### Michael J. Hageman, Ph.D.

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#### **Professional Job Experiences:**

Marketed Products Worked on

Human/Veterinary Prescription Drugs

Biologics -- Somavubove®, Hemopure®, Oxyglobin®, Ipilimumab/Yervoy®, Nivolumab/Opdivo®

Small Molecule – Tirilazad/Freedox®, Tipranavir/Aptivus®, Linezolid/Zyvox®, Semaxinib, Sunitinib/Sutent®, Celecoxib/Celebrex®, Valdecoxib/Bextra®, Tolterodine/Detrol®, Parecoxib/Dynastat®, Daclatasvir/Daklinza®, Asunaprevir/Sunepra®, Avagacestat, Atazanavir/Reyataz®, Deucravacitinib/Sotyktu®

**Human OTC Drugs** 

Triaminic® Line of Cough Syrups, Triaminicin® Line of Tablets, Eclipse® Sunscreen Lotions

2019- present

Director Biopharmaceutical Innovation & Optimization Center (BIOC) University of Kansas Lawrence, KS 66047

- Oversee core service labs for preclinical drug candidate characterization (solubility, dissolution, stability, plasma protein binding, microsome stability, permeability, rodent PK and preliminary metabolism, analytical method development, formulation development and preparation of supplies)
- Involvement with numerous colleagues in writing and supporting NIH grants, SBIR grants, STTR grants, NSF grants, grants from other funding sources
- Preclinical support of labs on KU Lawrence Campus and at KU Medical Center
- Preclinical support of labs within the Kansas University Cancer Center (KUCC)
- Preclinical support of Children's Mercy & Veterans Hospitals in Kansas City
- Preclinical and Formulation Support of labs at KU Biosciences and Technology Business Center – An Incubator for Business Startups
- Extensive experience with sulfo-butyl ether cylclodextrins for solubilization
- Provide core services for preclinical evaluation for external companies, startups and other academic institutions

2017- present

Valentino J. Stella Distinguished Professor Department of Pharmaceutical Chemistry University of Kansas Lawrence, KS 66047

- Lead the Physical Pharmacy & Drug Delivery (P2D2) Labs at KU
- Research on Delivery of small molecules, peptides, proteins
- Use of amorphous dispersions to enhance oral drug delivery of poorly soluble drugs by creating and sustaining supersaturation
- Stabilization of peptides and proteins in highly concentrated solution and highly hydrated amorphous solids

- Oral delivery of peptide drugs, interactions with bile acids, diffusion in mucin, tight junction modulation with cadherin binding permeation enhancers
- Overcoming developability challenges with prodrugs
- Simulation of subcutaneous(SC) drug delivery using Emulated SC Absorption and Release (ESCAR)
- Spray-drying solids and spray-coating of therapeutics on multiparticulates
- Coupling enabled formulation strategies for poorly soluble drugs (nanoparticulates, lipid-based, solid dispersions, prodrugs, cyclodextrins) with multiparticulate bead systems for oral delivery and targeting regions of GI tract
- Stability and viscosity of peptides and proteins in highly concentrated, hydrated systems mimicking the injection site or controlled release systems
- Dissolution behavior of drugs in ternary and quaternary solid dispersions in various GI milieu
- In Vitro supersaturation and flux assessment in mimics of GI milieu
- Examining propensity for in vivo crystallization from supersaturated drug delivery
- Teaching Solution Dosage Forms Class to PharmD Students
- Teaching Physical Chemistry of Solutions, Solids & Surfaces to Grad Students
- Teaching Advances in Biotechnology course to Grad Students
- Teaching course on Biomedical Science Careers for PhDs
- Faculty Advisor for Industrial Pharmacists Org. (IPhO) Student Chapter
- Steering committee for Chemical & Biological Training Grant for grad students
- Direct the Summer Undergraduate Research Program (URP) for Pharmaceutical Chemistry Department
- Oversee lab research activities of undergraduates, graduates, and post-docs
- External and Internal Consulting in the area of Physical Pharmacy and Drug Delivery for both small and large molecule therapeutics (large Pharma, small Pharma, start-ups) as Hageman Pharma Consulting LLC

#### 2013 – 2016 Executive Director

Discovery Pharmaceutics & Pharmaceutical Candidate Optimization Matrix Lead for Biologics Biophysical Characterization Network Bristol-Myers Squibb Co., Princeton, NJ

Responsibilities as with Group Director (2005-13 below) but also including:

- Global Matrix Team Head for BMS Biologics Biochemical & Biophysical Characterization Network across 6 US sites to advise governance decisions on biologics developability and drug candidate selection, facilitating CMC activities and speed to registration for monoclonals, protein therapeutics, antibody drug conjugates and cyclic peptides.
- Receive funding to support collaboration with Tsinghua University to explore drug-polymer interactions on dissolution and supersaturation from amorphous solid dispersions of varying composition into varying media.
- Establish a strong working relationship with downstream customers in Biologics Development including Global Manufacturing & Supply, Pharmaceutical Formulation Development and the corresponding analytical groups.
- Member of biologics technology innovation committee with > \$650,000 budget funding of new technologies to advance our biologics portfolio via enhanced cell expression, improved analytical methods, advanced drug delivery, etc..
- Member of corporate governance committees guiding the corporate portfolio decisions and prioritization of resources across Discovery.

- Participate in corporate due diligence evaluations for asset acquisition and/or company collaboration / merger to support business development strategies across numerous therapeutic areas and molecular modalities.
- Employ prodrug strategies to overcome gastrointestinal pH effects on absorption, resulting in a patent.
- Mentor scientists from other parts of the organization, both in US and abroad.
- Editor of Journal of Pharmaceutical Sciences and Chair of PhRMA Pharmaceutics Advisory Committee
- Establish early screening strategies for potential combination mAb products with marketed mAbs Yervoy® or Opdivo®

# 2005 – 2013 Group Director Discovery Pharmaceutics Molecular Sciences & Candidate Optimization Bristol Myers Squibb Co., Princeton, NJ

- Guiding ~20 scientists to enable Discovery of new molecules and facilitate molecule selection and transition to GLP, FIH and POC studies.
- Oversee resources for matrix teams in preclinical candidate optimization (~ 80 people in ADME, pharmaceutics, toxicology, biotransformation, analytical, bioanalytical) to support Discovery and liability assessment for 3 therapeutic disease areas in Lawrenceville, NJ.
- Lead Discovery enablement resources in drug delivery and pharmaceutics across three geographical Discovery sites (seven therapeutic areas).
- Receive funding in group to support an innovation grant proposal to explore permeability of peptides, working with Purdue University.
- Introduce miniaturized spray drying (sub-20mg scale) into the discovery environment to enable enhanced absorption via solid dispersions and align with development to insure line-of-sight to a product. Resulted in patent.
- Establish strong rapport with downstream customers in the Development organization while assessing developability and CMC readiness of assets.
- Assist in strategic planning within the Discovery organization for the design and selection of potential drug candidates which are de-risked for attrition.
- Facilitate and strengthen working relationships with other key organizations supporting Discovery (i.e. pharmacokinetics, drug metabolism, drug toxicology, analytical, medicinal chemistry and biology).
- Facilitate the development of high throughput, low API consumption technologies enabling improved decision making at very early stages of the screening funnel.
- Provide selection support, derisking and transition into late clinical development: Daclatasvir/Daklinza®, Asunaprevir/Sunepra®, Deucravacitinib/Sotyktu®, Avagacestat
- Act as the Discovery Pharmaceutics representative on the corporate Solid State Sciences Steering Committee including redesign of solid form selection process.
- Co-lead a matrix team across US and India for a centralized prodrug synthesis and pharmaceutical sciences characterization effort resourced in India.
- Provide training for a discovery pharmaceutics group in Bangalore, India and leverage resources in India for early preformulation characterization of assets.

Senior Research Fellow / Group Leader Exploratory Formulations Group Pfizer Inc., Exploratory Formulations, Pfizer Global Research and Development

(Level 9 of 9 on Scientific Career Ladder)

- Guide and leverage a group ~11 highly innovative and senior level scientists (with > 15 yrs. of experience) in exploratory formulation design.
- Re-engineer the group mission to align with Pfizer needs in both Drug Candidate Selection and Lifecycle Management by exploring specialized formulation design.
- Receive funding for grant proposal to use internal and external resources for rapid turnaround of bioperformance of novel dosage forms in preclinical animals.
- Receive funding for grant proposal on synthesis of biodegradable solubilizing surfactants to be used as solubilizers both IV and orally.
- Lead the group for continued development of technologies such as nanoparticulates, self-emulsifying systems, solid dispersions, oral films and coated beads to provide enabled dosage forms for poorly soluble drug delivery.
- Head a Michigan Cross-Divisional Pharmaceutical Sciences Technology
   Committee to evaluate new technology capital purchases and strategic alliances with external organizations, both academia and small company "vendors."
- Act as the Michigan representative for Pfizer Global Contributions & Alliances involved in corporate level philanthropy consistent with a health care mission.
- Co-chair a committee to strengthen cross-function collaboration between Pharmaceutical Sciences and Drug Metabolism (ADME) across two sites.
- Maintain active research program in novel solubilization technologies and understanding of solubilization by biological fluids.
- Authorize payment at signature level of \$150,000 for Purchase Order Invoices and \$30,000 for expenses.
- Editorial Advisory Board for Journal of Pharmaceutical Sciences

#### 2002 - 2003

Senior Fellow / Group Leader Exploratory Formulations Group Pharmacia Corporation, Exploratory Formulations, Global Pharmaceutical Sciences (Level 9 of 9 on Scientific Career Ladder)

- Work with 1 graduate co-op on the development of high throughput screening for physicochemical properties and 1 undergraduate intern on cyclodextrin binding impact on drug stability. Work with 4 high school students on HPLC project.
- Lead a group of highly innovative and senior level scientists (11-16 scientists with avg. yrs. of experience >15 and located across Kalamazoo and Skokie, IL sites).
- Foster an environment of creativity, innovation and problem solving through my own personally designed presentations and exercises for the group.
- Continue direct participation on anti-viral Discovery Team guiding direct lab support, interpreting results and influencing team strategy.
- Work with computational chemistry to input experimental data and provide timely predictions of solubility and pKa based on chemical structure / template.
- Lead a group to develop formulation-enabling and material sparing technologies at the Discovery Pharm Sci interface (nanoparticulates, cyclodextrins, emulsions, self-emulsifying systems, solid dispersions and coated beads). Utilize miniaturized processing equipment to enable work with limited bulk API material.
- Participate in the technical evaluation of external drug delivery technologies.
- Develop higher throughput screening assays for physicochemical measurements to support rapidly-paced discovery activities and guide molecular design.
- Head of one of the Global Work Streams for cross-divisional re-engineering of the Biological Target Selection to First in Human work process for Pharmacia.

- Promote and coordinate cross-site (San Francisco, St. Louis, Skokie, Kalamazoo, Nerviano, Stockholm) and cross-divisional formulation feasibility testing for product lifecycle enhancements.
- Coordinate the use of internal and external resources for rapid dosage form bioperformance evaluation in preclinical animal models.

#### 2000-2001

Senior Scientist V / Group Leader Exploratory Formulations Group Pharmacia Corporation, Exploratory Formulations, Global Pharmaceutical Sciences (Level 5 of 6 on Scientific Career Ladder)

- Work with a graduate student co-op on protein release from lipid delivery matrices and protein stability within the device matrix.
- Lead a group of 8-12 scientists establishing new technologies for drug discovery support, troubleshooting formulation problems and enhancing bioavailability in preclinical and clinical settings.
- Receive funding from internal grant process to explore high energy solids to enhance drug delivery options and increase oral exposure.
- Lead a technical team across sites and divisional lines for product enhancement opportunities for celecoxib (Celebrex®, Valdecoxib®, Parecoxib®)
- Enable molecules like Semaxinib through formulation and prodrugs, including the oral analog Sunitinib/Sutent®.
- Participate in Discovery Team for new target / mechanism antibiotics, leading to approval of Zyvox® for gram positive infections along with back-up alternatives.
- Lead development of 96-well based assays to rapidly assess physicochemical properties and deliver timely data to influence decisions in molecular design.
- Participate as the primary Pharmaceutics representative on anti-viral Discovery Team, overcoming solubility problems and forwarding compounds into clinic.
- Prepare formulated supplies (suspensions, solutions, capsules) for oral and intravenous animal studies to characterize ADME, pharmacology and toxicology.

#### 1996 - 1999

Senior Scientist IV / Group Leader Solubilized Formulations Group Pharmacia & Upjohn Inc., Pharmaceutical Development (Level 4 of 5 on Scientific Career Ladder)

- Work with 3 graduate and 2 undergraduate interns on the solid-state stability of proteins in amorphous matrices. Participate as an adjunct faculty at Kansas and Purdue, sitting on thesis committees, participating in the pre-doctoral training grant for biotechnology at Univ. of Kansas and co-authoring an NIH grant.
- Lead a group of 6-8 scientists pursuing new solubilized formulation technologies.
- Lead a group effort for development of an oral self-emulsifying drug delivery system (SEDDS) in a soft gel and provide clinical supplies, Tipranavir/Aptivus®.
- Lead extensive stability evaluations of drugs in lipid based vehicles.
- Support scale-up of multiparticulare controlled release Tolterodine/Detrol LA®
- Develop intravenous cyclodextrin formulations for highly insoluble drug to reduce injection site irritation / pain as a life-cycle possibility for Tirilazad/Freedox®.
- Develop high pressure miniaturized emulsion formulation capabilities to support discovery studies for intravenous dosing with very limited API availability.
- Participate as a pharmaceutics / drug delivery representative, in Discovery Teams for new mechanism antibiotic backups and antifungals.

- Participate in multiple Discovery Teams, each targeting blockage of cell adhesion at different intervention points, identifying problems around protein binding and compound solubility limitations in screening assays.
- Work to help establish a global preclinical profiling effort across Pharmacia global sites (US, Italy, Sweden) to support Discovery Teams globally.

#### 1991 – 1996 Senior Research Scientist III

The Upjohn Co., Solubilized Formulation Design, Pharmaceutical Development (Level 3 of 5 on Scientific Career Ladder)

- Work with 1 post-doc and 4 graduate interns on effects of moisture on solid state stability of lyophilized proteins and small molecules (aspartame) in glassy solids.
- Receive internal funding for grant proposal to have a postdoc study the role of glass transitions on stability of drugs trapped in amorphous glasses.
- Participate in Discovery Team for new anticancer drugs, including use of emulsions and cyclodextrins as solubilizing approaches to reduce the use of surfactants for intravenous formulations.
- Participate in Discovery Team for thrombosis / stenosis helping to deliver highly insoluble small molecule antiproliferative agents locally to cardiac vessels during balloon angioplasty.
- Work with outside company to formulate and evaluate a monoclonal antibody.
- Design extensive studies on solid-state stability of proteins as impacted by moisture, excipients and temperature.
- Assist in trouble shooting and optimizing a lyophilized bovine somatotropin (Somavubove®) formulation in commercial production.
- Explore use/limitations of volatile buffers for protein lyophilization and pH control.
- Examine freeze-thaw stability of protein solutions as means for intermediate bulk protein storage.
- Develop non-isothermal methods for characterizing protein aggregation and precipitation using hot-stage microscope.
- File patents on sustained release protein formulations of rbSt and GRF.
- Investigate dissolution behavior of protein solids and respective formulations.

#### 1987 - 1991

Research Scientist II
The Upjohn Company,
(Level 2 of 5 on Scientific Career Ladder)

- Work with 1 graduate student scholar to study preformulation of proteins.
- Design protein formulations spray-dried solids, protein gels, non-aqueous suspensions all for intramuscular and subcutaneous depot systems.
- Develop non-aqueous suspension formulation of rbSt and generate clinical supplies for testing in target animal species (bovine).
- Assemble and present a 2-day course on proteins for scientists at Upjohn.
- Participate in evaluation and experimental testing of numerous external company drug delivery technologies for depot delivery of proteins.
- Participate in site-directed mutagenesis programs to improve stability of recombinant porcine and bovine somatotropins.
- Contribute to New Animal Drug Application for regulatory filing of Somavubove®.

- Develop methods for extracting solid proteins from oil suspensions of proteins.
- Complete validation studies and generation of primary stability lots for lyophilized bovine somatotropin with manufacturing process transfer to production.
- Initiate stability and formulation work on cross-linked hemoglobin blood substitute (mainly Hemopure®, some Oxyglobin®) for human and veterinary clinical testing; also validating stability indicating assays.
- Minimize irreversible aggregation through formulation / design of polypeptide growth releasing factor analogs to permit subcutaneous drug delivery.
- Develop a lyophilized formulation of sCD4-183 antibody as a potential AIDS therapy and participate in visit to FDA concerning IND studies.

#### 1984 – 1987 Scientist I

The Upjohn Company, Pharmacy Research, Pharmaceutical R&D (Level 1 of 5 on Scientific Career Ladder)

- Work with Pharmacy Student on studies of protein chemical stability.
- Develop a lyophilized formulation of recombinant bovine somatotropin (rbSt) (Somavubove®) for veterinary use in a dairy farm setting.
- Explore protein formulation Lyophilized, spray-dried, biodegradable matrices
- Study protein stability solution, solid state, interfacial denaturation
- Develop methods for spray-drying and stabilizing proteins during processing.
- Learn analytical methods for proteins SE-HPLC, RP-HPLC, IE-HPLC, electrophoresis, turbidity, isoelectric focusing, CD, UV, Fluorescence
- Work with and develop tangential flow filtration and diafiltration systems along with dead-end sterile filtration of protein solutions.
- Explore the impact of terminal sterilization methods on protein integrity / stability.

1981	Graduate Teaching Assistant for Undergraduates Dept. of Pharmaceutical Chemistry University of Kansas, Lawrence, KS
1979 – 1984	Graduate Research Assistant Dept. of Pharmaceutical Chemistry University of Kansas, Lawrence, KS
1979	Pharmacy Intern at Wesley Medical Center Wichita, KS
1978 – 1979	Undergraduate Research Assistant Dept. of Pharmaceutical Chemistry University of Kansas, Lawrence, KS

1978 Research and Development Technician Grade III

Sandoz Pharmaceuticals Corp. (Dorsey Labs; OTC Products)

Lincoln, NE

1976 Teaching Assistant for Undergraduate Chemistry Labs

Wichita State University, Wichita, KS

1975 – 1976 Independent Undergraduate Research

Dept. of Organic Chemistry

Wichita State University, Wichita, KS

#### **Education:**

#### Pharmacy School

University of Kansas, Lawrence, Kansas 66045

B.S. Pharmacy (cum laude) 1979

Licensed Pharmacist in State of Kansas (inactive status)

Pharmaceutical Chemistry Graduate School

University of Kansas, Lawrence, Kansas 66045

M.S. Pharmaceutical Chemistry
Ph.D. Pharmaceutical Chemistry (with honors)
1982

Thesis: "Bisulfite-Induced Oxidation of 6-Selenoguanosine"

Advisor: Dr. Arnold Repta

#### **Professional Honors:**

Featured Article in October 2021 JPharmSci, "Particle size limits..." (2021) https://www.jpharmsci.org/

Editor for Journal Pharmaceutical Sciences (2015-present)

Selected for AAPS Member Spotlight in AAPS Newsmagazine (Jan 2015)

Bristol Myers-Squibb - Corporate Biopharma Leadership Award from CEO (2012)

Bristol-Myers Squibb – Jack Grebb Excellence in R&D Leadership Award (2009)

Senior Research Fellow at Pfizer (highest level on Pfizer Research Career Path, <1% of PhDs) (2004)

Pharmacia Preclinical Award for Highest Potential Impact Patent (WO 01/42224 A1) (2002)

Senior Fellow at Pharmacia (highest level on Pharmacia Research Career Path, <2% of PhDs) (2002)

Adjunct Faculty Member, School of Pharmacy, University of Utah (2001)

Editorial Advisory Board for Journal of Pharmaceutical Sciences (2001 - 2014)

Upjohn Award Winner for Long Term Corporate Level Contributions presented by CEO (1998)

Pharmacia & Upjohn Special Recognition for contributions to screening assays (1998)

Pharmacia & Upjohn Pharmaceutical Development Teamwork Award (1998)

American Association of Pharmaceutical Sciences Fellow (1996)

Adjunct Associate Professor, School of Pharmacy, University of Kansas (1996-2001)

Adjunct Faculty Member, School of Pharmacy, Purdue University (1996)

Best BIOTEC Poster-Applied Science at 9th Annual AAPS Mtg. (1994)

PhD Dissertation Honors (1984)

Ciba-Geigy-AFPE Pharmaceutics Fellow (1983-84)

Miriam Rosenfeld Scholarship in Pharmacy (1983)

AFPE-Albert H. Diebold Memorial Fellow (1982-83) and (1981-82)

A.W. Davidson Award to outstanding 1st yr. grad. Student in chemistry disciplines (1980)

Phi Lambda Upsilon (Honorary Chemical Society)

Rho Chi Society (Honorary Pharmacy Society)

Phi Kappa Phi Society (Honorary Interdisciplinary Society)

#### **Professional Activities:**

Organizing a Short course GPEN in Minnesota "Drug-Like Properties in Discovery and Development" (Oct. 2022)

Chair of the Drug Delivery Advisory Committee for PhRMA Foundation (2020-present)

NIPTE Outstanding Student Research Award Selection Committee (2020)

NIPTE Rising Star Scholarship Award Review Committee (2019)

JPharmSci Social Media Committee (2019)

Faculty Sponsor for KU Industrial Pharmacists Organization (IPhO) (2017-present)

Organized Short course 2018 GPEN in Singapore "Optimizing Drug-Like Properties in Discovery and Development" (Sept. 29, 2018)

Member of AAPS Fellows Planning Committee (2017-2018)

Member of AAPS PPB Section Fellows Selection Committee (2017)

Organized Short course at 2016 GPEN in Lawrence, "Strategies in Solid Form Design: From Amorphous Materials to Particle and Crystal Engineering" (Nov. 2016)

Student (HS) career discussions Governor's STEM Scholars Conference, NJIT, Newark, NJ (Feb. 2016)

Attend Panel Discussion and Legislative Briefing on Capitol Hill Regarding HIV Drug Access (Sept. 2014)

Participate as External Reviewer for ACPE Accreditation Review Kansas School of Pharmacy (2014)

Career Panel Discussion R&D Council of New Jersey for 2 Year Community College STEM Scholars, at Exxon Mobil, Annandale, NJ (Aug. 2013)

Participate/attend yearly PhRMA Hope & Research Awards Banquet in Washington DC (2012-present)

Nominations Review Committee for yearly PhRMA Foundation Hope & Research Award (2012-present)

Post-doc career discussions at UMDNJ Rutgers as Career Panelist for Post-docs (Sept. 2012)

Grant Review Support - National Institute for Pharmaceutical Technology and Education (NIPTE) (2012)

Chair of the Pharmaceutics Advisory Committee for PhRMA Foundation (2012-20)

AAPS Awards Task Force Committee (2011-12)

Organizing Committee for 2011 AAPS Workshop on Drug Delivery (2010-11)

Organizing Committee for 46th Annual AAPS Arden House Conference (2010)

Chair of AAPS Section on Physical Pharmacy and Biopharmaceutics (PBB) (2010)

Chair-Elect of AAPS Section on Physical Pharmacy and Biopharmaceutics (PBB) (2009)

Organizing Committee for AAPS Conference on "Physical Pharmacy and Biopharmaceutics" (2008-9)

Organizer and Moderator for Roundtable "Bioavailability Enhancement During Lead Optimization:

Enabling Discovery or Encouraging Challenges in Development" Nov. 2008

Co-organizer AAPS Symposia "Drug Discovery & Drug Developability for Lead Optimization" (Nov. 2008)

Moderator "Critical Issues for Candidate Selection-Formulation Design" in San Francisco, (May 2008)

Moderator "Assisting Lead Selection Screening and SAR" in San Francisco, May 2008. Member of

Member of Pharmaceutics Advisory Committee for PhRMA Foundation (2007-11)

Organizing Committee for AAPS "Drug Discovery Strategies and Clinical Candidate Selection" (2007-8)

Vice-chair for AAPS PDD Section reorganized to PBB Section (2008)

Elected via general member election to Chair Elect of AAPS PDD Section (2007)

Chair of AAPS Drug Design and Discovery (D3I) Implementation Committee (2006-7)

Member of AAPS Drug Discovery Interface Task Force (2005)

Organizing Committee for AAPS Symposia on Drug Candidate Selection (2005-6)

AAPS PT Programming Committee for 2005 AAPS Natl. Meeting

Organizing Committee for Symposia on Lead Optimization AAPS Meeting (2004)

Member of Committee to design an AAPS Training Program for Scientists (2003)

Chair of Pharmacia Fellows Committee responsible for Corporate Annual Fellows Symposia (2002)

Symposium Organizer for Symposia on Prodrugs at 2002 Natl AAPS Meeting (2002)

Past-chair and member of AAPS Committee for Selection of PDD Fellows (2002)

Planning Committee for 2002 AAPS Pharmaceutics and Drug Delivery Conference (2001)

Chair of AAPS Committee for Selection of PDD Fellows (2001)

Vice-Chair AAPS Committee for Selection of PDD Fellows (2000)

Member of AAPS Committee for Selection of PDD Fellows (1999)
Steering/Organizing Committee for National AAPS/NIGMS Symposium (1997-98)
AAPS Midwest Regional Planning Committee (1996)
Screening of BIOTEC Abstracts for 10th Annual AAPS Mtg. (1995)
AAPS Midwest Regional Planning Committee (1995)
Membership Committee for Biotechnology Section of AAPS (1989)
Participation in NIH site visit at the University of Kansas (1989)
Registered Pharmacist; State of Kansas (1979-88) currently inactive status

#### **Mentoring Activities:** (outside those with specific line reporting accountability)

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(2017-present) see undergraduates, graduates and post-docs listed below
(2021) Jian Qian, post-doc for Berkland, mentored with job search, employed at BMS now
(2016-2017) Richard Westhouse, Principal Scientist in Toxicology at BMS (Lawrenceville, NJ)
(2016) Connections Group Mentoring at BMS (~10 people seeking advanced leadership)
(2014-2017) Rao Mantri, Drug Development, BMS, Executive Director (New Brunswick, NJ)
(2010-2017) Mike Tobyn, Drug Development, BMS, Research Fellow (Moreton, England)
(2011-2016) Aiit Narang, Drug Development, BMS Scientist (now at Genentech)
(2009-2015) Sridhar Desikan, Biocon BMS Research Center (Bangalore, India)
(Feb. 05 - May 05) Kalamazoo Math/Science Group Project – work with 4 high school sophomores
(Nov. 04 - Mar. 05) Kalamazoo Math/Science Intern - Evelyn Hall, High School Senior
(Jun. 00 – Jun. 03) Research Scholar - Jeremy Guo, 3<sup>rd</sup> yr Graduate Student, Univ. of Utah
(Feb. 00 - Aug. 01) Research Scholar - Rong Li, 4th yr Graduate Student, Univ. of Kansas
(Jun. - Sep. 99) SIP Intern - Robert Hilliard, Senior, Kalamazoo College, Kalamazoo, MI
(Jun. - Aug. 99) Intern - Michelle Garceau, Sophomore, Washington Univ., St. Louis, MO
(Jun. - Sep. 98) Research Scholar – Susan Hovorka, 3rd yr Graduate student, Univ. Kansas
(Jun. - Nov. 96) Research Scholar – Mei Lai, 3rd yr Graduate Student, Univ. Kansas
(Feb. - May 96) Research Scholar – Brian Miller, 3rd yr Grad. Student, Univ. Kansas
(Nov. 94 – Aug. 95) Research Scholar – Jeanne Marie Sarciaux, Masters at Univ. of Paris, France
(Jun. - Aug. 93) Intern – Lee Muraoka, 2<sup>nd</sup> yr Graduate Student, Purdue Univ.
(Jun. - Sep. 93) Intern – Suzanne Admiraal, 1st yr Graduate Student, Stanford Univ., CA
(Nov. 92 - Jan. 94) Post doc - Dr. Leonard Bell, PhD in Food Science, Univ. Minnesota, now Auburn
(Jun. - Sep. 92) Intern – Abdi Tinwalla, 2<sup>nd</sup> yr Graduate Student, Univ. Utah
(Jun. - Sep. 89) Research Scholar – Todd Darrington, 2<sup>nd</sup> yr Grad. Student, Univ. Utah
(May - Aug. 86) Intern - Charles Winney, Senior Pharmacy Student, Howard University
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#### **Thesis Committees Ongoing:**

(2022-present) Jacob Theismann, PhD Candidate, Univ. Kansas, Chemistry Dept., Dr. Johnson advisor (2022-present) Grahmm Funk, PhD Candidate, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman (2021-present) Zahraa Al-Tamimi, PhD Candidate, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman advisor (2021-present) Jack Terry, PhD Candidate, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman advisor (2021-present) Vincent Cicale, Distance MS, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman advisor, ...scientist at Bristol Myers Squibb (2021-present) Negar Jafari, PhD Candidate, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman advisor (2020-present) Alex Langford, Distance PhD, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman advisor, ...scientist at Pfizer (2020-present) Casey Hurley, Distance MS, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman advisor, ...scientist at Gilead

- (2019-present) Hao Lou, Distance PhD, Univ. Kansas, Pharm. Chem.Dept., Dr. Hageman advisor, scientist at KU BIO Center.
- (2019-present) Anthony Tomlinson, Distance MS, Univ. Kansas, Pharm. Chem., Dr. Hageman advisor, ...scientist at Genentech
- (2019-present) Mikayla Smith, PhD Candidate, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman advisor (2019-present) Xi Luan, PhD Candidate, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman & Volkin advisors
- (2019-present) Waleed Elballa, PhD Candidate, Univ. Kansas, Pharm. Chem. Dept., Dr. Hageman & Siahaan advisors

#### **Thesis Defense Committees Completed:**

(2019-2022) **Kaushal Jerajani**, Univ. Kansas, Dept. Pharm. Chem., Dr. David Volkin advisor, PhD Diss. Defense, August 22, 2022...scientist at AstraZeneca in Gaithersburg

(2022) **Aric Huang**, Univ. Kansas, Dept. Pharm. Chem., Dr. Cory Berkland advisor, PhD Diss. Defense, August 8, 2022... scientist at Merck in Boston

(2019-2022) **Simon Velasquez Morales**, Univ. Kansas, School of Engineering, Dr. Alan Allgeier advisor, PhD Diss. Defense August 2, 2022...Senior Scientist at Abbvie in Chicago

(2017-2022) **Anil Basra**, Univ. Kansas, Dept. Pharm. Chem., Dr. Michael Hageman advisor, PhD Diss. Defense, May 13, 2022... scientist at Amgen in Thousand Oaks

(2022) **Tahlia Meola**, Univ. South Australia, Pharmaceutics, Dr. Clive Prestidge advisor, PhD Diss. Defense, February 16, 2022...Clinical Labs in Australia

(2021-2022) **Angelo Andres**, University Kansas, Chemistry Dept., Dr. Blake Peterson advisor, PhD Diss. Defense, February 8, 2022... scientist in Molecular Sciences at AstraZeneca in Boston

(2017-2022) **Zhaoxian (George) Wang**, Univ. Kansas, Dept. Pharm. Chem., Dr. Michael Hageman advisor, PhD Diss. Defense, January 14, 2022... scientist Discovery Pharmaceutics at Bristol Myers Squibb in New Jersey

(2018-2021) **Ahmed Fahad**, Univ. Kansas, Dept. Pharm. Chem., Dr. Brandon Dekosky advisor, PhD Diss. Defense December 10, 2021...Postdoc at MIT in Boston

(2021) **Juan Rincon**, University Kansas, Chemistry Dept., Dr. David Weis advisor, PhD Diss. Defense August 31, 2021... Postdoc at St. Louis University in Missouri

(2019-2021) **David Ingham**, Univ. Kansas, Molecular Biosciences, Dr. Chris Gamblin advisor, PhD Diss. Defense August 9, 2021...post-doc in Dr. Erik Lundqvist Lab University of Kansas in Lawrence

(2019-2021) **Nishant Sawant**, Univ. Kansas, Dept. Pharm. Chem., Dr. David Volkin advisor, PhD Diss. Defense July 30, 2021... scientist at Achillion/AstraZeneca

(2019-2021) **Olivia Henderson**, Univ. Kansas, Dept. Pharm. Chem., Dr. Michael Hageman advisor, MS Defense, July 13, 2021... scientist at Midwest Labs, Omaha, NE

(2018-2021) **Michael Kim**, University Kansas, Chemistry Dept., Dr. David Weis advisor, PhD Diss. Defense May 17, 2021...scientist at Genentech in San Francisco

(2020-2021) **Mei Feng**, Univ. Kansas, Dept. Pharm. Chem., Dr. Michael Wang advisor, PhD Defense, May 6, 2021...scientist at Abbyie in Chicago

(2019-2021) **Pamela Johnson**, Univ. Kansas, School of Engineering, Dr. Jennifer Robinson advisor, PhD Diss. Defense April 26, 2021.... Erise Law Practice Intellectual Property, Overland, KS

(2020) **Peter Kleindl**, Univ. Kansas, Dept. Pharma. Chem., Dr. Forrest Laird advisor, PhD Defense, December 15, 2020...scientist at Amgen in Thousand Oaks

(2020) **Natalia Subelzu**, Univ. Kansas, Dept. Pharma. Chem., Dr. Christian Schoeneich advisor, PhD Defense, July 29, 2020...scientist at Merck in West Point

(2019-2020) **Aaron Rudeen**, Univ. Kansas, Molecular Biosciences, Dr. Kristin Neufeld advisor, PhD defense July 30, 2020, ...scientist at Deciphera in Lawrence, KS

(2019-2020) **Jon Kretz**, Univ. Kansas, Dept. Pharm. Chem., Dr. Jeff Krise advisor, MS Defense, July 14, 2020, ...scientist at Amgen

(2019-2020) **Yue (Kathryn) Wang**, Univ. Kansas, Dept. Pharm. Chem., Dr. Teruna Siahaan advisor, Dist. MS/PhD Genentech, MS Defense, March 5, 2020, ...scientist at Genentech.

(2018-2019) **Brian Kopec**, Univ. Kansas, Dept. Pharm. Chem., Dr. Teruna Siahaan advisor, PhD Defense, December 6, 2019, ...scientist at Verge Genomics

(2017-2019) **Alex Langford**, Univ. Kansas, Pharm. Chem., Dr. Michael Hageman advisor, MS Defense, August 12, 2019, ...scientist at Pfizer

(2017-2019) **Hao Lou**, Univ. Kansas, Pharm. Chem., Dr. Michael Hageman advisor, MS Defense, July 11, 2019, ...scientist at Amgen, scientist at BIOC in Lawrence, KS

(2018-2019) **Yu (Martin) Hu**, Univ. Kansas, Pharm. Chem., Dr. David Volkin advisor, PhD Defense, February 19, 2019, ...scientist at Bristol Myers Squibb

(2018) **Martin Leon**, Univ. Kansas, Chemistry, Dr. Cory Berkland advisor, PhD Defense September 18, 2018, postdoc at University of Colorado; scientist at Novo Nordisk

(2018) **Stephanie (Kishbaugh) Vargas**, Univ. Kansas, Pharm. Chem., Dr. Teruna Siahaan advisor, MS Defense August 29, 2018, scientist at Biomarin

(2018) **Trey Ronnebaum**, Univ. Kansas, Molecular Biosciences, Dr. Aubrey Lamb advisor, PhD Defense August 17, 2018, ... postdoc at UPenn

(2018) **Abby Petrulis**, Univ. Kansas, Pharm. Chem., Dr. Laird Forrest advisor, MS Defense, January 29, 2018, Clinical Pharmacist at US Public Health

(2017- 2018) **Samantha Pace**, Univ. Kansas, Pharm. Chem., Dr. David Volkin advisor, PhD Defense June 14, 2018, ...scientist at Bristol-Myers Squibb in NJ

(2017-2018) **Vishal Toprani**, Univ. Kansas, Pharm. Chem., Dr. David Volkin advisor, PhD Defense February 19, 2018, scientist at Pfizer

(2017) **Sardar Mohammed Jakaria**, Univ. Kansas, Pharm. Chem., Dr. Teruna Siahaan advisor, MS Defense November 29, 2017

(2000-2005) **Jeremy Guo**, Univ. Utah, PhD Defense December 2005, scientist/manager at Regeneron Pharmaceuticals, executive director at Wuxi

(1998-2001) Susan Hovorka, Univ. Kansas, PhD Diss. Defense September 2001, consultant / Pfizer

(1999-2001) Rong Li, Univ. Kansas, PhD Defense August 2001, scientist at Pfizer

(1996-1999) Jeanne Marie Sarciaux, Univ. Purdue, MS Defense 1999, pharmacist in France

(1996-1998) Mei Lai, Univ. Kansas, PhD Defense May 1998, consultant Web Pharma LLC

(1996-1998) Brian Miller, Univ. Kansas, PhD Defense January 1998, Minnesota Dept. Agriculture

#### **Orals Committees:**

Jacob Theismann, Chemistry Dept., scheduled for November 10, 2022

Luan Xi, KU Dept. Pharmaceutical Chemistry, May 31, 2022

Mikayla Smith, KU Dept. Pharmaceutical Chemistry, May 26, 2022

Yaqi Wu, KU Dept. Pharmaceutical Chemistry, May 17, 2021

Yiru Jin, KU Dept. Pharmaceutical Chemistry, May 19, 2020.

Kyle Apley, KU Dept. Pharmaceutical Chemistry, May 18, 2020.

Simon Velasquez Morales, KU School of Engineering, August 14, 2019

Zhaoxian (George) Wang, KU Dept. Pharmaceutical Chemistry, September 2019.

Anil Basra, KU Dept. Pharmaceutical Chemistry, May 24, 2019

Natalia Subelzu, KU Dept. Pharmaceutical Chemistry, May 18, 2018

Rukmini Ladi, KU Dept. Pharmaceutical Chemistry, May 15, 2018

Ahmed Fahad, KU Dept. Pharmaceutical Chemistry, May 15, 2018

Josh Shipman, KU Dept. of Chemistry, September 13, 2017

#### **Graduate Students & Post-docs:**

Sheryhan Ahmed, Post-doc, KU Pharmaceutical Chemistry (2022-present), Grahmm Funk, PhD Candidate, KU Pharmaceutical Chemistry (January 2022-present) Zahraa Al-Tamimi, PhD Candidate, KU Pharmaceutical Chemistry (December 2021-present) Jack Terry, PhD Candidate, KU Pharmaceutical Chemistry (December 2021-present) Negar Jafari, PhD Candidate, KU Pharmaceutical Chemistry (January 2021-present) Casey Hurley, Distance MS, Gilead, KU Pharmaceutical Chemistry (August 2020-present) Mikayla Smith, PhD Candidate, KU Pharmaceutical Chemistry (May 2019-present) Xi Luan, PhD Candidate, KU Pharmaceutical Chemistry (May 2019-present) Waleed Elballa, PhD Candidate, KU Pharmaceutical Chemistry (2019-present) Hao Lou, Distance PhD, KU BIO Center, KU Pharmaceutical Chemistry (2019-present) Anthony Tomlinson, Distance Learning MS, Genentech, KU Pharmaceutical Chemistry (2019-present) Mei Feng, Post-doc, BIOC / Univ. Kansas, Dept. Pharm. Chem. (June 2021-Oct 2021), scientist at Abbvie Olivia Raine Henderson, MS Degree, KU Pharmaceutical Chemistry (2019-2021), scientist Midwest Labs Tahnee Dening, Post-doc, Univ. Kansas, Dept. Pham. Chem. (2018-2021), scientist at Genentech Yu (Cathy) Zhan, Post-doc Associate Researcher (2018-2019), scientist at Deciphera Anil Basra, PhD Candidate, KU Pharmaceutical Chemistry (2017-2022), scientist at Amgen Zhaoxian (George) Wang, PhD Candidate, KU Pharmaceutical Chemistry (2017-2022), scientist at BMS Alex Langford, Distance Learning MS, Pfizer, KU Pharmaceutical Chemistry (2017-2019), at Pfizer Hao Lou, Distance Learning MS, Amgen, KU Pharmaceutical Chemistry (2017-2019), at Amgen

#### **Undergraduate Students:**

Sivani Badrevinka, 1st year PharmD, KU School of Pharmacy (May 2022 – present) Austin Geer, 4th year Chemistry, Univ. North Carolina, (May-Jul 2022) Aiden Gregory, 4th year Chemistry, NW Missouri State (May-Jul 2022) Camille Addison, 3rd vear PharmD, KU School of Pharmacy (Oct 2021-July 2022; Dec 2022) Vimathi Gummala, 3<sup>rd</sup> year Math & Biochemistry, Univ. Berkley, (Jun-Aug 2021) Nicholas Korth, Engineering, Univ. Arkansas, (Jun-Aug 2021) Mikayla Smith, PharmD student, KU School of Pharmacy (Jan 2018-May 2019) Leqi (Margaret) Fan, Intl. Student Internship, Pharmacy, Shanghai Jiao Tong University (July-Sept 2019), attending Univ. Iowa for graduate school (Stephanie) Xiong, URP, Biochemistry, CSU Fullerton, (Jun-Aug 2019) Brandon Smith, 3rd year PharmD, KU School of Pharmacy (Jan-May 2019) Haley Fahnholz, 3<sup>rd</sup> year PharmD, KU School of Pharmacy (Aug 2018-May 2019) William Amsberry, 4th year Biochemistry, KU (Jul 2018-Aug 2019), Pharmacy School at KU Alexian Nguyen, 3<sup>rd</sup> year PharmD, KU School of Pharmacy (Jul-Dec 2018) Benjamin Rajewski, URP, Chemistry, Simpson College, (Jun-Aug 2018), grad school at Notre Dame John Kennedy (Ken) Ofosu, 3rd year PharmD, KU School of Pharmacy (Jun-Dec 2018) Brandon Kaub, 3rd year PharmD, KU School of Pharmacy (Jun 2018-May 2019)

#### **High School Students:**

Maggie Zhang, Senior, Blue Valley North High School, (Nov 2021-present)

#### Participation in Predoctoral Training in Biotechnology at Univ Kansas (1996-2001):

--Collaboration with Christian Schöneich on Formulation Projects regarding Mechanisms of Protein and Peptide Oxidation by Reactive Oxygen

- --Collaboration with Richard Schowen on Formulation Projects regarding around Kinetics and Mechanisms of Hydrolysis of a Hexapeptide-Derived Cyclic Imide in Polymer Matrices
- --Collaboration with Richard Schowen on Formulation Projects regarding Formation and Decomposition of Cyclic Intermediates in Peptide Deamidation
- --Collaboration with Elizabeth Topp on Formulation Projects regarding Role of Mobility in the Polymer in Peptide Deamidation in Polymer Matrices
- --Collaboration with Elizabeth Topp on Formulation Projects regarding Effect of Water/Polymer Interactions on Peptide Deamidation in Polymer Matrices

#### **Career Presentations:**

What companies are seeking in resumes, KU Dept. Pharm. Chem. Graduate Students (Oct. 18, 2018) Career Opportunities for STEM Graduate Students, KU Diversity in Science Training (Sept. 2018) Participate in Roundtable Panel on "Training Future Scientists", San Diego, CA (Nov. 2017) Presentation Yearly at West Windsor High School Career Days, Pharmacy Opportunities (2013-2017) Student career discussions at Governor's STEM Scholars Conference, NJIT, Newark, NJ (Feb. 2016) Presentation / Discussion PharmD & Grad. Careers in Industry, University of Kansas (August 28, 2015) Presentation at Hopewell Valley Timberlane Middle School Career Days on STEM Opportunities (2014) Career Panel discussion R&D Council of NJ for STEM Scholars, Exxon Mobil, Annandale, NJ (Aug. 2013) Post-doc career discussions at UMDNJ Rutgers as Career Panelist for Post-docs (Sept. 2012)

#### **Professional Organizations:**

(PDA) Parenteral Drug Association (2017-2021)

(IPhO) Industrial Pharmacists Organization (2016-present)

(ACS) Princeton Chapter of American Chemical Society (2012-2017)

(AAAS) American Association for the Advancement of Science (2010-present)

(ACS) American Chemical Society (1989-2005; 2010-present)

(AAPS) American Association of Pharmaceutical Scientists (1986 – present)

(CRS) Controlled Release Society (1991-2005)

(APhA) American Pharmaceutical Association (1979-86)

#### **Community Service Activities:**

(Feb 2021) CPR Training & Certification

(Feb 2021-present) Training and Foster Care

(April- May 2020) Use BIO Center Capabilities to Prepare Hand Sanitizer for the Community

(2013-2017) Presentation at High School Career Days on STEM Opportunities

(2009-2018) Church Ministry in Pennington, NJ

(2009-2010) Assistant Coach for High School Spring Hoops Basketball in Pennington, NJ

(2001-2005) Church Usher in Kalamazoo, MI

(1996-97, 1999) Coach Youth Soccer for Kalamazoo AYSO

(1995-99, 2002) Coach Youth Basketball for YMCA League and Courthouse League

(Sep.- Nov. 2001) Blue Ribbon Committee for New Strategies in Elementary Education, Kalamazoo

(Jan.-Mar. 2000) Chaired Committee on Financial Stability at Elem. School (Long Range Planning)

(July 1995 - June 1999) Church Finance Committee

(July 1995 - June 1999) Education Committee at Elementary School

(May - July 1998) Search Committee for a new Principal at Elementary School

(1996-1998) Coach Youth Softball/T-Ball for Oakwood Little League

#### **Peer Reviewed Publications:**

- 1. Lou H, Hageman MJ. Development of an In Vitro System to Emulate In Vivo Subcutaneous Environment: Small Molecule Drug Assessment, revision under review in Mol Pharm, September 2022.
- 2. Wang Z, Lou H, Denning TJ, Hageman MJ. Biorelevant dissolution method considerations for the appropriate evaluation of amorphous solid dispersions: are two stages necessary? submitted to J Pharm Sci, September 9, 2022.
- 3. Lou H, Feng M, Hageman MJ. Advanced Formulations/Drug Delivery Systems for Subcutaneous Delivery of Protein-Based Biotherapeutics, in press J Pharm Sci, August 2022.
- 4. Lou H, Hageman MJ. Investigating Protein Diffusivities in Diluted Hyaluronic Acid Solutions Using Dynamic Light Scattering, Analytical Methods 14(7), DOI: 10.1039/D1AY01832A, January 2022.
- Dening TJ, Douglas JT, Hageman MJ. Do Macrocyclic Peptide Drugs Interact with Bile Salts under Simulated Gastrointestinal Conditions? Mol Pharm. 2021 Jul 13. doi: 10.1021/acs.molpharmaceut.1c00309. Online ahead of print. PMID: 34255531
- Lou H, Hageman MJ. <u>Particle Size Limits to Pass the Acceptance Value (AV)-Based USP Content Uniformity Test for Tablets.</u> J Pharm Sci. 2021 Oct 110(10):3527-3534 doi: 10.1016/j.xphs.2021.07.005. PubMed PMID: 34302841..
- 7. Lou H, Berkland C, Hageman MJ. Simulating particle movement inside subcutaneous injection site simulator (SCISSOR) using Monte-Carlo method. Int J Pharm. 2021 Jun 24;605:120824. doi: 10.1016/j.ijpharm.2021.120824. Online ahead of print. PMID: 34171429
- 8. Lou H, Lian B, Hageman MJ. Applications of Machine Learning in Solid Oral Dosage Form Development, accepted in J Pharm Sci, May 2:S0022-3549(21)00235-5. doi: 10.1016/j.xphs.2021.04.013.
- 9. Lou H, Hageman MJ. Investigating the Influence of Tablet Location on Polymer Erosion and Drug Release of a Surface-Erodible Sustained-Release Tablet using Computational Simulation, accepted in AAPS PharmSciTech, March 1, 2021.
- Lou H, Hageman MJ. Machine Learning Methods for Predicting Subcutaneous Bioavailability of Monoclonal Antibodies. Pharm Res. 2021 Mar;38(3):451-460. doi: 10.1007/s11095-021-03022-y. Epub 2021 Mar 12. PMID: 33710513.
- 11. Dening TJ, Siahaan TJ, Hageman MJ. Enhancing Intestinal Absorption of a Model Macromolecule via the Paracellular Pathway using E-Cadherin Peptides. Journal of pharmaceutical sciences. 2020. Epub 2020/12/29. doi: 10.1016/j.xphs.2020.12.018. PubMed PMID: 33359310.
- 12. Lou H, Kiang Y-H, Alvarez-Nunez F, Li W, Hageman MJ. Modification of a Scale-up Model to Improve Prediction of the Effect of Lubrication on Tablet Tensile Strength. Adv Powder Tech, May 5, 2020 https://doi.org/10.1016/j.apt.2020.04.029.

- 13. Ruepp S, Janovitz E, Brodie T, White R, Santella J, Hynes J, Carman J, Pan D, Wu Y, Hanumegowda U, Gemzik B, Megill J, DiPiero J, Drexler D, Su CC, Hageman M. Assessing the risk of drug crystallization in vivo. J Pharmacol Toxicol Methods. 2019 Mar Apr;96:1-8. doi: 10.1016/j.vascn.2018.12.003. Epub 2018 Dec 13. PubMed PMID: 30553974.
- Lou H, Chung JI, Kiang YH, Xiao LY, Hageman MJ. The application of machine learning algorithms in understanding the effect of core/shell technique on improving powder compactability. Int J Pharm. 2019 Jan 30;555:368-379. doi: 10.1016/j.ijpharm.2018.11.039. Epub 2018 Nov 20. PubMed PMID: 30468845.
- 15. Hu XY, Lou H, Hageman MJ. Preparation of Lapatinib Ditosylate Solid Dispersions Using Solvent Rotary Evaporation and Hot Melt Extrusion for Solubility and Dissolution Enhancement. Int J Pharm. 2018 Sep 27. pii: S0378-5173(18)30719-1. doi: 10.1016/j.ijpharm.2018.09.062. [Epub ahead of print] PubMed PMID: 30268849.
- 16. Rautio J, Meanwell NA, Di L, Hageman MJ. The expanding role of prodrugs in contemporary drug design and development. Nat Rev Drug Discov. 2018 Aug;17(8):559-587. doi: 10.1038/nrd.2018.46. Epub 2018 Apr 27. Review. PubMed PMID: 29700501.
- 17. Chen XQ, Ziemba T, Huang C, Chang M, Xu C, Qiao JX, Wang TC, Finlay HJ, Salvati ME, Adam LP, Gudmundsson O, Hageman MJ. Oral Delivery of Highly Lipophilic, Poorly Water-Soluble Drugs: Self-Emulsifying Drug Delivery Systems to Improve Oral Absorption and Enable High-Dose Toxicology Studies of a Cholesteryl Ester Transfer Protein Inhibitor in Preclinical Species. J Pharm Sci. 2018 May;107(5):1352-1360. doi: 10.1016/j.xphs.2018.01.003. Epub 2018 Jan 6. PubMed PMID: 29317226.
- Chen H, Pui Y, Liu C, Chen Z, Su CC, Hageman M, Hussain M, Haskell R, Stefanski K, Foster K, Gudmundsson O, Qian F. Moisture-Induced Amorphous Phase Separation of Amorphous Solid Dispersions: Molecular Mechanism, Microstructure, and Its Impact on Dissolution Performance. J Pharm Sci. 2018 Jan;107(1):317-326. doi: 10.1016/j.xphs.2017.10.028. Epub 2017 Oct 26. PubMed PMID: 29107047.
- 19. Morgen M, Gudmundsson O, Haskell R, Kumar A, Rao A, Su C, Goodwin A, Holenarsipur V, Cape J, Hageman M, Saxena A, Chowan GS, Chen X, Miller W, Nkansah R. Lipophilic Salts of Poorly Soluble Compounds to Enable High-Dose Lipidic SEDDS Formulations in Drug Discovery. Eur. J. Pharm. Biopharm. 117 (2017) 212-223.
- Chen Y, Wang S, Wang S, Liu C, Su C, Hageman M, Hussain M, Haskell R, Stefanski K, Qian F. Sodium Lauryl Sulphate Competitively Interacts with HPMC-AS and Consequently Reduces Oral Bioavailability of Posaconazole / HPMC-AS Amorphous Solid Dispersion. *Mol Pharm.* 13(8):2787-95 (2016). DOI: 10.1021/acs.molpharmaceut.6b00391. Epub 2016 Jul 1.
- 21. Tye CK, Wang Z, Dockens R, Vakkalagadda B, Wang C, Zhang C, Su CC, Hageman MJ. Preabsorption Physicochemical Compatibility Assessment of 8-drug Metabolic Cocktail. *Int J Pharm.* 514(2):364-373 (2016). DOI: 10.1016/j.ijpharm.2016.06.028.
- 22. Chen Y, Wang S, Wang S, Liu C, Su C, Hageman M, Hussain M, Haskell R, Stefanski K, Qian F. Initial drug release from amorphous solid dispersions controlled by polymer release and drug-polymer interaction. *Pharm Res.* 2016 Oct;33(10):2445-58. DOI: 10.1007/s11095-016-1969-2. Epub 2016 Jun 9.

- CV M.J. Hageman (09/15/22)
- 23. Chen Y, Liu C, Chen Z, Su C, Hageman M, Hussain M, Haskell R, Stefanski K, Qian F. Drug-polymer-water Interaction and its Implication to the Dissolution Performance of Amorphous Solid Dispersions. *Mol Pharm.* 12 (2):576-89 (2015). DOI: 10.1021/mp500660m. Epub 2015 Jan 12.
- 24. Chen XQ, Stefanski K, Shen H, Huang C, Caporuscio C, Yang W, Lam P, Su C, Gudmundsson O, Hageman M. Oral Delivery of Highly Lipophilic Poorly Water-Soluble Drugs: Spray-Dried Dispersions to Improve Oral Absorption and Enable High Dose Toxicology Studies of a P2Y1 Antagonist. *J Pharm Sci.* 103: 3924–3931 (2014). DOI: 10.1002/jps.24199, October 10, 2014.
- 25. Foster KA, Fancher RM, Proszynski M, Dixon G, Ford K, Cornelius G, Gudmundsson O, Hageman MJ. Utility of Gastric Retained Alginate Gels to Modulate PK Profiles in Rats. *J Pharm Sci*. 102(8):2440-9 (2013) DOI: 10.1002/jps.23630, June 6, 2013.
- 26. Chen XQ, Gudmundsson O, Hageman M. Application of Lipid-Based Formulations in Drug Discovery. *J Med Chem.* 55(18):7945-56 (2012), DOI: 10.1021/jm3006433, July 10, 2012.
- 27. Foster KA, Morgen M, Murri B, Fancher RM, Ehrmann J, Gudmundsson O, Hageman MJ. Utility of in situ Sodium alginate/Karaya Gum gels to facilitate gastric retention in Rodents. *Int J Pharm.* 434(1-2):406-412 (2012), DOI: 10.1016/j.ijpharm.2012.06.009.
- 28. Hageman MJ. Preformulation Designed to Enable Discovery and Assess Developability. *Combin Chem High Throughput Screening.* 13(2):90-100 (2010).
- 29. Guo J, Elzinga PA, Hageman MJ, Herron JN. Rapid throughput screening of apparent Ksp values for weakly basic drugs using 96-well format. *J Pharm Sci.* 97(6):2080-90 (2008).
- 30. Guo J, Elzinga PA, Hageman MJ, Herron JN. Rapid throughput solubility screening method for BCS Class II Drugs in animal GI fluids and simulated human GI fluids using a 96-well format. *J Pharm Sci.* 97(4):1427-42 (2008).
- 31. Larsen SD, Zhang Z, DiPaolo BA, Manninen PR, Rohrer DC, Hageman MJ, Hopkins TA, Knechtel ML, Oien NL, Rush BD, Schwende FJ, Stefanski KJ, Wilkinson KF, Zamora KM, Wathen MW, Brideau RJ. 7-Oxo-4,7-dihydrothieno[3,2-b]pyridine-6-carboxamides: synthesis and biological activity of a new class of highly potent inhibitors of human cytomegalovirus DNA polymerase. *Bioorg Med Chem Lett.* 2007 Jul 15;17(14):3840-4. Epub 2007 May 10.
- 32. Huang T, Gao P, Hageman MJ. Rapid screening of antioxidants in pharmaceutical formulation development using cyclic voltammetry potential and limitations. *Current Drug Discovery Technologies*. 1(2), 173-179 (2004).
- 33. Hariharan M, Ganorkar CD, Amidon GE, Cavallo A, Gatti P, Hageman MJ, Choo I, Miller JL, Shah UJ. Reducing the time to develop and manufacture formulations for first oral dose in humans. *Pharm Tech.* 27(10), 68, 70, 72, 74, 76, 78, 82, 84 (2003).
- 34. Gao P, Rush BD, Pfund WP, Huang T, Bauer JM, Morozowich W, Kuo M, Hageman MJ. Development of a supersaturatable formulation of paclitaxel with improved oral bioavailability. *J Pharm Sci.* 92(12), 2386-2398 (2003).
- 35. Miller BL, Hageman MJ, Thamann TJ, Barròn LB, Schöneich C. Solid State Photodegradation of Bovine Somatotropin (Bovine Growth Hormone): Evidence for Tryptophan-mediated Photo-oxidation of Disulfide Bonds. *J Pharm Sci.* 92(8), 1698-1709 (2003).

- CV M.J. Hageman (09/15/22)
- 36. Li R, Hageman MJ, Topp EM. Effect of Viscosity on the Deamidation Rate of a Model ASN-Hexapeptide. *J Peptide Res.* 59, 211-220 (2002).
- 37. Hovorka SW, Hageman MJ, Schöneich C. Oxidative Degradation of a Sulfonamide-containing 5,6-dihydro-4-hydroxy-2-pyrone in Aqueous/Organic Cosolvent Mixtures. *Pharm Res.* 19, 538-545 (2002).
- 38. Sarciaux JM, Mansour S, Hageman MJ, Nail SL. Effects of Buffer Composition and Processing Conditions on Aggregation of Bovine IgG During Freeze-Drying. *J Pharm Sci.* 88, 1354-1361 (1999).
- 39. Lai MC, Hageman MJ, Schowen RL, Borchardt RT, Laird BB, Topp EM. Chemical Stability of Peptides in Polymers. II. Discriminating Between Solvent and Plasticizing Effects of Water on Peptide Deamidation in Poly(vinyl pyrrolidone). *J Pharm Sci.* 88, 1081-1089 (1999).
- 40. Lai MC, Hageman MJ, Schowen RL, Borchardt RT, Topp EM. Chemical Stability of Peptides in Polymers. I. Effect of Water on Peptide Deamidation in Poly(vinyl alcohol) and Poly(vinyl pyrrolidone) Matrices. *J Pharm Sci.* 88, 1073-1080 (1999).
- 41. Sarciaux JM, Hageman MJ. Effects of Bovine Somatotropin (rbSt) Concentration at Different Moisture Levels on the Physical Stability of Sucrose in Freeze-Dried rbSt/Sucrose Mixtures. *J Pharm Sci.* 86, 365-371 (1997).
- 42. Bell LN, Hageman MJ. Glass Transition Explanation for the Effect of Polyhydroxy Compounds on Protein Denaturation in Dehydrated Solids. *J Food Sci.* 61, 372-374, 378 (1996).
- 43. Amphlett G, Cacia J, Callahan W, Cannova-Davis E, Chang B, Cleland JL, Darrington T, DeYoung L, Dhingra B, Everett R, [......], Gombotz W, Hageman M, Harris R, Heller D, Herman A, Hershenson S, Hora M, Ingram R, Janes S, Watanabe C. A compendium and hydropathy/flexibility analysis of common reactive sites in proteins: reactivity at Asn, Asp, Gln, and Met motifs in neutral pH solution. *Pharmaceutical Biotechnology*. 9:1-140 (1996).
- 44. Stevenson CL, Hageman MJ. Estimation of Recombinant Bovine Somatotropin Solubility by Excluded-Volume Interaction with Polyethylene Glycols. *Pharm Res.* 12, 1671-1676 (1995).
- 45. Bell LN, Hageman MJ, Muraoka LM. Thermally-Induced Denaturation of Lyophilized Somatotropin and Lysozyme as Impacted by Moisture and Excipients. *J Pharm Sci.* 84, 707-712 (1995).
- 46. Bell LN, Hageman MJ. A Model System for Differentiating Between Water Activity and Glass Transition Effects on Solid State Chemical Reactions. *J Food Quality*. 18, 141-147 (1995).
- 47. Pena LE, Possert PL, Stearns JF, Lee BL, Hageman MJ. Rheological Characterization of rbSt Oil Suspensions. *Int J Pharmaceutics*. 113, 89-96 (1995).
- 48. Bell LN, Hageman MJ, Bauer JM. Impact of Moisture on Thermally Induced Denaturation and Decomposition of Lyophilized Bovine Somatotropin. *Biopolymers*. 35, 201-209 (1995).
- 49. Bell LN, Hageman MJ. Differentiating Between the Effects of Water Activity and Glass Transition Dependent Mobility on a Solid State Chemical Reaction: Aspartame Degradation. *J Agric Food Chem.* 42, 2398-2401 (1994).
- 50. Ron E, Turek T, Mathiowitz E, Chasin M, Hageman M, Langer R. Controlled Release of Polypeptides from Polyanhydrides. *Proc Natl Acad Sci USA.* 90, 4176-4180 (1993).

- 51. Hageman MJ, Possert PL, Bauer JM. Prediction and Characterization of the Water Sorption Isotherm for Bovine Somatotropin. *J Agric Food Chem.* 40(2), 342-347 (1992).
- 52. Hageman MJ, Possert PL, Bauer JM, Darrington RT. Preformulation Oriented Towards Sustained Delivery of Recombinant Somatotropins. *J Agric Food Chem.* 40(2), 348-355 (1992).
- 53. Hageman MJ. The Role of Moisture in Protein Stability. *Drug Develop Indus Pharmacy.* 14, 2047-2070 (1988).
- 54. Repta, AJ, Hageman MJ, Patel JP. Enol Esters as Potential Prodrugs. IV. Enhanced Delivery of the Quaternary Species Coralyne to the Rat Brain Using 6'-Acetylpapaverin and Its Enol Esters as Prodrugs. *Int J Pharm.* 10, 239-248 (1982).

#### **Chapter / Monograph / Editorial Publications:**

- 1. Su CC, Xiao L, Hageman MJ. "Drug Solubility and Solubilization," Chapt. 9 in Pharmaceutical Dosage Forms: Parenteral Medications, 4th ed., Sandeep Nema and John Ludwig, ed., Informa Healthcare Publishing, August 7, 2019.
- 2. Dening TJ, Amidon GE, He X, Hageman MJ. Physicochemical characterization and oral dosage form selection. In: Vol. 3, *Burger's Medicinal Chemistry, Drug Discovery and Development*, Eighth Edition. Abraham DJ, Rotella DP, eds.; John Wiley & Sons, Inc., in press, 2019.
- 3. Hageman MJ. "Symbiotic Relationship between Pharmaceutical Research and Pharmacy Practice," invited editorial, *J Pharmacy Practice and Research*, 47: 417–418 (2017). doi:10.1002/jppr.1414.
- 4. Morrison JS, Hageman MJ. Outlook for the Future. In: Chapt.14 (pp 421-447), *Translating Molecules into Medicines: Cross-Functional Integration at the Drug Discovery-Development Interface.* Bhattachar SN, Morrison JS, Mudra DR, Bender DM, eds., AAPS Advances in the Pharmaceutical Sciences Series, Vol. 25, Springer (2017).
- 5. Amidon GE, He X, Hageman MJ. Physicochemical characterization and oral dosage form selection based on the biopharmaceutics classification system. In: Vol. 3, *Burger's Medicinal Chemistry, Drug Discovery and Development*, Seventh Edition. Abraham DJ, Rotella DP, eds.; John Wiley & Sons, Inc., October 2010.
- 6. Su CC, Xiao L, Hageman MJ. "Drug Solubility and Solubilization," Vol. 1, Chapt. 6 (pp.134-157) in Pharmaceutical Dosage Forms: Parenteral Medications, 3<sup>rd</sup> ed., Sandeep Nema and John Ludwig, ed., Informa Healthcare Publishing, August 2010.
- 7. Hageman MJ, Morozowich W. Irinotecan (CPT-11), a water soluble prodrug of SN-38. Monograph in: *Prodrugs: Challenges and Rewards.* Stella VJ, Hageman MJ, Oliyai R, Borchardt RT, Tilley J, Maag H, eds.; Springer & AAPS Press, 2007, pp. 569-580.
- 8. Hageman MJ, Solubility, solubilization and dissolution in drug delivery during lead optimization. In: Optimizing the Drug-Like Properties of Leads in Drug Discovery. Borchardt RT, Kerns, EH, Hageman MJ, Thakker DI, Stevens JL, eds.; Springer, 2006, pp.99-130.

- 9. He X, Amidon GE, Hageman MJ. Physicochemical Characterization and Principles of Oral Dosage Form Selection. In: Chapter 18, *Burger's Medicinal Chemistry and Drug Discovery*, Sixth Edition. Abraham DJ, ed.; John Wiley & Sons, Inc., 2003.
- 10. Song Y, Wilson A, Li R, Hageman MJ, Schowen RL, Topp EM. Solid-State Chemical Stability of Peptides and Proteins: Application to Controlled Release Formulations. In: *Handbook of Pharmaceutical Controlled Release Technology.* Wise, DL, ed., 2000.
- 11. Schöneich C, Hageman MJ, Borchardt RT. Stability of Peptides and Proteins. In: Chapter 11, *Controlled Drug Delivery: Challenges and Strategies*. Park K, ed.: ACS Press, Washington, D.C., 1997, pp. 205-228.
- 12. Davio SR, Hageman MJ. Characterization and Formulation Considerations for Recombinantly Derived Bovine Somatotropin. In: Chapter 2, *Stability and Characterization of Protein and Peptide Drugs: Case Histories.* Wang YJ, Pearlman R, eds.; Plenum Press, New York, 1993, pp. 59-89.
- 13. Hageman MJ. Water Sorption and Solid State Stability of Proteins. In: Chapter 10, *Stability of Protein Pharmaceuticals, Part A: Chemical and Physical Pathways of Protein Degradation.* Ahern TJ, Manning MC, eds.; Plenum Press, New York, 1992, pp. 273-309.
- 14. Hageman MJ. Preformulation of Protein and Peptide Drugs Intended for Nasal Delivery. In: *Proceedings/Pharm Tech Conference '90.* Aster Publishing Co., pp. 102-126 (1990).
- 15. Hageman MJ. The Role of Moisture in Protein Stability. In: *Proceedings of the Seventh Wisconsin Update Conference on "The Role of Moisture in Solid Dosage Forms."* Extension Services in Pharmacy, University of Wisconsin, Madison, WI (1988).
- 16. Hageman M.J. Prostaglandin E<sub>2</sub>. In: *Chemical Stability of Pharmaceuticals*, 2<sup>nd</sup> Edition. Conners KA, Amidon GL, Stella VJ; John Wiley & Sons, 1986, Pgs. 719-727.
- 17. Hageman MJ. Bisulfite-Induced Decomposition of 6-Selenoguanosine. In: *Univ. Microfilms Order No. DA8529092*, Diss. Abstr. Int. B 1986, 46(10), 3456.

#### **Technical / Study Reports:**

#### Bristol-Myers Squibb (2006-2016)

Review and approve pharmaceutics sections of greater than 100 exploratory drug candidate documents over this 10 year period, including small molecule, peptide and protein drugs. These documents vary in length for the pharmaceutics section, from 2-20 pages and provide the pharmaceutics related data and corresponding knowledge to be used in the approval of the transition of the molecule into development for GLP studies and IND generation.

#### Upjohn, Pharmacia & Upjohn, Pharmacia (1985-2003)

Internal Technical and Study Reports were typically quite extensive and equivalent to a peer (internally reviewed) publication. They varied in length from 10-50 type-written pages and included theory, data and data analysis for preformulation drug characterizations, formulation design, technology assessments and preclinical in vivo characterizations. (Total reports ~130; Primary author on >30 and last author on > 25 reports).

#### **Editorial Activities:**

- 1. Editor for Journal of Pharmaceutical Sciences (2015-present)
- 2. Editorial Board of AAPS Open (2018-2020)
- 3. Editorial Advisory Board for Journal of Pharmaceutical Sciences (2001-2014).
- 4. Stella VJ, Hageman MJ, Oliyai R, Borchardt RT, Tilley J, Maag H. eds. "*Prodrugs: Challenges and Rewards,*" as Volume #4 in the AAPS Series entitled "Biotechnology: Pharmaceutical Aspects", Borchardt, RT, Middaugh CR (Series Editors), Springer Press, NY, NY, 2007.
- 5. Borchardt RT, Kerns EH, Hageman MJ, Thakker DI, Stevens JL. eds. "Optimizing the Drug-Like Properties of Leads in Drug Discovery" Springer Press, NY, NY, 2006.

<u>Manuscript reviewer</u> for Journal of Pharmaceutical Sciences, Pharmaceutical Research, International Journal Pharmaceutics, Molecular Pharmaceutics, AAPS Open, Trends in Biotechnology, Nature Biomedical Engineering, Pharmaceutics (ISSN 1999-4923; CODEN: PHARK5)

#### Patent Publications / Applications / Approvals:

- 1. Lou H, Hageman MJ, In-vitro system for SC formulation testing, provisional submitted, 2022.
- 2. Vickery RD, Stefanski KJ, Su CC, Hageman MJ, Vig BS, Betigeri S, Bioavailable Compositions of Amorphous Piperidinyl Compounds, **Granted** as Patent #US 9,095,585 allowed on August 4, 2015.
- 3. Kick EK, Hageman MJ, Guarino VR, Su CC, Wei C, Warrier J, Nair S. Imidazole Prodrug of LXR Modulators. **Granted** as Patent #US 8,901,106 allowed on December 2, 2014.
- 3. Gao P, Hageman MJ, Morozowich W, Dalga RJ, Stefanski KJ, Huang T, Karim A, Hassan F, Forbes JC. Pharmaceutical Composition having Reduced Tendency for Drug Crystallization. Published as International Application WO 0256878A2, July 25, 2002.
- 4. Hageman MJ, He X, Kararli TT, Mackin LA, Miyake PJ, Rohrs BR, Stefanski KJ. Solid State Form of Celecoxib Having Enhanced Bioavailability. Filed December 6, 2000 in U.S., Published as International Application WO 0141536A1, June 14, 2001.
- 5. Kararli TT, Kontny MJ, Desai S, Hageman MJ, Haskell, RJ. C-3267/1: Cyclooxygenase-2 Inhibitor Compositions Having Rapid Onset of Therapeutic Effect. Filed December 6, 2000 in U.S., Published as International Application WO 0141760A2, June 14, 2001.
- 6. Foster TP, Moseley WM, Caputo JF, Hageman MJ. Aqueous Prolonged Release Parenteral Formulation. Filed as divisional of now U.S. Patent 6,150,330 on September 1, 2000, **Granted** as U.S. Patent 6,429,195 on August 6, 2002.
- 7. Foster TP, Moseley WM, Caputo JF, Hageman MJ. Aqueous Prolonged Release Parenteral Formulation. Filed in U.S. January 11, 1996 (priority US 96-9738 960111), Published as International Application WO 9725057 A1 970717. **Granted** U.S. Patent 6,150,330, November 21, 2000.

- 8. Hageman MJ, Possert ML. Aqueous Prolonged Release Formulation", Filed as a divisional patent of now US patent 6,471,977 on September 16, 2002, **Granted** U.S. Patent 6,699,490 on March 2, 2004.
- Hageman MJ, Possert PL. Aqueous Prolonged Release Formulation", Filed in the United States on January 25, 1994, (Priority US 94-186572 940125), Published as International Application WO 95-19787 A1 950727, Continuation filed in US August 2, 1996, <u>Granted</u> as U.S. Patent 6,471,977 on October 29, 2002
- Hageman, MJ. Sustained-release protein formulations. patent cases 4752 and 4757 below combined and filed Internationally on August 23, 1993, (priority US 92-947872 920921), Published as International Application WO 9406452 A1 940331, Filed in US March 20, 1995, <u>Granted</u> as U.S. Patent 6,011,011 on January 4, 2000.
- 11. Hageman MJ. Case 4752, Filed in the United States on October 20, 1992, Sustained-Release Protein Formulations, (Water-miscible polyethylene glycols as a vehicle for redispersible somatotropin suspensions and sustained delivery somatotropin).
- 12. Hageman MJ, Case 4757, Filed in the United States on September 21, 1992, "Sustained-Release Protein Formulations," (Water-miscible triacetin as a vehicle for redispersible somatotropin suspensions and sustained delivery somatotropin).

#### **External & Internal Research Proposals while in Industry:**

- Su CC, Hageman MJ. "Establishing Methods to Investigate the Supersaturation and Release Mechanism of BMS Drugs from Spray-Dried Dispersions (SDD)" with Professor F. Qian at Tsinghua University, 2016-17 BMS Innovation Grant Proposal FUNDED second round, \$60,000 for one year (< 15% proposals funded in second round).</li>
- 2. Su CC, Hageman MJ, "Investigating the Drug-Polymer-Water Interaction and Dissolution Mechanism of Amorphous Solid Dispersion Supersaturation and Release Mechanisms for Model Poorly Soluble Drugs in Spray-Dried Dispersions" with Professor F. Qian at Tsinghua University. 2013-16 BMS Innovation Grant Proposal FUNDED in first round, \$150,000 over 3 years (< 8% proposals funded in first round).
- 3. Gudmundsson O, Hageman MJ. "Understanding Physicochemical Properties of Millamolecules and their Impact on Pharmaceutics" with Professor Greg Knipp at University of Purdue. 2011-12 BMS Innovation Grant Proposal FUNDED at \$90,000 over 2 years.
- 4. Hageman MJ, Morozowich W, Mitchell MA. "Synthesis and Evaluation of Novel Solubilizing Surfactants," Pfizer Michigan Pharm Sci Tech Board, September 2004, --FUNDED-- ~\$50,000
- 5. Hageman MJ, Mollan M. "External Biopharmaceutical Evaluation of Oral Absorption Enabling Technologies," Pfizer Michigan Pharm Sci Tech Board, November 2003 --FUNDED-- ~ \$150,000
- 6. Goodwin JT, Morozowich W, Hageman MJ. "Discovery Prodrug Strategy Group." Pharmacia Emerging Technology Committee, 30 March 2001. ---Approved for hiring of Research Scientist---
- 7. Hageman MJ, "High Energy Solids Technology Initiative" Pharmacia Emerging Technology Committee, 30 March 2001. FUNDED through Global Pharmaceutical Sciences with shift of resources, prioritization and capital to carry out activities.

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- 8. He M, Hageman MJ, Schmitt WJ. Supercritical Fluids Technology Proposal," Pharmacia Emerging Technology Committee, 30 March 2001. Supported to be combined into High Energy Solids proposal above and "FUNDED" through Global Pharmaceutical Sciences Resource Prioritization and Capital Allocation
- 9. Martini A, Hageman MJ. "Use of polymer libraries as an added tool for HTP and MTP screenings for hit selection and for expanding early formulation design," Pharmacia Emerging Technology Committee, 20 July 2001 ---Supported with prioritization of workstream and collaboration effort between Nerviano, Italy and Kalamazoo, MI sites
- 10. Topp EM, Borchardt RT, Laird BB, Vander Velde BB, Middaugh CR, Schöneich C, Cleland JL, Hageman MJ, Schowen RL. "Peptide Degradation in Polymer Matrices," NIH competing continuation submission, October 28, 1999. ---FUNDED by NIH---
- 11. Schowen RL, Borchardt RT, Topp EM, Vander Velde D, Laird BB, Hageman MJ, "Peptide Degradation in Polymer Matrices," revised and resubmitted NIH Grant Application, October 31, 1996. ---FUNDED by NIH---
- 12. Borchardt RT, Schowen RL, Topp EM, Vander Velde, D, Hageman MJ, "Peptide Degradation in Polymer Matrices," revised and resubmitted NIH Grant Application, March 15, 1996. ---Revisions requested---
- 13. Hageman MJ, "Core Platform Formulations for Lyophilized Proteins," Upjohn Company Technology Assessment Proposal, June 2, 1995. ---Supported with reprioritization of internal resources---
- 14. Borchardt RT, Schowen RL, Topp EM, Vander Velde D, Hageman MJ. "Peptide Degradation in Polymer Matrices," NIH Grant Application, May 30, 1995. ---Good score but NOT FUNDABLE---
- 15. Hageman MJ. "Glass Transition Temperatures and Stability of Proteins in Amorphous Solids," Upjohn Research Project Proposal, September 25, 1991. ---FUNDED with money to hire Postdoc---
- 16. Hageman MJ. "Controlled and Sustained Release Systems for the Parenteral Delivery of Proteins: Characterization of Solubilities and Dissolution Rates," Upjohn Research Project Proposal, September 15, 1987. ---Supported but with reduced funding---

#### **Invited Symposium / Lecture Presentations:**

- 1. *Hageman MJ*, Early Assessment of Developability to Inform Molecule Progression, invited remote presentation for Oric Pharmaceuticals, August 30, 2022.
- 2. *Hageman MJ*, Jafari N, Lou H, Ways to Study Subcutaneous Route, invited remote presentation for Genentech, August 25, 2022.
- 3. *Hageman MJ*, Dening TJ, Douglas JT, Henderson O, and Al-Tamimi Z, Tackling the Challenges of Oral Peptide Delivery, invited remote presentation at 10th Scientific Conference, University of Baghdad, June 3, 2022.
- 4. *Hageman MJ*. Challenges in development of emerging modalities like oligonucleotides, synthetic proteins or non-biologic complex drugs, invited to give Keynote at AAPS National Meeting, Virtual Meeting, New Orleans, LA, November 2, 2020.
- 5. *Hageman MJ*. Two Day Short Course on Discovery and Development Interface, Gilead Pharmaceuticals, San Mateo, CA, October 28-29, 2019.
- 6. *Hageman MJ.* Amorphous Transitions: Industry to Academia and Solid Forms, Invited presentation at Uppsala University, Uppsala, Sweden, September 26, 2019.
- 7. Hageman MJ. Discovering and Developing Non-Traditional Drug Modality Molecules with Optimal Pharmaceutical Properties, invited presentation at 4<sup>th</sup> FDA/PQRI Conference, Rockville, MD, April 9, 2019.
- 8. Hageman MJ. Physical Pharmacy and Drug Delivery Research: Amorphous Applications, invited presentation at AbbVie, North Chicago, IL, January 23, 2019.
- Hageman MJ. Optimizing for Developability and Maximizing Oral Exposure in Discovery, lecture at short course, 2018 GPEN Meeting, National University of Singapore, Singapore, September 29, 2018.
- 10. Hageman MJ. Physical Pharmacy and Drug Delivery at the University of Kansas, invited presentation at Merck, West Point, PA, August 27, 2018.
- 11. Hageman MJ. Translating Molecular Design into Patient Care through Pharmaceutical Chemistry, invited presentation at Lilly Corporation, Indianapolis, IN, June 29, 2018.
- 12. Hageman MJ. The Drug Discovery / Formulation Development Interface, invited presentation at Special Symposia for Val Stella: Celebrating 43 Years of Innovation in Pharmaceutical Research, November 10, 2017 San Diego, CA.
- 13. *Hageman MJ.* Drug Discovery in Industry, invited to give undergraduate lecture to PharmD students at University of Kansas, August 24, 2017.
- 14. Hageman MJ. Managing a Shifting Landscape at the Drug Discovery Development Interface from Small Molecules to Biologics, to be Keynote Speaker at the AAPS DDDI Section Regional Meeting, University of Maryland, August 4, 2017.
- 15. *Hageman MJ*, Facilitated Progression of New Molecular Entities Through the Discovery to Development Interface and Beyond, to be presented at CPhI North America, Philadelphia, PA, May

16. 2017.

- 16. Hageman MJ, Chen P. Expedite Your Early Drug Development with Unique Pre-Formulation Techniques Know Your Molecule, webinar, March 28, 2017, sponsored by Catalent.
- 17. *Hageman MJ*. Oral Absorption Facilitated Through Creating and Maintaining Supersaturation, University of Michigan Dept. of Pharmaceutical Sciences, March 31, 2017.
- 18. *Hageman MJ*. Creating and Maintaining Metastable Conditions to Drive Absorption, University of Kansas, Dept. of Pharmaceutical Chemistry, March 16, 2017.
- 19. *Hageman MJ.* Prodrugs and Parenteral Controlled Release, undergraduate PharmD Lecture in PHRM 829 Dosage Forms II Course, Purdue University, School of Pharmacy, March 9, 2017.
- 20. *Hageman MJ*. Building a Developability Conscious Culture in Biologics Research, Purdue University Dept. of Industrial & Physical Pharmacy, March 8, 2017.
- 21. *Hageman MJ*. Enhanced Oral Exposure through Solid Form Control in Discovery, lecture at short course, 2016 GPEN Meeting, University of Kansas, Lawrence, KS, November 12, 2016.
- 22. *Hageman MJ*. Industry Perspective on the New Directions of Amorphous Materials and Dispersions. keynote at Land O'Lakes 2016 Conference, Madison, WI, June 7, 2016.
- 23. *Hageman MJ*. Mitigating Risk in Drug Discovery Through Preclinical Optimization of Molecules. Bionomics Limited, Thebarton, Southern Australia, May 10, 2016.
- 24. *Hageman MJ.* Application of Supersaturation and Solid Dispersion Technology to Enhance Oral Absorption. Royal Australian Chemical Institute (RACI) and faculty of the University of Southern Australia, Adelaide, Australia, May 9, 2016.
- 25. *Hageman MJ*. Overview of the Early Discovery Process. class lecture to undergraduates at University of Southern Australia School of Pharmacy, Adelaide, Australia, May 9, 2016.
- 26. *Hageman MJ*. Integrating Pharmaceutics into Drug Discovery to Manage Molecules outside the Rule-of-5 Chemical Space. Mawson Lakes Campus at University of Southern Australia, Adelaide, Australia, May 9, 2016.
- 27. *Hageman MJ*. Formulation to Manage a Discovery Portfolio as it Evolves Beyond Rule-of-5 Chemical Space. Monash Institute of Pharmaceutical Sciences, Monash University, Parkville, Victoria, Australia, May 5, 2016.
- 28. *Hageman MJ*. Integrating Solid Dispersion Manufacturing into Drug Discovery. 51<sup>st</sup> AAPS Arden House Conference on Contemporary Perspectives on Developing Amorphous Pharmaceuticals, Baltimore, MD, April 19, 2016.
- 29. *Hageman MJ*. Managing a Portfolio as it Evolves Beyond Rule-of-5 Chemical Space. 7<sup>th</sup> Symposium on Pharmaceutical Profiling in Drug Discovery and Development, University of Uppsala, Uppsala, Sweden, January 28, 2016.
- 30. *Hageman MJ.* Who me Bias? Does that Matter? Unknowingly Hampering Creativity. University of Kansas, Lawrence, KS, August 28, 2015.

- 31. *Hageman MJ.* The Drug Discovery Process. 2 hr lecture to undergraduate PharmD students at University of Kansas, Lawrence, KS, August 27, 2015.
- 32. *Hageman MJ.* Opportunities for Formulation of Ligands Beyond Rule-of-5 Chemical Space. 49<sup>th</sup> Journées Galéniques de St. Rémy de Provence Conference, St. Rémy, France, June 24-27, 2015.
- 33. *Hageman MJ.* Biopharmaceutics Driven Product Development: Science, Technology, and Business Perspective. keynote at Land O'Lakes 2015 Conference, Madison, WI, June 1-4, 2015.
- 34. *Hageman MJ.* Pharmaceutics and Drug Delivery as a Means to Expand Available Chemical Space for Drugs. University of Kansas, Lawrence, KS, February 24, 2015.
- 35. *Hageman MJ.* Building a Developability Conscious Culture in Biologics Research. AAPS National Biotechnology Conference, San Diego, CA, May 19, 2014.
- 36. *Hageman MJ*. Who me Bias? Hampering Creativity?, luncheon seminar to students at University of Michigan, Ann Arbor, MI, Jan. 12, 2012.
- 37. *Hageman MJ*. Interface of Drug Discovery and Development: Lead Optimization and Drug-Like Properties. class lecture at University of Michigan, Ann Arbor, MI, Jan. 12, 2012.
- 38. *Hageman MJ*. Enabling Drug Discovery: Drug Delivery to Target. University of Michigan, Ann Arbor, MI, Jan. 11, 2012.
- 39. *Hageman MJ.* Discovery and Development Interface: Introducing Drug-Like Properties During Lead Optimization. University of Tennessee Health Sciences Center, Nov. 21, 2011.
- 40. *Hageman MJ*. *T*hinking Differently Creativity and Innovation. 53<sup>rd</sup> Annual Intl. Industrial Pharmaceutical Research and Development Conference at Land O'Lakes on Solubilization and Bioavailability Enhancement: Product Development Strategies for Classic Challenges, Merrimac, WI, June 8, 2011.
- 41. *Hageman MJ*. Keynote: Product Development Strategies for Classic Challenges. 53<sup>rd</sup> Annual Intl. Industrial Pharmaceutical Research and Development Conference at Land O'Lakes on Solubilization and Bioavailability Enhancement: Product Development Strategies for Classic Challenges, Merrimac, WI, June 7, 2011.
- 42. *Hageman MJ*. Lead Candidate Selection Criteria and Developability Assessment of Challenging Molecules. 2011 AAPS Workshop on Emerging Oral Delivery Strategies and Technologies to Enable Biopharmaceutical Performance of BCS II, III and IV Molecules, Drug Delivery, Baltimore, MD, April 14, 2011.
- 43. *Hageman MJ*. Introduction to Drug-Like Properties and Selection of Drug-Like Leads During Lead Selection and Lead Optimization. short course on Fundamentals of Formulation Development for Small Molecules, Boston, MA, March 3, 2011.
- 44. *Haskell RJ*, Hageman MJ. Excipients in Early Toxicology Testing: Will Standardization Help or Hinder Drug Discovery? AAPS National Meeting, Nov. 10, 2009.
- 45. *Haskell RJ*, Hageman MJ. Enablement of Drug Discovery Through Supersaturation and Amorphous Solids. AAPS National Meeting, Nov. 18, 2009.

- CV M.J. Hageman (09/15/22)
- 46. *Hageman MJ.* Pharmaceutical Careers in a Globally Staffed M & A World. Higuchi Research Seminar, Lawrence, KS, Oct. 15-16, 2009.
- 47. *Hageman MJ*. Solubility and the Role it Plays from Drug Discovery to Development. AAPS Workshop on Evolving Science and Technology in Physical Pharmacy and Biopharmaceutics, Baltimore, MD, May 13-15, 2009.
- 48. *Hageman MJ*. Perspectives on the Merging of Discovery and Development Concepts. AAPS National Meeting, Atlanta, Nov. 2008.
- 49. *Hageman MJ.* Specialized Formulations Enhancing Oral Exposure During Lead Optimization Converse to Formulation Developability? AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidate Selection. San Francisco, CA, May 19-21, 2008.
- 50. *Hageman MJ*. Enabling the Drug Discovery and Delivery Interface (D3I). AAPS National Meeting, San Diego, Nov. 2007.
- 51. *Hageman MJ*. Drug Discovery: A Partnership Between Synthetic, Biological and Physical Sciences. University of Mississippi Medicinal Chemistry Seminar Series, Oct. 30, 2007.
- 52. Hageman MJ, Chen XQ, Gudmundsson OS, *Hauss D.* The Challenges of Oral Lipid-Based Delivery During Lead Optimization and Selection," Saint-Remy, France, Jun. 14, 2007.
- 53. *Hageman MJ*, Gudmundsson OS, Gemzik B, Chen XQ, Car BD. Lipid and Surfactant Formulation Strategies and Considerations for Non-Clinical Safety Assessment. Society Toxicology and Pathology Meeting, Rio Grande, Puerto Rico, June 11, 2007.
- 54. *Hageman MJ*. Role of Drug Delivery During Lead Optimization and Drug Candidate Selection. Fine Particle Society Meeting, San Diego, Dec. 18-22, 2006.
- 55. *Hageman MJ, Raghavan KS.* Role of Pharmaceutical Sciences and Formulation in Facilitating Early Clinical Testing. AAPS National Meeting, San Antonio, TX, Nov. 2006.
- 56. *Hageman MJ*. Analysis and Performance Characterization at the Pharmaceutics / Discovery Interface. University of Kansas, Lawrence, KS, August 25, 2005.
- 57. *Hageman MJ*. Drug Delivery During Lead Optimization and Candidate Selection. 9<sup>th</sup> Annual Drug Delivery Partnerships 2005, San Diego, CA, January 24-26, 2005.
- 58. *Hageman MJ*, Solubility, Solubilization, and Dissolution in Drug Delivery During Lead Optimization. AAPS Symposia on Optimization of Drug-Like Properties During Lead Optimization. Parsippany, NJ, Sept. 19-22, 2004.
- 59. *Hageman MJ*. Importance of Drug Delivery and Preformulation in Lead Optimization. 226<sup>th</sup> ACS National Meeting, New York, NY, September 7-11, 2003.
- 60. *Hageman MJ*, Amidon GE, Bergren MS. Fast to Humans Using the Powder in a Bottle Approach. 2002 AAPS Meeting, Toronto, Canada, November 14, 2002.
- 61. *Hageman MJ.* Solubility and Solubilization in Drug Delivery. University of Utah, Salt Lake City, UT, January 29, 2001.

- CV M.J. Hageman (09/15/22)
- 62. *Hageman MJ.* Strategies for Solubility Enhancement. Symposia presentation at the 2000 AAPS National Meeting, Indianapolis, IN, November 1, 2000.
- 63. *Hageman MJ*. At the Interface of Discovery Research and Pharmaceutical Development. Keynote at Enz Award Ceremony at the University of Kansas, Lawrence, KS, October 5, 1998.
- 64. *Hageman MJ*, Bauer JM. Protein Stability from the Laboratory to the Manufacturing Environment. 3rd Annual European Arden House Conference on Current Issues in Parenteral Formulation. Cambridge, United Kingdom, March 9, 1998.
- 65. *Hageman MJ*. Identification and Control of Oxidative Decomposition in Parenteral Products. 3rd Annual European Arden House Conference on Current Issues in Parenteral Formulation. Cambridge, United Kingdom, March 9, 1998.
- 66. *Hageman MJ*. Solubilisation: Options and Approaches. 3rd Annual European Arden House Conference on Current Issues in Parenteral Formulation. Cambridge, United Kingdom, March 9, 1998.
- 67. *Hageman MJ*, Bauer JM. Protein Stability from the Lab to the Production Environment. 33rd Annual AAPS Arden House Conference on "Current Issues in Parenteral Product Development. Harriman, NY, January 19, 1998.
- 68. *Hageman MJ*, Identifying and Controlling Oxidative Decomposition in Parenteral Formulations. 33rd Annual AAPS Arden House Conference on Current Issues in Parenteral Product Development. Harriman, NY, January 19, 1998.
- 69. *Hageman MJ*, Strategies for Solubility Enhancement in the Design of Parenteral Formulations 33rd Annual AAPS Arden House Conference on Current Issues in Parenteral Product Development. Harriman, NY, January 19, 1998.
- 70. *Hageman MJ*, Solid State Stability of Proteins and Peptides: Water Activity vs Molecular Mobility. University of Kansas, Lawrence, KS, January 29, 1996.
- 71. *Hageman MJ*, Irreversible Aggregation of Bovine Somatotropin: Chemical versus Physical Stability. Western Biotech Conference, San Diego, CA, October 18-21, 1995.
- 72. *Hageman MJ*, Bell LN, Sarciaux JM. Mobility, Water Activity and Solid-State Stability of Proteins and Peptides. ACS Conference on Formulations and Drug Delivery, Boston, MA, October 10-13, 1995.
- 73. *Hageman MJ*, Bauer JM. Evaluation of Physical and Chemical Decomposition Pathways of Recombinant Bovine Somatotropin. 109th AOAC Intl. Mtg. in Nashville, TN, Sept. 17-21, 1995.
- 74. *Hageman MJ.* The Balancing Act of Formulation Design for Recombinant Proteins. AAPS Natl. Mtg. in San Diego, CA, Nov. 6-10, 1994.
- 75. *Hageman MJ*, Bell LN, Bauer JM, Muraoka LM. Role of Polymer/Material Science Principles in Controlling Solid-State Stability of Proteins. University of Utah, Salt Lake City, UT, September 13, 1994.
- 76. Hageman MJ, Bell LN, Bauer JM, Muraoka LM, Polymer Science Approach to the Impact of Water, Temperature and Excipients on Solid State Decomposition of Proteins. Colorado Protein Stability Conference, Keystone, CO, July 17-20, 1994.

- 77. *Hageman MJ*, Polymer Science Approach to the Stability of Lyophilized Proteins: Impact of Moisture and Excipients, Midwest Regional AAPS Meeting, Chicago, IL, May 23, 1994.
- 78. *Hageman MJ*, Bauer JM, Shiou L, Vidmar TJ, Inherent Instability of Somatotropins: A Critical Factor in Sustained Release Dosage Forms. Controlled Release Society Meeting, July 28, 1992, Orlando, FL.
- 79. *Hageman MJ*. Preformulation Studies Oriented toward Sustained Delivery of Recombinant Somatotropins. College of Pharmacy, University of Texas at Austin, December 5, 1991.
- 80. *Hageman MJ*. Preformulation Studies Oriented toward Sustained Delivery of Recombinant Somatotropins. College of Pharmacy, University of Purdue, November 1991.
- 81. *Hageman MJ.* Solid State Stability of Proteins: A Key Determinant in Sustained Release of Proteins. Hudson Valley Discussion Group, October 22, 1990.
- 82. *Hageman MJ*. Preformulation of Protein and Peptide Drugs Intended for Nasal Delivery. part of a Workshop on Permeation Enhancers and Intranasal Delivery of Peptides. 1990 Pharm Tech Conference, September 24, 1990.
- 83. *Hageman MJ.* Possert PL, Bauer JM, Darrington, RT. Preformulation Oriented Toward Sustained Delivery of Recombinant Somatotropins. University of Maryland, August 31, 1990.
- 84. *Hageman MJ.* Possert PL, Bauer JM, Darrington RT. Preformulation Oriented Toward Sustained Delivery of Recombinant Somatotropins. 200th National ACS Meeting in Washington D.C., August 26-31, 1990.
- 85. *Hageman MJ.* Preformulation and Early Formulation of Bovine Somatotropin. lecture at Short Course on Formulation and Delivery of Proteins and Peptides at the 4th Annual AAPS Meeting, Atlanta, Georgia, October 22, 1989.
- 86. *Hageman MJ, Davio SR*. Protein and Peptide Formulation Development Course," two-day course for Upjohn Employees, September 14-15 and again October 3-4, 1989.
- 87. *Hageman MJ.* Dosage Form Development of Protein and Peptide Drugs. Eleventh Annual Eino Nelson Memorial Conference, St. Thomas, U.S. Virgin Islands, November 27-30, 1988.
- 88. *Hageman MJ.* Pharmaceutical Considerations in the Development of Proteins as Therapeutic Agents. Walter Enz Memorial Lectures at the University of Kansas, July 21-22, 1988.
- 89. *Hageman MJ.* Role of Moisture in Protein Stability. Seventh Wisconsin Update Conference, Madison, Wisconsin, April 11-13, 1988.
- 90. *Hageman MJ.* Preformulation Solubility Studies on Proteins: Recombinant Bovine Somatotropin. 194th National ACS Meeting in New Orleans, September 1, 1987.
- 91. *Hageman MJ*. Water Adsorption and Stability of Proteins in the Solid State: Recombinant Bovine Somatotropin. 2nd Annual AAPS meeting in Boston, June 7-12, 1987.

#### **Additional Poster/Podium Presentations:**

- 1. Wang Z, Lou H, Denning TJ, Hageman MJ. Biorelevant Dissolution Method Considerations for the Appropriate Evaluation of Amorphous Solid Dispersions: Are Two Stages Necessary? poster accepted for AAPS PharmSci 360, October 16-19, 2022, Boston, MA.
- 2. Lou H, Hageman M. Developing an In Vitro System to Emulate the In Vivo Subcutaneous Environment and Predict the Fate of Drugs in Subcutaneous Delivery: Assessment of Small Molecule Drugs poster accepted for AAPS PharmSci 360, October 16-19, 2022, Boston, MA.
- 3. Lou H, Hageman M. Developing an In Vitro System to Emulate the In Vivo Subcutaneous Environment and Predict the Fate of Drugs in Subcutaneous Delivery: Assessment of Biologics, poster accepted for AAPS PharmSci 360, October 16-19, 2022, Boston, MA. **Selected as 2022 AAPS Best Abstract Award**
- 4. *Lou H*, Hageman MJ, Develop and In Vitro System to Model In Vivo Subcutaneous Environment, 2022 PGSRM, University of Nebraska, June 2022.
- 5. Wang Z, Lou H, Dening T, Hageman M. Dissolution Method Considerations for Successful Evaluation of the Dissolution Performance of Amorphous Solid Dispersions, [Poster] Merck Emerging Talent Symposia, virtual meeting, November 4, 2021.
- 6. Wang Z, Lou H, Hageman M. Design of Experiment for Formulation Evaluation and Optimization of Drug-Polymer-Polymer Ternary Amorphous Solid Dispersion, [Poster] AAPS PharmSci 360, October 17-20, 2021: Philadelphia, PA.
- 7. Wang Z, Lou H, Xiong S, Hageman M. Develop Drug-Polymer-Polymer Ternary Amorphous Solid Dispersions to Inhibit Precipitation and Extend the Supersaturation, [Poster] AAPS PharmSci 360, October 17-20, 2021: Philadelphia, PA.
- 8. *Wang Z*, Xiong S, Hageman M. Strategies to Inhibit Precipitation of an Amorphous Solid Dispersion During Dissolution, [Poster] AAPS PharmSci 360, October 17-20, 2021: Philadelphia, PA.
- 9. *Basra AK*, Day V, Jafari, N, Hageman M. The Impact of Glass Transition Width on the Physical Stability of an Amorphous Solid Dispersion Containing the Surfactant TPGS [Poster] AAPS PharmSci 360, October 17-20, 2021: Philadelphia, PA.
- 10. Finocchario-Kessler S, Hageman M, Nicolay Z, Wang Z, Wexler C, Maliski E. Proof of Principle Oral Dissolvable Strip Formulation for Pediatric ARV Prophylaxis [ePodium] 11<sup>th</sup> IAS Virtual Conference on HIV Science, July 18-21, 2021, Berlin, Germany.
- 11. Basra AK, Day V, Jafari, N, Hageman M. The Impact of TPGS on Solid State Stability in a Spray Dried Amorphous Solid Dispersion [ePoster] AAPS PharmSci 360, held virtually, October 2020: New Orleans, USA.

- 12. *Basra AK*, Day V, Rajewski B, Hageman M. The Impact of TPGS and PEG 1000 as Surfactants in a Spray Dried Ternary Amorphous Solid Dispersion on Glass Transition Width and Miscibility [ePoster] AAPS PharmSci 360, held virtually, October 2020: New Orleans, USA.
- 13. *Dening TJ*, Douglas JT, Hageman MJ. Do Peptide Drugs Interact with Bile Salts in the Gastrointestinal Environment? [ePoster] Peptide Therapeutics Symposium, held virtually, October 22-23, 2020.
- 14. Dening TJ, Douglas JT, Hageman MJ. Understanding Interactions of a Peptide Drug with Bile Salts under Simulated Gastrointestinal Conditions via NMR Spectroscopy [ePodium] Great Plains Regional Annual Symposium on Protein & Biomolecular NMR, held virtually, October 10, 2020
- 15. *Dening TJ*, Douglas JT, Hageman MJ. Interaction of Biologically Relevant Bile Salts with a Peptide Drug under Mimicked Gastrointestinal Conditions In Vitro. [ePoster] Controlled Release Society Annual Meeting, held virtually, June 29 July 2, 2020.
- 16. Wang Z, Xiong S, Hageman M. Spray Dried Solid Dispersions of Hypromellose (HPMC) and Hypromellose Acetate Succinate (HPMCAS) with Nifedipine to Minimize Precipitation during Dissolution [Poster]. Pharmaceutical Science and Technology: New & Emerging Technologies, Sep 2019, Chicagoland Pharmaceutical Discussion Group, CPDG.
- 17. *Dening TJ*, Smith MM, Hageman MJ. Effect of octreotide-bile salt interactions on octreotide flux through polymeric membranes [Poster]. Boulder Peptide Symposium, 24 Sept 2019: Boulder CO, USA.
- 18. *Nandi P*, Stetsko P, Huang R, Stevens B, Arabanas J, Liu Z, Hageman M, Gudmundsson O. Stability and Shelf-Life Prediction of a Therapeutic IgG1 with Fc Mutation. Poster at 2016 Workshop on Protein Aggregation and Immunogenicity, Breckenridge, CO, August 2-4, 2016.
- 19. Cheng Y, Deyanova E, Dai J, Meengs B, Wang Y, Wert J, Chen J, Susan J, Zhang Y, Chen G, Hageman M, Gudmundsson O. Rapid Identification and Characterization of a Fragmentation Product of a Hydrophobic IgG1 Monoclonal Antibody. Oral presentation at 2016 Workshop on Protein Aggregation and Immunogenicity, Breckenridge, CO, August 2-4, 2016.
- 20. *Tye CK*, Wang Z, Su CC, Crison JR, Hageman MJ. The Use of GastroPlus Modeling in Enabling Drug Discovery Research. Poster at 2015 Annual AlChE Meeting, Salt Lake City, UT, November 8-13, 2015.
- 21. *Chen X*, Morgen M, Miller W, Nkansah R, Chowan G, Kumar A, Saxena A, Singh S, Desikan S, Mandlekar S, Su C, Haskell R, Gudmundsson O, Hageman M. Novel Lipophilic Salts of Atazanavir for Improved Drug Loading in Lipid Vehicles. Poster at AAPS Annual Meeting, San Diego, CA, November 2-6, 2014.
- 22. *Tye C*, Su C, Haskell R, Morgen M, Shaffer M, Holenarsipur V, Sinha J, Rao I, Palanisamy K, Italia J, Desai S, Nigam A, Mandlekar S, Desikan S, Hageman M. Designer Modified Release Microspheres for Preclinical Drug Discovery Research—In Vivo Performance. Poster at AAPS Annual Meeting, San Diego, CA, November 2-6, 2014.
- 23. Chen Y, Liu C, Chen Z, Su C, Hageman M, Hussain M, Haskell R, Stefanski K, *Qian F.* Drugpolymer-water Interaction and its Implication to the Dissolution Performance of Amorphous Solid Dispersions. Oral presentation at AAPS Annual Meeting, San Diego, CA, November 2-6, 2014.

- 24. *Morgen M*, Tye CK, LaChapelle E, Markovich M, Murri B, Millard D, Konagurthu S, Su CC, Haskell R, Hageman MJ. Small-Scale Manufacture of Modified Release Coated-Beads for Preclinical Drug Discovery Research. Poster at AAPS Annual Meeting, San Antonio, TX, November 11-14, 2013.
- 25. *Tye CK*, Su CC, Haskell R, Morgen M, Markovich M, LaChapelle E, Murri B, Millard D, Konagurthu S, Hageman MJ. Manufacture of Modified Release Coated-Beads for Preclinical Drug Discovery Research. Poster at AAPS NERDG Meeting, Rocky Hill, CT, April 19, 2013.
- 26. *Ziemba T*, Dabros M, Gao Q, Hageman M. Effect of Additives on the Anhydrate to Hydrate Form Transition in Piroxicam. Poster at AAPS Annual Meeting, Chicago, IL, October 14-18, 2012.
- 27. *Dabros M*, Ziemba T, Hageman M, Gao Q. Effect of Additives on the Anhydrate to Hydrate Form Transition in Piroxicam. Poster at the American Crystallographic Association Conference, Boston, MA, July 28, 2012.
- 28. *Varshney D,* Gudmundsson O, Hageman M. Lyo-Concentration Solubility Evaluation for Proteins Using a Scale-Down Approach. Poster at AAPS National Biotechnology Conference, San Diego, CA, May 21-23, 2012.
- 29. *Chen XQ*, Stefanski K, Huang C, Shen H, Xu C, Su C, Gudmundsson O, Hageman M. Application of Spray-dried Dispersions to Improve Oral Absorption and Enable High Dose Toxicology Studies of a Poorly Soluble Compound. Poster at AAPS Annual Meeting, Washington D.C., October 26, 2011.
- 30. Foster K, Fancher R, Ehrmann J, Morgen M, Murri B, Gudmundsson O, Hageman M. Utility of In Situ Sodium Alginate/Karaya Gum Gels to Facilitate Gastric Retention in Rodents. Poster at AAPS Annual Meeting, Washington D.C., October 25, 2011.
- 31. Stetsko P, Gong J, Wang L, Washburn W, Hageman M, Gudmundsson O. Application of Reactive Oxygen Species Assay to Predict Potential Phototoxicity for PreClinical Candidates. Poster at AAPS Annual Meeting, Washington D.C., October 25, 2011
- 32. *Chen XQ*, Johnson S, Everlof G, Ziemba T, LaMarre L, Morrison J, Su C, Haskell R, Gudmundsson O, Hageman M. Application of Co-solvents for Solubility Measurement and in silico Prediction of Aqueous Solubility. Poster at AAPS Annual Meeting, New Orleans, LA, November 16, 2010.
- 33. *Nophsker MJ*, Everlof GG, Morrison JS, Ziemba TM, Haskell RJ, Hageman MJ. Development of a Medium Throughput Oxidative Stability Assay for the Evaluation of Potential Drug Candidates. Poster at AAPS Annual Meeting, Atlanta, GA, November 17, 2008.
- 34. *Johnson SR*, Claus BL, Elzinga PA, Everlof GG, Hageman MJ. Mining SAR with a Functional Group Approach. AAPS Workshop on Drug Discovery Strategies and Critical Issues for Clinical Candidate Selection, San Francisco, CA, May 21, 2008.
- 35. *Johnson SR*, Claus BL, Gudmundsson OS, Elzinga PA, Everlof GG, Hageman MJ. Data Mining with the Fragment Activity Comparison Tool. National ACS Mtg, New Orleans, LA, April 9, 2008.
- 36. *Everlof G*, Chen XQ, Gudmundsson O, Hageman M. Use of in vitro Precipitation Models for the Selection of Preclinical IV Dosing Formulations. Poster at AAPS annual meeting, San Diego, CA, Nov. 2007.

- 37. Chen XQ, Huang C, Timoszyk J, Chang M, Xu C, Adam L, Salvati M, Gudmundsson O, Hageman M. Evaluation of Lipid-based Formulations in Dogs and Monkeys for a Highly Lipophilic Compound. Poster at AAPS annual meeting, San Diego, CA, Nov. 2007.
- 38. *Claus BL*, Johnson SR, Gudmundsson OS, Elzinga PA, Everlof GG, Hageman MJ. Data Mining with the Fragment Activity Comparison Tool (FACT). Poster at Keystone Symposia, October 31, 2007.
- 39. *Claus BL*, Johnson SR, Gudmundsson OS, Elzinga PA, Everlof GG, Hageman MJ. Data Mining with the Fragment Activity Comparison Tool. Poster at IEEE/ACM International Conference on Grid Computing, September 20, 2007.
- 40. *Gao P*, Rush BD, Pfund WP, Huang T, Bauer JM, Morozowich W, Hageman MJ. Development of a Supersaturatable Formulation of Paclitaxel with Improved Oral Bioavailability. Poster at 2003 AAPS Meeting, Salt Lake City, UT, October 26-30, 2003.
- 41. *Guo J*, Elzinga PA, Herron J, Hageman MJ. Screening the Effects of Excipients on BCS Class II Drug Solubility in Animal and Simulated Human GI Fluids Mimicking the Fed and Fasted States Using a 96-well Format. Poster at 2003 AAPS Meeting, Salt Lake City, UT, October 26-30, 2003.
- 42. *Guo J*, Elzinga PA, Herron J, Hageman MJ. Rapid Throughput Solubility Screening Method for BCS Class II Drugs in Animal GI Fluids and Simulated Human GI Fluids Using a 96-well Format. Poster at 2003 AAPS Meeting, Salt Lake City, UT, October 26-30, 2003.
- 43. *Hovorka SW*, Hageman MJ, Schöneich C. Impact of Non-aqueous Cosolvents on the Oxidative Degradation of an HIV- Protease Inhibitor: Are the Components in your Accelerated Stability System Inert? Poster at 2002 AAPS Meeting, Toronto, Canada, November 10-14, 2002.
- 44. *Guo J*, Elzinga PA, Herron J, Hageman MJ. Rapid Throughput Screening of Ksp Values for Wealkly Basic Drugs Using a 96-well Format. Poster at 2001 AAPS Meeting, Denver, CO, October 21-24, 2001.
- 45. *Hageman MJ*, Dalga RJ, Higgins MJ, Zamora KM, Mesfin GM. Solubilization and Reduced Venous Irritation of Tirilazad when Complexed with Cyclodextrins. Poster at 2000 AAPS Meeting, Indianapolis, IN, October 29-November 2, 2000.
- 46. *Ganorkar LD*, Bauer JM, Strong GL, Hageman MJ. Impact of Ionization of a Weakly Baskic Drug on Its Solubilization by Cyclodextrins. Poster at 2000 AAPS Meeting, Indianapolis, IN, October 29-November 2, 2000.
- 47. *Li R,* Hageman MJ, Schowen RL, Borchardt RT, Topp EM. Effect of Viscosity on the Deamidation Rate of Asn-Hexapeptide. Poster at the 2000 AAPS Meeting, Indianapolis, IN, October 29-November 2, 2000.
- 48. *Hovorka SW*, Hageman MJ, Shoneich C. Chemical Stability of Tipranavir: Characterization of a Complex Oxidation Mechanism. Oral presentation at Millenial World Congress of Pharmaceutical Sciences, San Francisco, CA, April 16-20, 2000.
- 49. *Hageman MJ*. Expanding the Role of Pharmaceutical Scientists in Discovery Support. Seminar presented for the Enz Award Ceremony at the University of Utah, Salt Lake City, UT, October 2, 1999.

- 50. Sarciaux JM, Hageman MJ, Nail SL. Effect of Cations and Anions on IgG Aggregation During Lyophilization. Poster at 1998 Annual AAPS Meeting, San Francisco, CA, November 15-19, 1998
- 51. Sarciaux JM, Mansour S, Hageman MJ, Nail SL. Effect of Species, Processing Conditions and Phosphate Buffer Composition on IgG Aggregation During Lyophilization. Poster at 1998 Annual AAPS Meeting, San Francisco, CA, November 15-19, 1998.
- 52. *Sarciaux JM*, Hageman MJ, Nail SL. Physical Stability of IgG During Lyophilization. Oral presentation at Fourth European Congress of Pharmaceutical Sciences, Milan, Italy, September 11-13, 1998.
- 53. *Lai MC*, Schowen RL, Borchardt RT, Hageman MJ, Laird BB, Topp EM. The Effect of Glass Transition Temperature and Plasticizer on the Stability of a Hexapeptide in Polymeric Formulations. Poster at 1997 Annual AAPS Meeting, Boston, MA, November, 1997.
- 54. *Lai MC*, Hageman MJ, Schowen RL, Borchardt RT, Topp EM. Effect of Water on Peptide Deamidation in Solid Polymeric Formulations. Poster at 1997 Annual AAPS Meeting, Boston, MA, November, 1997.
- 55. *Lai MC*, Schowen RL, Borchardt RT, Topp EM, Hageman MJ. Effect of Processing Conditions on the Water Vapor Sorption Behavior of Poly(Vinyl Alcohol) and Poly(Vinyl Pyrrolidone). Poster at 1997 Annual AAPS Meeting, Boston, MA, November, 1997.
- 56. Bauer JM, Hageman MJ. Viscosity of Recombinant Bovine Somatotropin (RBST) Aqueous Solutions at Various pH, Drug Concentrations and Temperature. Poster at 1997 Annual AAPS Meeting, Boston, MA, November, 1997.
- 57. *Lai MC*, Schowen RL, Borchardt RT, Hageman MJ, Topp EM. The Effect of Water and Glass Transition Temperature on the Solid State Stability of a Model Peptide in Polymers. Poster at 1997 Colorado Biopharmaceutical Delivery Conference, Breckenridge, CO, July, 1997.
- 58. Dalga RJ, Hageman MJ, Weaver KM, Secreast SL. Phase Solubility and Stability Studies of Tirilazad Mesylate in Hydroxypropyl-β-Cyclodextrin (HPB) or Sulfobutylether-β-Cyclodextrin (SBE) as a Function of pH. Poster at Pharmaceutical Applications of Cyclodextrins Conference, Lawrence, KS, June 29-July 2, 1997.
- 59. *Lai MC*, Schowen RL, Borchardt RT, Hageman MJ, Topp EM. Effect of Water Content and Activity on the Degradation of a Model Hexapeptide in the Solid-State. Poster at AAPS Southeast Regional Meeting, Research Triangle Park, NC, 1997.
- 60. Sarciaux JM, Hageman MJ, Bauer JM, Chao RS, Sado PA, Nail SL. Chemical Stability of RBST in a Colyophilized RBST/Sucrose Mixture as Influenced by the Ratio of RBST to Sucrose. Oral presentation at 23rd Annual Meeting of the Controlled Release Society, Kyoto, Japan, July 7-10, 1996.
- 61. Sarciaux JM, Bauer JM, Chao RS, Hageman MJ. Influence of Bovine Somatotropin (bSt) Concentration on the Physical/Chemical Stability of Freeze-Dried Sucrose/bSt Formulations. Poster at the 10th Annual AAPS Meeting, Miami, FL, November 5-9, 1995.
- 62. *Hageman MJ*, Sarciaux JM. Inhibition of Sucrose Crystallization by Bovine Somatotropin (BST) in Lyophilized BST/Sucrose Formulations. Oral presentation at ACS Western Biotech Conference, San Diego, CA, October 18-21, 1995.

- 63. Sarciaux JM, Bauer JM, *Hageman MJ*. Influence of Bovine Somatotropin (bSt) Concentration on the Physical Stability of Freeze-Dried Sucrose/bSt Formulations. Poster at ACS Conference on Formulation and Drug Delivery, Boston, MA, October 10-13, 1995.
- 64. Sarciaux JM, Hageman MJ. Inhibition of Sucrose Crystallization by Recombinant Bovine Somatotropin (rbSt) in a Colyophilized Sucrose/rbSt Mixture: Correlation Between Physical and Chemical Stability. Oral presentation at 5th Annual Purdue/Wisconsin Water/Mobility in Solids Symposium, Purdue University, West Lafayette, IN, October 5-6, 1995.
- 65. *Bell LN*, Hageman MJ. Differentiating the Effects of Water Activity and Glass Transition Dependent Mobility on Aspartame Degradation in the Solid State. Poster at ACS National Meeting in Anaheim, CA, April 3, 1995.
- 66. *Hageman MJ*, Admiraal SJ, Bauer JM. Temperature-Induced Irreversible Aggregation/Precipitation of Bovine Somatotropin: Connection Between Chemical and Physical Stability? Poster at 9th Annual AAPS Meeting, San Diego, CA, November 6-10, 1994.
- 67. Stevenson CL, Hageman MJ. Diafiltration of Aqueous Zinc-Bovine Somatotropin Suspensions to Remove Excess Zinc. Poster at 9th Annual AAPS Meeting, San Diego, CA, November 6-10, 1994.
- 68. Stevenson CL, Hageman MJ. Characterization of Spray-Dried and Lyophilized Suspensions of Zinc-Bovine Somatotropin Salts. Poster at 9th Annual AAPS Meeting, San Diego, CA, November 6-10, 1994.
- 69. *Bell LN*, Hageman MJ, Muraoka LM. Thermal Stability of Solid State Globular Proteins: A Polymer Science Explanation. Oral presentation at Institute Food Technology Meeting, Atlanta, GA, June 25-29, 1994.
- Bauer JM, Hageman MJ, Vidmar TJ. Interaction of pH and Protein Concentration on the Stability of Bovine Somatotropin. Poster at 8th Annual AAPS Meeting, Orlando, Florida, November 14-18, 1993.
- 71. *Bell LN.*, Hageman MJ. The Effect of Glass Transition Temperature on Moisture Sorption Isotherms of Plasticized Polyvinylpyrrolidone Polymers. Oral presentation at 8th Annual AAPS Meeting, Orlando, Florida, November 14-18, 1993.
- 72. *Bell LN*, Hageman MJ, Bauer JM. Effect of Moisture and Additives on the Thermally Detected Transitions of Solid Bovine Somatotropin. Poster at 8th Annual AAPS Meeting, Orlando, Florida, November 14-18, 1993.
- 73. *Hageman MJ*, Tinwalla AY, Bauer JM. Kinetics of Temperature-Induced Irreversible Aggregation/Precipitation of Bovine Somatotropin as Studied by Initial Rate Methods. Poster at 8th Annual AAPS Meeting, Orlando, Florida, November 14-18, 1993.
- 74. Dalga RJ, *Hageman MJ*, Vidmar TJ. Nonisothermal Stability Screening for Thermally-Induced Aggregation/Precipitation of Proteins Using a Hot Stage Microscope. Pposter at 8th Annual AAPS Meeting, Orlando, Florida, November 14-18, 1993.
- 75. *Muraoka LM*, Bell LN, Hageman MJ. Effect of Moisture, Excipients, and the Excipient's Glass Transition on the Thermal Stability of Lyophilized Lysozyme. Oral presentation at 3rd Annual

- Purdue/Wisconsin Water/Mobility in Solids Symposium, Purdue University, West Lafayette, IN, September 22-23, 1993.
- 76. *Bell LN*, Hageman MJ. Evaluating the Relation Between Glass Transition and Moisture Sorption Isotherms in Plasticized Polyvinyl Pyrrolidone. Oral presentation at 3rd Annual Purdue/Wisconsin Water/Mobility in Solids Symposium, Purdue University, West Lafayette, IN, September 22-23, 1993.
- 77. Shiou L, Hageman MJ. Challenges in the Development of a RP-HPLC Method for Recombinant Soluble CD4-183. Poster at Midwest AAPS Regional Meeting, Chicago, Illinois, May 6, 1991.
- 78. Possert PL, *Hageman MJ*. Prediction and Characterization of Water Sorption Isotherm for Bovine Somatotropin," oral presentation at 200th National ACS Meeting in Washington D.C., August 26-31, 1990.
- 79. Ron E, Turek T, Mathiowitz E, Chasin M, Hageman M, Langer R. The Effect of Polymers Hydrophobicity on the Release of Polypeptides. American Institute of Chemical Engineers Meeting, San Francisco, November, 1989.
- 80. Stevenson CL, Hageman MJ. Estimation of Protein Solubilities by Excluded Volume Interactions with Polyethylene Glycols. Poster at the Third Annual AAPS Meeting, Orlando, Florida, October 31 November 3, 1988.
- 81. *Hageman MJ*, Repta AJ. Reaction of 6-Selenoguanosine with Bisulfite: A Case of Induced Oxidation and Subsequent Nucleophilic Substitutions. Poster at 35th National APS Meeting, Miami Beach, Florida, 1983.
- 82. *Hageman MJ*, Repta AJ. Reaction of 6-Selenoguanosine with Bisulfite: Characterization and Kinetic Evaluation of an Intermediate, Guanosine-6-sulfonic Acid. Oral presentation at 15th Annual Pharmaceutics Graduate Student Research Meeting, June 1983.
- 83. Patel JP, *Hageman MJ*, Repta AJ. Prodrugs for Delivery of the Quaternary Anti-neoplastic Coralyne Ion to the Brain. Poster at APS Meeting, San Antonio, Texas, 1980.

## <u>Internal Invited Presentations (Upjohn, Pharmacia & Upjohn, Pharmacia)</u> (1985-2003)

Internal invited presentations not listed here (~22) were typically 20-60 min presentations to groups varying from 5 to 150. These presentations were similar to those made at symposia of professional society meetings, often with a number of senior company leaders present. These were presentations which fell outside the typical program team related presentations (5-20 min) which occurred for multiple teams on approximately monthly basis. There were also other poster type presentations (~75) which occurred at various internal symposia at the company.