/j.xphs.2018.11.041

Xiaochi Xu; Chaitanya Krishna P Vallabh; Stephen W Hoag; Vivek S Dave and Cetin Cetinkaya, "Early Detection of Capping Risk in Solid Dosage Forms with an Acoustic Technique", Int. J. Pharm., **553**(1-2):338-348 (2018). DOI: https://doi.org/10.1016/j.ijpharm.2018.10.052

Bowen Jiang, Ahmed Ibrahim, Russell Martin, Corinne Keet, Hai-Quan Mao, Stephen W. Hoag, "Development and validation of a HPLC with fluorescence detection method to quantify the peanut allergen Ara h 2 in peanut extract and sublingual films", Separation Science Plus, **1**(9):579-587 (2018). DOI: |https://doi.org/10.1002/sscp.201800068

Heather J. Boyce, Ahmed Ibrahim and Stephen W. Hoag, "Physical barrier type abuse-deterrent formulations: monitoring sintering-induced microstructural changes in polyethylene oxide placebo tablets by near infrared spectroscopy (NIRS)", Drug Dev. Ind. Pharm., **14**(11):1885-1894 (2018). DOI: https://doi.org/10.1080/03639045.2018.1504965

Bhaveshkumar H. Kothari, Raafat M. Fahmy, Gregg Claycamp, Christine M. V. Moore, Sharmista Chatterjee and Stephen W. Hoag, "Comparing a Statistical Model and Bayesian Approach to Establish the Design Space for the Coating of Ciprofloxacin HCl Beads at Different Scales of Production", *AAPS PhamSciTech*, **19**(8):3809–3828 (2018). DOI: https://doi.org/10.1208/s12249-018-1116-y

Tanvi M. Deshpande, Anisul Quadir, Sakae Obara and Stephen W. Hoag, "Impact of Formulation Excipients on the Thermal, Mechanical, and Electrokinetic Properties of Hydroxypropyl methylcellulose acetate succinate (HPMCAS)", Int. J. Pharm., **542**(1-2):132-141 (2018). DOI: https://doi.org/10.1016/j.ijpharm.2018.02.024

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Bowen Jiang, Hua Yu, Yongrong Zhang, Hanping Feng and Stephen Hoag, "A Multiparticulate Delivery System for Potential Colonic Targeting Using Bovine Serum Albumin as a Model Protein", Pharm Res, **34**(12):2663-2674 (2017) **Invited manuscript**. DOI: https://doi.org/10.1007/s11095-017-2237-9

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Performance and Implication on Biowaiver Regulation of Oral Extended Release Dosage Forms", AAPS J, **18**(2):333-345 (2016). DOI: 10.1208/s12248-015-9861-2

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US Provisional Patent Application no.: 63/742,465, filed 1-7-2025 Title: HYDROGELS FOR ULTRAFAST BIO-ADHESION AND SUBMUCOSAL INJECTION

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ABSTRACTS

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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 32nd 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 Rations 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. Tatavarti1, 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)

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 31st 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 Bensely, 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 Bensely, Bill Marnane, Dilara Jappar, Peter Poczatek, Gary Hollenbeck and Stephen W. Hoag, "Assessment of the NIR for Process Analytical Testing of Bolus Dosage Forms"

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 Tatavarti, 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 Pharmaceutics and Drug Delivery Conference, Arlington, VA, April 2002; Aditya S Tatavarti, 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)

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

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

Eastern Analytical Society Meeting November1999; 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. Ramachandruni, 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."

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 Kuppuswamy, 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 γ-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).

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."

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

IFPAC Annual Meeting, Bethesda, MD, March 2025, Stephen W. Hoag, "PAT and Excipients in 3D Printing" Invited Seminar.

Prologue AAPS PharmSci360, Online, November 2024, Stephen W. Hoag, "The Effect of Excipients on the Colloidal Stability of Monoclonal Antibodies" Invited Seminar.

21st International Diffuse Reflectance Conference (IDRC), Knoxville, TN, August 2024, Stephen W. Hoag, "Quality Modeling for 3D Drug Printing via NIRS" Invited Seminar.

FDA Close-Out Presentation, Online, July 2024, UMB and Biopharma Services Inc., "ORS Scientific Presentation, Clinical/Data Analytics Track, Targin Project".

Lonza, Bend, OR, July 2024, Dongyue Yu and Stephen W. Hoag, "Effect of Excipients on the Performance of Spray-dried Amorphous Solid Dispersion (ASD) in Tablets" Invited Seminar.

Tech Transfer office Innovation Series, Baltimore, MD, March 2024, Stephen W. Hoag, "GMP manufacturing: Issues to consider for early-stage drug developer: i.e., costly and time consuming pitfalls to avoid to enhance the chances of success with cGMP projects" Invited Seminar.

IFPAC Annual Meeting, Bethesda, MD, March 2024, Stephen W. Hoag, "The use of Excipients in the Compression of Amorphous Solid Dispersions" Invited Seminar.

National Academies Sciences, Engineering and Medicine (NASEM) Workshop, Washington DC, June 2023, "Defining and Evaluating In-Home Drug Disposal Systems for Opioid Analgesics", On planning committee.

Emerging Trends in the Pharma Industry: Drug Development, Sustainability, and Digitalization: Online Symposium, June 2023, Dongyue Yu and Stephen W. Hoag, "Effect of Excipients on the Performance of Spray-dried Amorphous Solid Dispersion (ASD) in Tablets", Invited Seminar.

NIPTE Research Conference: Integrating Quality Into Pharmaceutical Technology Research and Education, Online, November 2022, Stephen W. Hoag, "Workforce Development", session organizer and Panel Moderator.

IPEC-Americas, Excipient World Academy, Online, November 2022, Stephen W. Hoag, "3D Printing of Microparticles Using Light: Direct Laser Writing", Invited Seminar.

14th Conference of the European Paediatric Formulation Initiative (EuPFI), "Acceptability of Pediatric Formulations: Some considerations for patient and drug product interface focusing on swallowability", Online, September 2022, Invited Seminar.

NIPTE Annual Research Conference, "Accelerating the Drug Development Process", Online, December 2021, "Educational Center Session" Moderator and on meeting planning committee.

IPEC-Americas, Excipient World Academy Innovations in Pharmaceutical Coating Development, Online, May 2021, Stephen W. Hoag, "Introduction to Coating" Invited Seminar.

IFPAC Annual Meeting, Online, March 2021, Stephen W. Hoag, "Excipient Risk Mitigation" Invited Seminar.

DFE Webinar Series Online Conference: Innovations in OSD, Online, October 2020, Stephen W. Hoag, "Methods for Cataloging and Assessing Excipient Variability and Risk Mitigation Approaches" Invited Seminar.

IFPAC Annual Meeting, North Bethesda, MD, March 2020, Stephen W. Hoag, "Excipient Variability and Risk Mitigation" Invited Seminar.

C&EN Webinars, Online, February 2020; Stephen W. Hoag and Adam J. Hopkins, "Redefining the Limits of Handheld Raman Spectroscopy" Invited seminar.

UMB-JHU Joint Symposium on Drug Discovery, Baltimore, MD, December 2019; Stephen W. Hoag, "UMB drug Discovery and Development Cores: GMP Facilities" Invited Seminar

Eastern Analytical Symposium and Exhibition, Princeton, NJ, November 2019, Stephen W. Hoag, "Data Fusion Methods for Improved Process Monitoring" Coblentz Invited Seminar.

NIPTE Research Conference: Collaborative Innovations In pharmaceutical Product Development, Alexandria VA, June 2019, Stephen W. Hoag, "Experimental Considerations in the Evaluation of Abuse Deterrent Formulations (ADF)" Invited Seminar (On meeting planning committee)

Granulation Seminar, Montgomeryville PA, October 2019, Stephen W. Hoag, "Use of a Compaction Simulator for the Evaluation of Pharmaceutical Formations" Invited Seminar

Fourth Category 1 Focus Group meeting, Alexandria VA, June 2019, Stephen W. Hoag and Chris Altomare, "Emerging Technologies - Vaping" Invited Seminar (On meeting planning committee)

IFPAC Annual Meeting, North Bethesda, MD, March 2019, Stephen W. Hoag, "Excipient Risk Assessment Database" Invited Seminar.

Eastern Analytical Symposium and Exhibition, Princeton, NJ, November 2018, Stephen W. Hoag and Adam J. Hopkins, "Counterfeit Tablet Analysis Using a Handheld Raman Spectroscopy" Invited Seminar.

2018 Compaction Simulation Forum, Genentech South San Francisco, CA, June 2018, Stephen W. Hoag and Raghunadha Reddy Seelam, "Evaluation of the effects of tablet compression force and tableting speed on polyethylene oxide polymers in abuse deterrent formulations" Invited Seminar.

FY 2018 Generic Drug Regulatory Science Initiatives Public Workshop, Silver Spring, MD, May 2018, Stephen W. Hoag, "Critical Issues in The Use and Evaluation of Excipients in Dosage Forms Such As Pediatric, Geriatric and Abuse Deterrent Dosage Forms" Invited Seminar.

Computer-Aided Drug Design Symposium, Baltimore, MD, May 2018, Stephen W. Hoag, "The formulation of therapeutic antibodies for colonic delivery" Invited Seminar.

FDA Seminar, Silver Spring, MD, April 2018, Stephen Byrn, Feng Zhang and Stephen W. Hoag, "Effect of Excipient Variability on the Critical Quality Attributes of Opioid Drugs based on Polyethylene Oxide" Invited Seminar.

Third Category 1 Focus Group Meeting, Alexandria, VA, January 2018, Stephen W. Hoag, "New methods and technologies in ADT – academia perspective" Invited Seminar and was on organizing committee.

FDA Seminar, Silver Spring, MD, January 2018, Fang Wang, Chandima Nadungodage, Andres Bejarano, Ann Christine Catlin and Stephen W. Hoag, "Report and Demonstration of the Excipient Risk Assessment Database" Invited Seminar.

Eudragit® Advanced Workshop , Piscataway, NJ, December 2017, Stephen W. Hoag, "Analysis of curing of a sustained release coating formulation by application of NIR spectroscopy" Invited Seminar.

NIPTE Annual Conference, USP, Rockville, MD, September 2017; NIPTE Planning Committee; "Re-thinking Pharmaceutical Technology Continuing Education" Member of Organizing committee

NIPTE Center of Excellence for Abuse Deterrent Opioid Technologies, Purdue University, West Lafayette, IN, June 2017; Feng Zhang and Stephen W. Hoag; "Standardizing Procedures for Category 1 Testing" Invited Seminar

FDA lecture, Silver Spring, MD, May 2017; Stephen W. Hoag; "Real Time Release Testing of Ciprofloxacin HCl Modified Release Capsules: Case Study" Invited Seminar

AAPS Annual Meeting and Exposition/BASF symposium, Denver, CO, November 2016; Stephen W. Hoag; "Recent Trends in Instant and Modified Release Formulations" *PharmSci*: Available from: http://www.pharmsci.org/journal (2016) Invited Seminar

Public Meeting on Pre-Market Evaluation of Abuse-Deterrent Properties of Opioid Drug Products, College Park, MD, November 2016, Stephen W. Hoag, "Foundations of in vitro comparisons of generic opioids to reference listed drugs (RDLs) with labeling describing abuse-deterrent properties" Invited Seminar

Evonik Technical Symposium on Controlled Release & Solubility Enhancement, San Francisco, CA, October 2016, Stephen W. Hoag, "Use of Colonic Delivery Systems for the Local Delivery of Proteins to the Colon" Invited Seminar.

NIPTE Research Conference: Scientific Design of Pharmaceutical Product: 21st Century Methodologies, Technologies & Perspectives, FDA White Oaks Campus, Silver Spring, MD, October 2016, Stephen W. Hoag, "Material Characterization and Control and Knowledge Management Consideration for Continuous Manufacturing with the Real-Time Release" Invited Seminar and I was on the meeting planning committee.

SciX2016 National Meeting, Minneapolis, MN, September 2016, Heather Boyce and Stephen W. Hoag, "Analysis of Polyethylene Oxide in Sintered Pharmaceutical Tablets by Transmission Raman"

LyoHUB-NIPTE workshop at NIST, Gaithersburg, MD, September 2016, Stephen W. Hoag, "NIPTE excipients database" Invited Seminar

SciX2016 National Meeting, Minneapolis, MN, September 2016, Stephen W. Hoag and Ahmed Ibrahim, "Combining fluid bed process data with spectral data to improve model prediction of product performance" Invited Seminar

Lab Manager "Ask the Expert" Webinar Series, Online, March 2016, Keith Freel and Stephen W. Hoag, "Reagent-Free Tablet Manufacturing Analysis by Near-IR Spectroscopy" Invited Webinar

2nd Excipient Workshop: Focus on Excipient Quality, Compendial Testing, and Regulatory Impact, Rockville, MD, November 2015, Stephen W. Hoag, "Global Excipient Databases – NIPTE Overview" Invited Seminar

FDA Abuse Deterrent Formulation Presentation, Silver Spring, MD, November 2015, Heather Boyce, Daniel Smith, Vadim Gurvich, Stephen Byrn and Stephen W. Hoag, "Material Properties in Abuse Deterrent Formulations and the development of a nasal test method" Invited Seminar

Category 1 Focus Group meeting, Washington, DC, November 2015, Heather Boyce, Daniel Smith, Vadim Gurvich, Stephen Byrn and Stephen W. Hoag, "Can we standardize household tools?" Invited Seminar

Second FDA/PQRI Conference on Advancing Product Quality, North Bethesda, MD, October 2015, Stephen W. Hoag and Sau Larry Lee, "Botanical Drug Development and Quality Standards" Meeting organizer and presented wrap up summary

Shin-Etsu Meeting: Recent Advances in Drug Delivery and Solubility Enhancement Based on Cellulosic Polymers, Somerset, NJ, September 2015, Tanvi Deshpande and Stephen W. Hoag, "The Effect of Plasticizers on the Thermal, Mechanical and Colloidal Properties of Cellulosic Polymers" Invited Seminar

GDUFA: FY 2015 Regulatory Science Initiatives Part 15 Public Meeting; Regulatory Science Initiatives Part 15 Public Meeting; Request for Comments, FDA, Silver Spring, MD, June 2015, Stephen W. Hoag, "Research needs in pharmaceutical excipients: implications of a global supply chain"

NIPE Research Conference: Pharmaceutical Critical Path Manufacturing-2015, Shady Grove, MD, April 2015, Stephen W. Hoag, "Methods for the Assessment of Cold Flow in Matrix Transdermal Drug Delivery Systems" Invited Seminar and I was on the meeting planning committee.

Excipient Fest Americas, San Juan, Puerto Rico, April 2015, Stephen W. Hoag, "The Pharmaceutical Excipients Database Hosted on PharmaHUB" Invited Seminar

APhA 2015 Annual Meeting and Exposition, San Diego, CA, March 2015, Stephen W. Hoag, "A Review of Abuse Deterrent Formulations" Invited Educational Seminar

50th AAPS Arden Conference, Baltimore, MD, March 2015, Sharmista Chatterjee and Stephen W. Hoag, "Case Studies in Continuous Manufacturing Session Moderators" On Program Committee

Excipient Qualification Committee Meeting, Alexandra, VA, February 2015, Stephen W. Hoag, "The Pharmaceutical Excipients Database Hosted on PharmHUB" Invited for Seminar

Drug Delivery Partnerships, Boca Raton, FL, January 2015, Debra Bingham, Will Clodfelter, Danchen Gao, Stephen W. Hoag and Fernando Salles, "Panel Discussion: The Evolution of Life-Cycle Management as the Driving Force behind Drug Delivery. What Does the Future Look Like?" Invited for Panel

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

Zhenjiang 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"

Colorcon Lunch and Learn Seminar, Harleysville, PA, April 2014, Stephen W. Hoag, "The development of control strategies for coating multiparticulate beads with ethyl cellulose polymers" Invited Seminar

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

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® Advanced Workshop, Piscataway, NJ, June 2013, Stephen W. Hoag, "Developing QbD and PAT Systems for the Monitoring of EUDRAGIT® 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® Advanced Workshop, Malvern, PA, April 2012, Stephen W. Hoag, "Methods for Monitoring of Functional Film Coat Curing: EUDRAGIT® 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

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

37th 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

51st 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 21st 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® Advanced Workshop, New Brunswick, NJ, October 2007, Stephen W. Hoag, "Compaction Properties of Eudragit® 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® Advanced Workshop, New Brunswick, NJ, October 2006, Aditya Tatavarti and Stephen W. Hoag, "Compaction Properties of Eudragit® 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

32nd 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

1st Eudragit® Advanced Workshop, New Brunswick, NJ, October 2005, Aditya Tatavarti and Stephen W. Hoag, "Compaction Properties of Eudragit® 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

31st 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

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

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, Nov 2024, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

Excipient World, Orlando, FL, May 13 2024, "Excipient 101" IPEC Workship and gave 2 lectures.

University of Maryland, School of Pharmacy, Baltimore MD, Sept 2022, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, Oct 2019, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, May 2019, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, Oct 2018, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, May 2018, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, October 2017, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, May 2017, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, October 2016, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, April 2016, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, October 2015, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

University of Maryland, School of Pharmacy, Baltimore MD, March 2015, "Tablet and Capsules Hands-on Short Course" Organized and gave 5 day short course 17 lectures 10 laboratory exercises.

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.

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

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.

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[1]

Source: FDA (Award Number: 3U01FD005946-08S6)
Task Order Title: The Assessment of Commercially-Available In-Home Drug Disposal Products
Amount: $499,999
Period: 6/18/2024 to 6/17/2026
PI: Stephen W. Hoag
Goal: The broad regulatory science issue being addressed by this project is how in-home disposal systems may contribute to FDA's goal of reducing the risks associated with opioid medications.

Source: NIH/NCATS (Task Order PRF Number: N01TR-17-2003-03)
Task Order Title: Dosage Form Development, Manufacture, and Stability Studies of Mitragynine
Amount: $460,105
Period: 1/1/2020 to 2/28/2024
PI: Steve Byrn James Purdue at UMB Stephen W. Hoag
Goal: Formulate Mitragynine and assess product stability and prepare clinical supplies for tox studies and human clinical trials.

Source: CERSI (Via FDA: U01FD005946)
Title: Patient acceptance of oral medications in neonates and infants
Amount: $5,000
Period: June 2019
PI: James E. Polli
Goal: The grant goes to cover the costs associated with putting on a meeting as part of the CERSI consortium.

Source: NIH (?????????????)
Title: Computer-guided excipient selection for protein biologics formulation Amount: $499,999
Period: 6/18/2024 to 6/17/2026
PI: Alex Mackerell
Goal: Develop computer aided methods for excipient selection.

Source: Battelle Memorial Institute (Via FDA: HHSF223201310030I)
Title: The Effects of E-liquid Nicotine Concentration on the Abuse Liability of ENDS in Current Users
Amount: $42,588 (direct costs)
Period: 1/31/2019 – 1/30/2020
PI: Stephen W. Hoag
Goal: The goal of this project is to modify nicotine concentration in E-liquids used for vaping; this is done to support clinical research on effects of nicotine in vaping products.

Source: BioPharma Services USA, Inc.
Title: Pharmacokinetic and pharmacodynamics studies for agonist/antagonist combination abuse deterrent products

[1] Unless indicated the costs are total costs, i.e., including direct costs

Amount: $199,613.00
Period: 11/15/2018 to 11/14/2020
PI: Stephen W. Hoag
Goal: The goal of this study is develop a methods to simulate the abuse of Embeda, and ADF product, and then make GMP batches of the simulated product for PD/PK studies.

Source: Johns Hopkins University/NIH (UL1TR003098)
Title: Johns Hopkins Institute for Clinical and Translational Research
Amount: $1,386 773
Period: 05/01/2019-04/30/24
PI: Ford / Unit Co-Director, Pharmaceutical Manufacturing and Enabled Clinical Trial Formulations Unit: Stephen W. Hoag
Goal: The subcontract with Johns Hopkins University includes the development of training future generations of translational clinical scientists, expansion of joint Dug Development and Repurposing Programs, amplification of community and collaboration across Baltimore and Maryland, and bringing IRB and Regulatory Science Programs together.

Source: Maryland Industrial Partnerships (MIPS: 6102.23) Phase II
Title: Formulation development for bone control therapy
Amount: $98,820.00
Period: 2/1/2019 – 1/31/2020
PI: Stephen W. Hoag
Goal: The goal of this project is to develop a formulation for the treatment of heterotopic ossification.

Source: Maryland Industrial Partnerships (MIPS: 6102.23) Phase I
Title: Formulation development for bone control therapy
Amount: $98,820.00
Period: 2/1/2018 – 1/31/2019
PI: Stephen W. Hoag
Goal: The goal of this project is to develop a formulation for the treatment of heterotopic ossification.

Source: Roquette America Inc. (CPS 18-235)
Title: Excipient analysis and formulation testing for oral delivery systems
Amount: $40,000
Period: 12/06/2018-12/05/2020
PI: Stephen W. Hoag
Goal: The purpose of the agreement is to provide the sponsor with excipient analysis and formulation testing.

Source: NASA (NNJ15HK11B)
Title: ExMC (Exploration Medical Capability) Pharmacy Lab Analysis
Amount: $239.600
Period: 07/24/2018 to 08/31/2018
PI: Stephen W. Hoag
Goal: The goal of this project is to assess the stability of pharmaceutical products exposed to conditions that mimic space travel.

Source: FDA - CVM (HHSF223201810180P)
Title: Manufacturing an In Vitro Component of an Assessment of a Proposed In Vitro Bioequivalence Approach for Evaluating Generic and New Animal Formulations that are not Systemically Absorbed
Amount: $50,000
Period: 07/11/2018 to 04/30/2020
PI: Stephen W. Hoag
Goal: The goal of this project is to develop formulation with different in vitro release rates for Ivermectin and Praziquantel combination project, characterize the release rate of these formulations and manufacture clinical supplies for animal testing.

Source: FDA (HHS 3U01FD005946-03S1 // 3U01FD005946-02S4-(pilot study)**)**
Title: Clinical Use of Bulk Drug Substances Nominated for use in Compounding by Outsourcing Facilities
Amount: $1,828,541
Period: 9/1/2018 – 8/31/2019
PI: Ashlee Mattingly (coinvestigator: Stephen W. Hoag)
Goal: The goal of this project is to assess how outsourcing compounding facilities use compounds of interest to the FDA to determine their suitability for compounding.

Source: NIPTE (FDA: U01FD004275)
Title: Formulation of hydrocodone bitartrate opioid drug product expected to have similar rate and extent of release as HYSINGLA intact tablet but designed to be inferior product when chewed
Amount: $205,000.00
Period: 07/15/2019-1/31/2021
PI: Parent PI: Gurvich; Project PI: Stephen W. Hoag
Goal: The major goals of this project are to produce a hydrocodone bitartrate opioid copy drug product that has similar rate and extent of release as Hysingla when intact, but is inferior (more rapid release) to Hysingla following intentional simulated chewing of the product; evaluate the copy drug product according to the FDA guidance for ADF formulations; produce, package, release test and ship the Hysingla copy product under cGMP conditions for PKPD clinical studies in Humans.

Source: NIPTE (NIPTE-U01-UM-2018-001)
Title: Methods for Evaluation of Abuse Deterrence *via* Smoking and Vaping
Amount: $205,000.00
Period: 3/1/2018 – 2/28/2019
PI: Stephen W. Hoag
Goal: The goal of this project is to assess the potential for abuse of abuse deterrent formulation via smoking and vaping.

Source: Institute for Translational Research (ICTR) - Accelerated Translational Incubator Pilot (ATIP)
Title: Translational Studies of Taro Extract for Clinical Trial Development
Amount: $40,000.00
Period: 6/1/2018 – 5/31/2019
Co-PI: Amy Fulton and Stephen W. Hoag

Goal: The goal of this project is to develop a formulation for Taro extract for the assessment of inhibitory effects on tumor metastasis in Triple Negative Breast Cancer (TNBC) models.

Source: Battelle Memorial Institute (Via FDA: HHSF223201310030I)
Title: Effect of pH of smokeless tobacco products on the pharmacokinetics of nicotine in current users
Amount: $89,746.46
Period: 12/1/2016 – 5/31/2019
PI: Stephen W. Hoag
Goal: The goal of this project is to modify smokeless tobacco products to see how these modifications influence absorption of nicotine.

Source: NIPTE (NIPTE-U01-MD-2017-002)
Title: Effect of Excipient Variability on the Critical Quality Attributes and Clinical Performance of Opioid Drugs Based on Polyethylene Oxide Matrix Tablets
Amount: $99,999.00
Period: 4/1/2017 – 3/31/2018
PI: Feng Zhang, Ph.D. / Co-Principal Investigators Stephen W. Hoag & Steve Byrn
Goal: The goal of this project is to evaluate the equivalency of PEOs from two manufacturers in regards to drug-PEO interactions, product stabilities, and abuse-deterrence characteristics.

Source: NIPTE (NIPTE-U01-MD-2017-001)
Title: Excipient Risk Assessment Database
Amount: $112,143
Period: 1/18/2017 – 3/31/2018
PI: Stephen W. Hoag
Goal: The goal of this project is to create and excipient risk management systems for the FDA reviewers to use when they have questions about excipients in their regulatory filings.

Source: FDA (HHSF223201610366P)
Title: In vitro and Manufacturing Component Study
Amount: $32,000
Period: 9/1/2016 – 3/31/2018
PI: Stephen W. Hoag
Goal: The goal of this project is to develop formulations that have a varying drug release rates that can be tested in dogs to assess best methods for developing in vitro in vivo correlations.

Source: NIPTE (NIPTE-RFP-2015-006)
Title: Patient Acceptance of Drugs
Amount: $600,000
Period: 3/1/2016 – 2/28/2018
PI: Stephen W. Hoag
Goal: The goal of this project is to determine the formulation factors that influence how pediatric patients perceive the taste and texture of medicines and how this can be predicted using in vitro measurements.

Source: NIPTE (Via FDA: NIPTE-RFP-2015-003)
Title: Evaluation of Biorelevant Alternative Methods for Predictions of Drug Release

Amount: $750,000
Period: 3/3/2015 – 2/28/2018
PI: James E. Polli // Stephen W. Hoag co-investigator
Goal: The goal of this project is to work with low solubility compounds and see how dissolution media type can affect prediction of drug release.

Source: NIPTE (Via FDA: NIPTE-RFP-2015-003)
Title: Development and Validation of a Clinically-relevant In Vitro Dissolution Test for the Poorly Soluble, Weakly Basic Drug Itraconazole in Spray-dried Amorphous Solid Dispersion.
Amount: $750,000
Period: 3/1/2016 – 2/28/2018
PI: James E. Polli // Stephen W. Hoag co-investigator
Goal: The goal of this project is to work with low solubility compounds and see how dissolution media type can affect prediction of drug release.

Source: Metrohm Inc.
Title: Metrohm UMB Agreement
Amount: $15,000
Period: 9/24/2015 – 9/23/2016
PI: Stephen W. Hoag

Source: NIAID (Grant #: U19-AI109776)
Title: Center of Excellence for Translational Research (CETR) Network
CETR Title: Immunoprophylactic Strategies to Control Emerging Enteric Infections.
Amount: $3,315,262 (direct costs)
Period: 3/1/14 – 2/28/20
PI: Myron M, Levine // Stephen W. Hoag co-investigator:
Goal: The goal of the project is to develop treatments for enteric infectious diseases.

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 – September 31, 2015
PI: Corinne Keet, MD // Stephen W. Hoag co-investigator

Source: UMB-UMCI Seed Grant
Title: Development and in Vivo Evaluation of a novel antimicrobial agent
Amount: $19,000
Period: October 27, 2014 – June 30, 2015
PI: Mary Rizk, Ph.D. // Stephen W. Hoag co-investigator

Source: Antwerp University Research Center for Equilibrium and Aerospace
Title: Development and manufacture of Scopolamine Nasal Spray Devices
Amount: $15,040
Period: March 7, 2013 – March 7, 2014
PI: Stephen W. Hoag

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: FMC Inc.
Title: Spray Coating of Aquacoat ECD® - The Application of QbD Principles
Amount: $32,000
Period: April 20, 2012 – April 20, 2014
PI: Stephen W. Hoag

Source: USP
Title: Development of a Spectral Database for Excipients and Drug Products
Amount: $282,939
Period: July 1, 2012 – June 26, 2014
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 – Mach 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: Johns Hopkins University
Title: Immunotherapy Peanut Film Strip

Amount: $52,500
Period: January 1, 2011 – July 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: $8,495
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
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: DMV – Fonterra Excipients, GmbH & Co. KG
Title: Application of Lactose to Formulations Intended for Direct Filling into Hard Shell Capsules
Amount: $24,943 6 month extension $48,731 - yr 2 and $43,564 - yr 1
Period: July 1, 2006 – December 31, 2009
PI: Stephen W. Hoag & Larry L. Augsburger

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: Aerscher Diagnostics, Inc.
Title: Suboxone Strip – Formulation Feasibility Studies
Amount: $50,000
Period: March 1, 2008 – September 31, 2008
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

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: GloboAsia
Title: Preformulation and Stability Testing of Botanical Products
Amount: $104,528
Period: Sept 01, 2005 - Aug 31, 2006
PI: Stephen W. Hoag

Title: Formulation of Botanical Products
Amount: $92,144 + 8,500 cost extension
Period: Nov 01, 2003 - Oct 31, 2004
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

Source: Rohm America Inc.
Title: Analysis and Prediction of Tablet Coat Curing: via NIR Spectroscopy and in vitro Dissolution
Amount: $30,000
Period: January 1, 2005 - December 31, 2005
PI: Stephen W. Hoag

Title: Acrylic Polymers for the Controlled Release of Lowly Soluble Basic Drugs
Amount: $25,000
Period: June 1, 2003 - May 31, 2004
PI: Stephen W. Hoag

Title: The Effects of Lakes on Film Coating Polymers: Assessment of the Electrosteric Stabilization of Polymer-Lake Interactions in Eudragita Latex Dispersions and Films
Amount: $25,000
Period: June 1, 2002 - May 31, 2003
PI: Stephen W. Hoag

Title: Assessment of Lake-Polymer Interactions in Eudragit Latex Dispersions and Films
Source: Rohm America Inc.
Amount: $20,000
Period: May 15, 2000 - May 15, 2001
PI: Stephen W. Hoag

Source: CyDex
Title: CAPTISOL® Compaction Study
Amount: $12,400
Period: March 13, 2003 - June 30, 2003
PI: Stephen W. Hoag

Source: GelTex
Title: Contract: Analysis of Sevelamer Hydrochloride Samples
Amount: $47,467.46
Period: July 1, 2001 ~ September 30, 2002
PI: Stephen W. Hoag

Source: Pfizer Inc.
Title: Development of an Instrumented Die for a Compaction Simulator
Amount: $7,986
Period: September 25, 2000 - January 25, 2001
PI: Stephen W. Hoag

Source: SmithKline Beecham Pharmaceuticals
Title: Design of an Instrumented Die for a Compaction Simulator
Amount: $100,000
Period: June 2, 1997 - July 31, 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: SPI Polyols, Inc.
Title: The Development and Optimization of Advantose Formulations for Improving Folic Acid Dissolution
Amount: $43,779.22
Period: January 1, 1999 - December 31, 1999
PI: Stephen W. Hoag

Source: FMC Corporation
Title: Comparison of Drug Stability in Tablets Containing Lactose Monohydrate With Tablets Containing Anhydrous Lactose at Different Relative Humidities
Amount: $27,801
Period: October 1, 1998 - June 30, 1999
PI: Stephen W. Hoag

Source: FMC Corporation
Title: Flow Analysis of Avicel PH-200
Amount: $23,931
Period: March 1, 1997 - August 31, 1997
PI: Stephen W. Hoag

Source: Nutramax, Laboratories, Inc.
Title: Optimization of a Novel Granulation Method
Amount: $9,476
Period: March 1, 1997 - July 31, 1997
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: Oncor Inc.
Title: Development of a Delayed Release Tablet for Controlling Tissue Fixing Time
Amount: $51,319
Period: February 1, 1996 - September 30, 1997
PI: Stephen W. Hoag

Source: Lilly Research Laboratories (Division of Eli Lilly and Co.)
Title: Lilly Young Investigator Award in Pharmaceutics (unrestricted funds)
Amount: $20,000 ($10,000 per year)
Period: June 1993 - June 1995
PI: Stephen W. Hoag

Source: Abbott Laboratories
Title: Visiting Professor at Abbott Laboratories
Amount: $60,000/year plus living expenses (approx. $1,500/month)
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: $5,000
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
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: Novartis
Title: Research in Pharmaceutics: Evaluation and Prediction of Compaction Performance
Amount: $70,000
Period: November 13, 1997 - November 12, 1999
PI: Larry Augsburger

Source: Maryland Industrial Partnerships (MIPS)
Title: Chewable Cosequin Tablet
Amount: $96,180
Period: August 1, 1997 - July 31, 1998
PI: Natalie Eddington

CONSULTING ACTIVITIES

June 2024, Deposition testimony as an expert witness for ImmunityBio, Inc. (ImmunityBio is represented by the law firms of Bartko Zankel Bunzel Miller and Taft Stettinius & Hollister LLP in Federal Machinery and Equipment Company dba Federal Equipment Company v. Tousey, et al. in the N.D. Ohio Case No. 1:21-cv-01422
December 2018, Deposition testimony as an expert witness for Actavis Elizabeth LLC and Teva Pharmaceuticals USA, Inc. in Orexo AB and Orexo US, Inc. versus Actavis Elizabeth LLC, Teva Pharmaceuticals USA Inc. (Civil Action No. 17-205-GMS; District of Delaware)
September 2016, Trial testimony as an expert witness for Shire in Shire Development, Inc. versus Mylan Pharmaceuticals Inc., and Mylan Inc. (Case Number 8:12-CV-1190-T-36AEP; Middle District of Florida, Tampa Division)
March 2016, Trial testimony as an expert witness for Shire in Shire Development, Inc. versus Cadila Healthcare and Zydus Pharmaceuticals Inc. (Civil Action No. 10-581-KAJ; District of Delaware)
June 25, 2015, Deposition testimony as an expert witness in Shire Development, Inc. versus Mylan Pharmaceuticals, Inc. (Case Number 8:12-CV-1190-T-36AEP; Middle District of Florida, Tampa Division)
November 2014, Deposition testimony as an expert witness in Shire Development, Inc. versus Cadila Healthcare and Zydus Pharmaceuticals Inc. (Civil Action No. 10-581-KAJ; District of Delaware)
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. Synthon
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.)