HARVEY M. ARBIT, BS Pharm, PharmD, MBA, RPh, RAC, CCRP

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Professional Experience, Current

ARBIT CONSULTING, LLC, Saint Paul, MN
President and CEO

University of Minnesota College of Pharmacy, Minneapolis, MN
Adjunct Professor, Dept of Pharmaceutical Care & Health Systems

Albany College of Pharmacy and Health Science, Albany, NY
Adjunct Professor, Department of Pharmaceutical Sciences

Professional Experience, Previous

University of Minnesota, Minneapolis, MN
Office of the VP Research, Research Integrity and Oversight Programs
Director, IND/IDE Assessment Program
Academic Health Center, Clinical and Translational Science Institute
Director, IND/IDE Assistance Program
Leader, Regulatory Knowledge and Support

COLOPLAST CORP., North Mankato, MN
Vice President, Research & Development, Skin Care Division

SMITHKLINE BEECHAM, INC., Bloomington, MN
Diversified Pharmaceutical Services
Product Director, Pharmaceutical Cost Management
Director, Drug Formulary Compliance

CVS HEALTH (formerly Target Pharmacy), Minneapolis, MN
Pharmacy Operations
Pharmacist (Part-time relief)

DENVEY PHARMACEUTICALS, St. Paul, MN
Executive Vice President

Professional Experience, Previous continued

UPSHER-SMITH LABORATORIES, INC., Minneapolis, MN
Vice President, Regulatory Affairs
Director, Scientific Affairs

3M COMPANY, St. Paul, MN
*Manager, Regulatory Affairs and Clinical Research , **M**edical Products Division*

BAXTER TRAVENOL LABORATORIES, INC., Deerfield, IL
Manager, Regulatory Affairs and Clinical Development, Hyland Diagnostics Division
Supervisor, Regulatory Documentation, Travenol Laboratories, Inc.
Senior Clinical Research Coordinator, Travenol Laboratories, Inc.

Education

Pharm.D. - Duquesne University, Pittsburgh, PA
Clinical Residency - Mercy Hospital, Pittsburgh, PA
M.B.A. - Northern Illinois University, DeKalb, IL
B.S. Pharm. - Albany College of Pharmacy, Albany, NY

Licenses, Certificates, Appointments and Offices

Regulatory Affairs Certification (RAC)	
Certified Clinical Research Professional (CCRP)	
Licensed Pharmacist - Minnesota	
Licensed Pharmacy Preceptor – Minnesota	
Albany College of Pharmacy and Health Sciences – President's Advisory Council	2017 - Present
Joe Namath Neurological Research Center at Jupiter Medical Center – Hyperbaric Oxygen Therapy Advisory Panel	2016 - 2020
Society of Clinical Research Associates – Board of Directors	2008-2011
Society of Clinical Research Associates – Treasurer	2011-2013
The Green Edge, Inc. – Chief Regulatory Officer	2015 - Present
Cureium Therapeutics, LLC – Scientific Advisory Board	2010 - 2015
National Association of Pharmaceutical Manufacturers – Board of Directors	1985 - 1994
National Association of Pharmaceutical Manufacturers – Vice Chairman of the Board	1994
FBI Minneapolis Citizens Academy Alumni Association - Chasing the Dragon: The Life of an Opiate Addict. Program Committee	2018 - 2020

Teaching Experience

Society of Clinical Research Associates – Pre-conference workshop. "Investigator-initiated sponsored research"

Associates of Clinical Research Professionals – Pre-conference workshop. "Investigator-initiated research"

Albany College of Pharmacy and Health Sciences – Lecturer on regulatory affairs and product development

University of Minnesota College of Pharmacy – Lecturer on regulatory affairs and drug development

University of Minnesota School of Public Health – Lecturer on regulatory affairs, FDA inspection process, and clinical research

University of Minnesota Carlson School of Management – Lecturer on pharmaceutical business and drug product development

North Hennepin Community College. Regulatory Affairs Certificate Program – program coordinator, advisory committee member, and lecturer (2007-2011)

Publications - Books

Arbit HM, Teeple, WM. Chapter 3 – New Drug Application, Chapter 9 – Investigator-Initiated and Sponsored Research. In "FDA Clearance: Integrated Clinical, Engineering, and Business Approaches". Rosen Y, Elman N and Gurman P, eds., CRC Press, Taylor & Francis Group. (In progress.)

Mézes M, Arbit HM. Chapter 31 – Regulatory Affairs: The Investigator-Initiated Oncology Trial. In "Oncology Clinical Trials: Successful Design, Conduct and Analysis". Kelly WK and Halabi S, eds., Demos Medical Publishing, 2010.

Spilker B. Guide to Drug Development: A Comprehensive Review and Assessment. Wolters Kluwer Health, Lippincott, Williams & Wilkins. 2009. (Reviewed and edited 4 chapters.)

Publications - Electronic

Arbit HM. “Hi, I’m From the FDA.” (http://resources.complion.com/fda-inspections-article). Complion, Inc. Cleveland, OH. April 27,2016.

Arbit HM. Significant risk / non-significant risk determination and IDE applicability. (http://www.imarcresearch.com/blog/bid/133211/Significant-Risk-Non-Significant-Risk-Determination-Whitepaper). IMARC Research, Inc. Fairview Park, OH. April 16, 2012.

Arbit HM. Clinical Trials e-Alert. Weekly publication for PIs in clinical trials. Principal Investigators Association. Naples, FL. 2010.

- PI bears heavy responsibility in medical device Study. No. 12: August 16-20, 2010.
- Why it's best to respond in writing to FDA's Form 483. No. 11: July 19-23, 2010.
- Is an IND necessary for pregabalin and paclitaxel studies? No. 10: July 5-12, 2010.
- What to do when the researcher is the only study subject. No. 9: July 2-5, 2010.
- Who is responsible for an IND annual report? No. 8: June 28-July 2, 2010.
- When is an IND necessary? No. 7: June 21-25, 2010.
- Conducting a multi-site trial with individual IND applications. No. 6: June 14-18, 2010.
- Why it's best to cooperate with an unannounced FDA inspection. No. 5: June 7-11, 2010.
- Does study of botanical product require an IND? No. 4: May 31-June 4, 2010.
- Marketed drug for cancer treatment. No. 3: May 24-28, 2010.
- Medical practice vs. clinical research. No. 2: May 17-20, 2010.
- Faulty transfer triggers IND termination. No. 1: May 10

Publications - Journals

Arbit HM. Clinical investigator responsibilities: Explaining the FDA’s guidance document. SoCRA Source. 100(2):56-63. 2019 May.

Arbit HM. FDA and Health Canada perspectives on homeopathic products. SoCRA Source. 93(3):12-18. 2017 Aug.

Arbit HM. The IND expanded access program. SoCRA Source. 87(1):65-70. 2016 Feb.

Lu L, Arbit HM, Herrick JL, Segovis SG, Maran A, Yaszemski MJ. Tissue engineered constructs: Prospectives on clinical translation. Ann Biomed Eng. Accepted for publication. 2015 Feb.

Arbit HM. Determining whether human research can be conducted without an IND. SoCRA Source. 79(1):13-17. 2014 Feb.

Publications – Journals continued

Arbit HM. Basic physiological research with devices: 21 CFR 812 does not apply. SoCRA Source. 70(4):61-64. 2011 Nov.

Arbit HM. Regulatory support in an academic health center. SoCRA Source. 69(3):28-33. 2011 Aug.

Arbit HM. How to prepare for an FDA inspection. SoCRA Source. 65(3):61-66. 2010 Aug.

Arbit HM. How to prepare an investigational device exemption (IDE) as a sponsor-investigator. SoCRA Source. 62(4):58-63. 2009 Nov.

Arbit HM. Investigator-initiated research. J Clin Res Best Prac. 4(6):1-6. 2008 Jun.

Arbit HM. Investigator-initiated research: The IND and IDE processes. SoCRA Source. 53(3):19-24. 2007 Aug.

Arbit HM, Paller MS. A program to provide regulatory support for investigator-initiated clinical research. Acad Med. Management Series: Managing the Research Enterprise. 30-37, 2007 May.

Arbit HM, Paller MS. Regulatory support for investigator-initiated clinical research. RA Focus. 12(2):23-28, 2007 Feb.

Arbit HM, Paller MS. A program to provide regulatory support for investigator-initiated clinical research. Acad Med. 81(2):146-153, 2006 Feb.

Van Buskirk GA, Arbit HM, et al. Scale-up of liquid and semisolid disperse systems. Pharm Res. 11:1216-1220, 1994.

Cloyd J, Arbit H, Beniak T, Freeman R, Jones-Saete C, Lalonde R. Rectal diazepam: absolute bioavailability and cognitive effects in healthy volunteers. Epilepsia. 34(Suppl 2):123, 1993.

Skelly JP, Arbit HM, et al. Scale-up of immediate - release oral solid dosage forms. Pharm Res. 10:313-316, 1993.

Skelly JP, Arbit HM, et al. Scale-up of oral extended - release dosage forms. Pharm Res. 10:800-1805, 1993.

Arbit HM. Regulatory aspects of investigational new drugs. Amer J Hosp Pharm. 35:81-85, 1978.

Online Education

Arbit HM. FDA Inspections Need Not Be Stressful. Complion webcast series. April 27, 2016.

Arbit HM. Investigator-Initiated Clinical Trials-Do You Have What It Takes? ACRP webinar series. Continuing education credits for ACRP CE, Nurse CNE, and AMA PRA Category 1 Credits. March 23, 2016.

Arbit HM. Informed Consent-It Really is a Process. SoCRA On-demand webinar. Continuing education credits for SoCRA CE, Nurse CNE, and AMA PRA Category 1 Credits. December 2015.

Arbit HM. When IND/IDE research and FDA inspections intersect: How to prepare. What to expect. Webinar. Principal Investigators Association. November 11, 2010. Naples, FL. (Cancelled due to technical difficulties)

Presentations

"The role of regulatory oversight on clinical research at an academic institution." Society of Clinical Research Associates. 2022 Annual Conference. September 16, 2022. Virtual.

"My interesting career path." Albany College of Pharmacy and Health Sciences. Industry Pharmacists Organization. Northeast Regional Meeting. March 19, 2022. Virtual.

"The value in networking." University of Minnesota College of Pharmacy. Industry Pharmacists Organization. Student Chapter. March 3, 2022. Virtual.

"EUAs - Navigating regulations during a public health emergency." Human Subjects Research Ethics: Lesson from the COVID-19 Frontlines. University of Minnesota Center for Bioethics. March 29, 2021. Virtual.

"Regulatory support program: Keys to success." Society of Clinical Research Associates. 2020 Annual Conference. September 25, 2020. Virtual.

"Understand principal investigator needs for investigator-initiated clinical trials." ExL Events. Investigator-Initiated Trials (IIT). November 19, 2019. Philadelphia, PA.

"Lasagna's Law: The reality of enrollment expectations." Society of Clinical Research Associates. 2019 Annual Conference. September 29, 2019. San Antonio, TX.

Pre-conference workshop – "Investigator-initiated sponsored research." Society of Clinical Research Associates. 2019 Annual Conference. September 26, 2019. San Antonio, TX.

"Regulatory inspections of research sites." MAGI Clinical Research Conference 2019 East. May 6, 2019. Boston, MA.

Presentations continued

"Steps to begin an investigator-initiated and sponsored medical device study." Society of Clinical Research Associates. 13th Annual Device Research & Regulatory Conference. April 3, 2019. Newport Beach, CA.

"Investigator-initiated sponsored research: Are you and your institution prepared for the dual roles?" The Frankel Cardiovascular Center Clinical Research Group. University of Michigan. January 8, 2019. Ann Arbor, MI.

"Investigator-Initiated Research." Society of Clinical Research Associates. 2018 Summer Educational Conference. October 10, 2018. Plymouth, MN.

Pre-conference workshop – "Investigator-initiated sponsored research." Society of Clinical Research Associates. 2018 Annual Conference. September 27, 2018. New Orleans, LA.

"Investigator Responsibilities - Explaining FDA's Guidance Document." Society of Clinical Research Associates. 2018 Annual Conference. September 29, 2018. New Orleans, LA.

"Sponsor-Investigators have regulatory obligations too." ExL Events. Medical Affairs Strategic Summit. April 11, 2018. New Brunswick, NJ.

"The role of regulatory affairs in the pharmaceutical industry: The rewards and the conflicts on the way to the market." University of Minnesota College of Pharmacy. Social and Administrative Pharmacy Seminar. March 22, 2018. Minneapolis, MN.

"Building a career - Turning lemons into lemonade." University of Minnesota College of Pharmacy. Multicultural Pharmacy Student Organization. March 9, 2018. Minneapolis, MN.

"FDA inspections - Be prepared." Society of Clinical Research Associates. 2017 Fall Educational Conference. November 18, 2017. Rochester, MN.

Pre-conference workshop – "Investigator-initiated sponsored research." Society of Clinical Research Associates. 2017 Annual Conference. October 5, 2017. Lake Buena Vista, FL.

"Adverse drug events – What they are and are not." Society of Clinical Research Associates. 2017 Annual Conference. October 6, 2017. Lake Buena Vista, FL.

"Expectations from supporters for quality and compliant investigator-initiated research." Society of Clinical Research Associates. 2017 Annual Conference. October 7, 2017. Lake Buena Vista, FL.

Presentations continued

"Examine investigator-initiated clinical trials. Industry consideration to ensure your organization truly understands what the researcher is doing." ExL Events. Medical Affairs Strategic Summit. September 27, 2017. San Diego, CA.

"Homeopathic products." Metropolitan Professional Pharmacists Society Continuing Education Program. February 21, 2017. Bloomington, MN.

"What does it mean to be an IND/IDE Sponsor." 5th Annual Levine Cancer Institute Research Academy Program. November 4, 2016. Charlotte, NC.

"FDA and Health Canada perspectives on homeopathic products." Society of Clinical Research Associates. 2016 Annual Conference.
October 1, 2016. Montreal, Canada.

Pre-conference workshop – "Investigator-initiated sponsored research." Society of Clinical Research Associates. 2016 Annual Conference. September 29, 2016. Montreal, Canada.

"Adverse events – What / When / How." Society of Interventional Radiologists. 2016 Annual Conference. April 5, 2016. Vancouver, Canada.

"FDA inspections – Start / During / End / After." Society of Interventional Radiologists. 2016 Annual Conference. April 5, 2016. Vancouver, Canada.

"Responsibilities – Investigator / Sponsor / Monitor." Society of Interventional Radiologists. 2016 Annual Conference. April 5, 2016. Vancouver, Canada.

"IND / IDE – What / When / Why." Society of Interventional Radiologists. 2016 Annual Conference. April 5, 2016. Vancouver, Canada.

"FDA inspections." Society of Clinical Research Associates. 2016 Spring Educational Conference. March 6, 2016. Plymouth, MN.

"Investigator-initiated trials: Do you have what it takes?" Medical College of Wisconsin. Second Annual Clinical Research Symposium. October 3, 2015. Milwaukee, WI.

"FDA inspections: Be prepared." Medical College of Wisconsin. Second Annual Clinical Research Symposium. October 3, 2015. Milwaukee, WI.

Presentations continued

"IND expanded access programs." Society of Clinical Research Associates. 2015 Annual Conference. September 18, 2015. Denver, CO.

Pre-conference workshop – "Investigator-initiated sponsored research." Society of Clinical Research Associates. 2015 Annual Conference. September 17, 2015. Denver, CO.

"When alternative medicine may be a drug." Society of Clinical Research Associates. 2014 Annual Conference. September 20, 2014. Orlando, FL.

Full-day workshop. – "Investigator-initiated research. The IND application, process, and responsibilities." Universidad Central del Caribe School of Medicine. May 23, 2014. Bayamón, PR.

"Key initiatives for industry partners to overcome investigator challenges that are regulatory and beyond in scope." CBI. IISR 2014: Investigator-Initiated & Sponsored Research. March 19, 2014. Philadelphia, PA.

"Sponsor-Investigator: Obligations and compliance." CBI. IISR 2014: Investigator-Initiated & Sponsored Research. March 19, 2014. Philadelphia, PA.

"Models of shared responsibility between investigators and manufacturers." Q1 Productions. Third Annual Medical Device Investigator Initiated Studies. February 10, 2014. Raleigh-Durham, NC.

"Blurred lines: The role of 'sponsorship' defined." Q1 Productions. Third Annual Medical Device Investigator Initiated Studies. February 10, 2014. Raleigh-Durham, NC.

"FDA inspections: Preparation-Expectation-Follow up." Society of Clinical Research Associates. 2013 Fall Educational Conference. October 26, 2013. Rochester, MN.

"What every IRB member needs to know about device review." Society of Clinical Research Associates. 2013 Annual Conference. September 28, 2013. New Orleans, LA.

"Investigator-initiated research: It's more than just a study." Society of Clinical Research Associates. Minnesota North Central Regional Meeting. July 10, 2013. Minneapolis, MN.

"IDE assessment: A walk through the decision process." Society of Clinical Research Associates. 2013 Medical Device Conference. May 9, 2013. Scottsdale, AZ.

"Investigator-initiated trials: Who-What-Why." ExL Pharma. Medical Affairs Strategic Summit. April 16, 2013. Philadelphia, PA.

Presentations continued

"Pharmacists in research: Interactions with clinical staff." Society of Clinical Research Associates. 2012 Annual Conference. September 22, 2012. Las Vegas, NV.

"Determining whether human research can be conducted without an IND." Society of Clinical Research Associates. 2012 Annual Conference. September 21, 2012. Las Vegas, NV.

"Investigator-initiated trials: Preparing not to fail – Do you have what it takes?" MAGI's Clinical Research Conference 2011 West. October 24, 2011. Las Vegas, NV.

"What every IRB member needs to know about device review." Northwestern University Office of Research. 2011 IRB Member Retreat. October 14, 2011. Chicago, IL.

"Understanding the value an investigator gains from working on IITs and meeting their expectations." ExL Pharma. 14th Investigator Initiated Trials. September 27, 2011. San Diego, CA.

"Translational research-What is being translated?" Society of Clinical Research Associates. 2011 Annual Conference. September 24, 2011. San Diego, CA.

"Understanding regulatory challenges involved in device company / investigator relationships." Q1Productions. Medical device investigator-initiated studies. September 19, 2011. Chicago, IL.

"IDE assessment: A walk through the decision process." Air Force Research Laboratory. IRB Town Hall Meeting. September 9, 2011. Wright-Patterson Air Force Base, OH.

"Selection of investigational sites." Society of Clinical Research Associates. Device Research Conference. FDA IDE Interactive Case. May 20, 2011. Las Vegas, NV.

"Basic physiological research – 21CFR812 does not apply." Society of Clinical Research Associates. Device Research Conference. Regulations and Guidance for Device Clinical Research. May 19, 2011. Las Vegas, NV.

"Industry-supported, investigator-sponsored clinical trials." MAGI's Clinical Research Conference. October 25, 2010. San Francisco, CA.

"Investigator-initiated clinical trials: Where do I start?" SUNY-Stony Brook. 4th ICB&DD Annual Symposium. October 14, 2010. Stony Brook, NY.

"Basic physiological research – 21CFR812 does not apply." Society of Clinical Research Associates. 2010 Annual Conference. September 25, 2010. Dallas, TX.

Presentations continued

Pre-conference workshop – "Investigator-initiated research – Oversight and responsibilities at an academic institution." Investigator Initiated and Sponsored Research Association. 2010 Conference. April 29, 2010. Arlington, VA.

"Investigator-initiated research at an academic institution – oversight and responsibilities." Medtronic, Inc. Medtronic Neuro Forum Chapter. January 29, 2010. Minneapolis, MN.

"Current good manufacturing practices for phase 1 clinical trials." Society of Clinical Research Associates. 2009 Annual Conference. September 26, 2009. Nashville, TN.

"Regulatory support in an academic health center." Society of Clinical Research Associates. 2009 Annual Conference. September 26, 2009. Nashville, TN.

"What you should know before the FDA arrives." Society of Clinical Research Associates. 2009 Annual Conference. September 25, 2009. Nashville, TN.

"Investigator-initiated research at an academic institution." Investigator Initiated and Sponsored Research Association. 2009 Conference. September 16, 2009. San Diego, CA.

"How to prepare an IDE as a sponsor-investigator." Society of Clinical Research Associates. 2009 Medical Device Conference. May 21, 2009. Chicago, IL.

"How to prepare for an FDA inspection." Society of Clinical Research Associates. Southeast Minnesota Chapter Meeting. May 18, 2009. Rochester, MN.

"Investigator-initiated drug trials – When investigators become sponsors they accept additional responsibilities." MAGI's Clinical Trial Agreements, Budgets & Regulatory Conference - West. October 14, 2008. Las Vegas, NV.

4 hour workshop – "Investigator-initiated research: The INDependent world of sponsor-investigators." MAGI's Clinical Trial Agreements, Budgets & Regulatory Conference - West. October 12, 2008. Las Vegas, NV.

"Step-by-step process on how to prepare an IDE as a sponsor-investigator." Society of Clinical Research Associates. 2008 Annual Conference. September 27, 2008. Vancouver, BC, Canada.

"Investigator-initiated drug trials – Obligations of an IND sponsor-investigator." MAGI's Clinical Trial Agreements, Budgets & Regulatory Conference - East. May 20, 2008. Arlington, VA.

Presentations continued

"Filing an investigator-initiated IND." Association of Clinical Research Professionals. Global Conference. April 27, 2008. Boston, MA.

"The difference between practice and research – What the FDA expects you to understand." University of Cincinnati. Research, etc Symposium. November 16, 2007. Cincinnati, OH.

"IND/IDE overview." Society of Clinical Research Associates. 2007 Annual Conference. September 27, 2007. Denver, CO.

"Investigator-initiated IND and IDE: Assessment and responsibility." Mayo Clinic. Clinical Research Workshop. July 11, 2007. Rochester, MN.

"Investigator-initiated IDE at University of Minnesota." Society of Clinical Research Associates. Device Workshop: Clinical Research Guidance for Research Professionals. June 22, 2007. Baltimore, MD.

"Establishing a clinical trial monitoring service at an academic health center." Association of Clinical Research Professionals. Global Conference. April, 2007. Seattle, WA.

"IND applicability." University of Arkansas for Medical Sciences. Navigating the Sponsor-Investigator IND Minefield. April 16, 2007. Little Rock, AR.

"Academic research and an industry partner." Cincinnati Children's Hospital Medical Center. The Future of Research in Academic Settings. March 26, 2007. Cincinnati, OH.

"Investigational new drug applications: What, why, and how?" Mayo Clinic and University of Minnesota. Current Issues in Clinical Research. October 5, 2006. Minneapolis, MN.

"IND/IDE regulations and investigator initiated research." Society of Clinical Research Associates. 2006 Annual Conference. September 22, 2006. Chicago, IL.

"IND applicability: A University of Minnesota perspective." University of Florida. IRB Retreat 2006. August 30, 2006. Gainesville, FL.

"How to prepare for and conduct investigator-initiated research." Drug Information Association. 42nd Annual Meeting. June 21, 2006. Philadelphia, PA.

"IND exemptions – The determination process." Drug Information Association. 42nd Annual Meeting. June 21, 2006. Philadelphia, PA.

Presentations continued

"Common issues and concerns in academic research." Association of Clinical Research Professionals Global Conference. May 1, 2006. Phoenix, AZ.

"How to determine if your protocol needs an IND/IDE." Washington Information Source Expert Briefing. Audio conference. November 22, 2005.

"Investigator INDs – Overview and Application." Advocate Center for Pediatric Research. 2nd Annual Conference. September 30, 2005. Chicago, IL.

"The ABC's of Regulatory Issues." Association of University Technology Managers. Central Division Conference. July 19, 2005. Detroit, MI.

"Regulatory Obligations of an IND Sponsor-Investigator." Drug Information Association. 41st Annual Meeting. June 30, 2005. Washington, DC.

"Regulatory Obligations of Investigator Sponsored IND Research." Association of Clinical Research Professionals. 29th Annual Conference. April 3, 2005. Orlando, FL.

"Understanding the IND and IDE Processes." Hot Topics in Research. SUNY-Upstate Medical University. March 24, 2005. Syracuse, NY.

"Managing the Rapids of Change." Destination Discovery '05. SUNY-Binghamton. March 24, 2005. Binghamton, NY.

"The Investigator as IND Sponsor." Association of Clinical Research Professionals. 2nd Annual Smooth Sailing in Clinical Research Trials. February 20, 2005. Tampa, FL.

"Investigator Sponsored Research." Society of Research Administrators. 2004 Annual Meeting. October 27, 2004. Salt Lake City, UT.

"What do I need to do to get this orphan drug on the market?" National Organization of Rare Diseases. 2004 Family Conference. October 15, 2004. Minneapolis, MN.

"Investigator Sponsored IND Research." Drug Information Association. 40th Annual Meeting. June 16, 2004. Washington, DC.

"Drug/Botanical Drug Development Process: The IND Application." Minnesota Consortium for CAM Clinical Research. November 4, 2003. Minneapolis, MN.

"Academia & Industry: Together is Better." Medical Alley. July 9, 2003. Minneapolis, MN.

Presentations continued

"IND/IDE – What, Why, When, How." Association of Clinical Research Professionals. February 20, 2003. Minneapolis, MN.

"Investigator Initiated Clinical Trials." MedicalSuds. January 30, 2003. Minneapolis, MN.

Numerous previous presentations at professional and trade association meetings.