Kirsten Mease

SENIOR MANAGING SCIENTIST

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Ms. Mease is a Senior Managing Scientist with ToxStrategies, based in Research Triangle Park, NC. She has more than 20 years of experience in the pharmaceutical industry, focusing on nonclinical biopharmaceutical and pharmaceutical development. During her career, she has accrued extensive experience in the overall drug development process, particularly the nonclinical safety assessment studies required for the development of biopharmaceutical and pharmaceutical products. This broad experience allows her to provide unique and innovative solutions to drug development challenges. Ms. Mease has extensive experience in the design, conduct, data interpretation, and reporting of *in vivo* pharmacokinetic and toxicology studies (GLP and non-GLP). She works closely with high-quality Contract Research Organizations (CROs) across multiple countries to identify the most appropriate one to perform various *in vivo* and *in vitro* studies, and oversees all aspects of study conduct, including cost management, protocol development, study monitoring, report finalization, and regulatory submission support.

Ms. Mease has worked on the development of multiple therapeutic areas, including monoclonal antibodies, enzyme replacement therapies, and small molecules for various indications (e.g., hematology, immunology, neurology, oncology, ophthalmology, pain, and rare diseases), using various routes of administration (intravenous, subcutaneous, intravitreal, epidural, intrathecal, and oral), across nonclinical species (rodents, rabbits, dogs, minipigs, and non-human primates). In addition, she has written the nonclinical sections of various regulatory documents, including pre-IND (investigational new drug) packages, INDs/CTAs, Investigator Brochures, pediatric study plans, and DSUR annual reports. She also develops nonclinical strategy and regulatory briefing packages for Type B, Type C, and European Scientific Advice interactions, as well as providing representation at regulatory authority meetings in the US and EU.

Ms. Mease's small-molecule experience also includes drug transporter study design and data interpretation in the assessment of drug candidates.

Ms. Mease began her pharmaceutical career in biopharmaceuticals and has experience engineering and characterizing high-producing, antibody-secreting, mammalian cell lines for therapeutic products, and evaluating and optimizing novel approaches to increase mammalian protein expression. In addition, she has supported regulatory submissions (e.g., investigational new drugs, biologic license applications [INDs, BLAs]) for biopharmaceutical products. As a scientist in drug metabolism and pharmacokinetics (DMPK), Ms. Mease developed expertise in drug transporters for the purpose of predicting potential drug/drug interactions of small molecules. Thereafter, she became a Study Director, overseeing GLP and non-GLP studies in rodents, canines, and non-human primates. Ms. Mease also worked at the National Institute of Environmental Health Sciences (NIEHS), supporting the small business grant program, with a focus on grants that support exposome research, the National Toxicology Program, and the Superfund Research Program. In this role, she mentored small businesses, providing guidance on bringing technologies from bench to bedside and beyond.

EDUCATION AND DEGREES EARNED

2003 B.S., Biochemistry and Molecular Biology, The Pennsylvania State University, University Park, PA

PROFESSIONAL ASSOCIATIONS

2015–Present Healthcare Businesswoman's Association (HBA) RTP Chapter

2016–Present Society of Toxicology (SOT)

2016–Present American College of Toxicology (ACT)

SCIENTIFIC ADVISORY PANELS, COMMITTEES, AND WORKGROUPS

2022–Present Planning committee for annual Charles River Laboratories Biotech Symposium

2022 Planning committee for BioSafe General Membership meeting (virtual), October 2022

2015 National Institutes of Health Commercialization Accelerator Program (CAP) Mentor

2015 Eastern Carolina University Commercialization HUB Mentor

HONORS AND AWARDS

2016 National Institutes of Health Cross-Divisional Merit Award

PEER REVIEWER

Regulatory Toxicology and Pharmacology

Toxicological Sciences

SELECTED PROFESSIONAL EXPERIENCE

Pharmaceutical Toxicology

Led the preclinical development of multiple biologics and small molecules through program and study design, as well as execution, study monitoring, data interpretation, and IND, IB, PSP, and Type C briefing package writing. Primary focus has been in the rodent and non-human primate species, with study types ranging from pilot pharmacokinetic and pharmacodynamic studies, to IND-enabling GLP studies, to 3- and 6-month chronic studies, as well as juvenile toxicology and reproductive and developmental studies. Developed regulatory documents by integrating customized summaries of nonclinical toxicology study results and related these results to the larger clinical programs. Fiscally responsible for nonclinical programs in excess of $10M yearly, and responsible for quarterly nonclinical finance reviews. Nonclinical representative for internal project team meetings and regulatory interactions in the US and EU. Maintained client focus by introducing several new tools to assist with study planning; these tools increase transparency to clients during the study proposal/cost/bid process, test-article and vehicle planning, and overall study scheduling, conduct, and data interpretation.

Supported small-molecule projects through literature searches, interviews with key opinion leaders, and reviews of regulatory documents to evaluate risks and provide development recommendations for novel therapeutics and novel vehicle components. Reviews and provides recommendations on drug transporter interactions with small molecules.

Oversight of Toxicology Studies

As a Study Director, planned, executed, and reported on GLP and non-GLP toxicology studies in rodents, canines, and non-human primates, which included collating and interpreting in-life, clinical pathology, anatomical pathology, biomarker, and toxicokinetic data to support Phase I clinical dose selection. Also conducted internal data searches and reviews to analyze toxicity potential of excipients and formulations used *in vivo*. Implemented a novel, completely electronic method of study protocol development, which was developed in coordination with the Quality Assurance and Medical Affairs groups, providing new insights into the regulatory filing process.

Drug Transporters

As a DMPK scientist, developed expertise in the burgeoning field of drug transporters. Employed cell-based assays to elucidate the interaction of late-state small molecules, with clinically relevant uptake and efflux transporters to predict potential drug/drug interactions. Building on cell-line development expertise, developed a robust transient protein expression system to evaluate uptake transporters, which was used in a consortia comparison trial to improve data interpretation of uptake transporter data across the field of study. Another contribution to the science of drug transporters was development of a published practical strategy for the conduct and interpretation of efflux transporter interactions in Caco-2 cells, which express multiple efflux and uptake transporters.

Collaboration and Business Development

CRO relationship management through participation in team calls, surveys, preference document generation, participation in client tool interviews. Lead efforts to track CRO spend across programs to negotiate discounts across nonclinical toxicology portfolios.

Contributor of technical qualification sheets describing the capabilities of the company and staff.

Initiated and implemented several novel, cross-functional knowledge management projects to support the overall drug development process.

As a member of NIEHS, broadened the toxicology knowledge base beyond therapeutics, and supported the NIH small business grant programs known as SBIR and STTR. Participated in all aspects of grant management, from

application, to review, through award. Served as a mentor for the NIH Commercialization Accelerator Program (CAP), which provided technology and business development feedback to top-tier grantees.

Volunteer mentor for the Eastern Carolina University Commercialization HUB, which provides guidance to faculty on bringing technologies from bench to bedside

MANUSCRIPTS

Grover A, Sankaranarayanan S, Mathur V, Suri P, Qiu H, Andrews-Zwilling Y, **Mease K**, Taylor LK, et al. 2023. Pharmacokinetic and target engagement measures of ANX007, an anti-C1q antibody fragment, following intravitreal administration in nonhuman primates. Invest Opthalmol Visual Sci 64(2):3; doi: 10.1167/iovs.64.2.3.

Knotts T, **Mease K**, Sangameswaran L, Felx M, Kramer S, Donovan J. 2022. Pharmacokinetics and local tissue response to local instillation of vocacapsaicin, a novel capsaicin prodrug, in rat and rabbit osteotomy models. J Orthop Res 40(10):2281-2293; doi: 10.1002/jor.25271.

Mease KM, Kimzey AL, Lansita JA. 2017. Biomarkers for nonclinical infusion reactions in marketed biotherapeutics and considerations for study design. Curr Opin Toxicol 4(Jun):1–15; doi: 10.1016/j.cotox.2017.03.005.

Lansita J, **Mease KM**, Qiu H, Yednock T, Sankaranarayanan S, Kramer S. 2017. Nonclinical development of ANX005: A humanized anti-C1q antibody for treatment of autoimmune and neurodegenerative diseases. Int J Toxicol 36(6):449-462; doi: 10.1177/1091581817740873.

Sane RS, Steinmann GG, Huang Q, Li Y, Podila L, **Mease K**, Olson S, Taub ME, et al. 2014. Mechanisms underlying benign and reversible unconjugated hyperbilirubinemia observed with faldaprevir administration in HCV patients. J Pharmacol Exp Ther 351(2):403–412; doi: 10.1124/jpet.114.218081.

Mease K, Sane RS, Podila L, Taub ME. 2012. Differential selectivity of efflux transporter inhibitors in Caco-2 and MDCK-MDR1 monolayers: A strategy to assess the interaction of a new chemical entity with P-gp, BCRP and MRP2. J Pharm Sci 101(5):1888–1897; doi: 10.1002/jps.23069.

Taub ME, **Mease K**, Sane RS, Watson CA, Chen L, Ellens H, Hirakawa B, Reyner EL, et al. 2011. Digoxin is not a substrate for organic anion transporting polypeptide transporters OATP1A2, OATP1B1, OATP1B3, and OATP2B1 but is a substrate for a sodium dependent transporter expressed in HEK293 cells. Drug Metab Disp 39(11):2093–2102; doi: 10.1124/dmd.111.040816.

Tao L, Wadsworth S, Mercer J, Mueller C, **Lynn K**, Siekierka J, August A. 2002. Opposing roles of serine/threonine kinases MEKK1 and LOK in regulating the CD28 responsive element in T- cells. Biochem J 363(Pt 1):175–182; doi: 10.1042/0264-6021:3630175.

BOOK CHAPTERS

Kimzey A, **Mease K**, Mounho-Zamora B, Wood M. 2021. 13. Biosimilar products—A review of past and current regulatory approval standards for preclinical safety studies. In: Translational Medicine: Optimising Preclinical Safety Evaluation of Biopharmaceuticals. CRC Press: Boca Raton, FL.

PRESENTATIONS

Mease K. High safety bar, low safety margin case studies. Presented at 29th Annual Charles River Biotech Symposium, Carlsbad, CA, September 8-10, 2025.

Wood M, **Mease K**, Lueth J. Study monitoring: Expert approaches for a successful nonclinical program. Exhibitor-Hosted Session, Society of Toxicology 64th Annual Meeting, Orlando, FL, March 2025.

Mease K. Development of ANX007, a novel anti-C1q fab fragment for the treatment of complement-mediated ocular diseases. Presentation at Charles River Annual Biotech Symposium, "Biotechnology-derived therapeutics: Perspectives on nonclinical development," La Jolla, CA, September 2023.

Fryzek J, Bylsma L, **Mease K**, Movva N, Welsh BT, Wood M. Nonclinical toxicology and real-world epidemiology essential for a successful rare disease product launch. Presentation at World Orphan Drug Congress, virtual conference, August 2020.

Mease K. Managing immunogenicity in the absence of an ADA assay is no monkey business (case study). Presentation at 25th annual Charles River Biotech Symposium, "Biotechnology-derived therapeutics: Perspectives on nonclinical development," Carlsbad, CA, September 2019.

Mease KM. Managing ADA-mediated infusion (and confusion) reactions in nonclinical studies. Charles River 23rd Annual Biotech Symposium, "Biotechnology-Derived Therapeutics: Perspectives on Nonclinical Development," Carlsbad, CA, September 2017.

Mease KM. Managing infusion (and confusion) reactions in nonclinical studies. Seventh Annual Biologics Symposia—Envigo. Bridgewater, NJ, February 2017.

Mease KM. NIEHS small business (SBIR/STTR) funding opportunity for the "Validation and commercialization of approaches to reduce animal use in toxicology testing (U44)." Scientific Advisory Committee on Alternative Toxicological Methods (SACATM), Research Triangle Park, NC, September 2015.

Mease KM, Henry H, Richards A, Balan P. SBIR funding opportunity webinar for environmental technologies. NIEHS Superfund Research Program, EPA, NSF. April 2015, https://clu-in.org/conf/tio/sbirsttr_040215/.

POSTERS

Knotts T, Diokno R, Husfeld C, Weinberger D, **Mease K**, Wollowitz S, Kramer S, Donovan J. Vocacapsaicin (formerly CA-008): A water-soluble prodrug for rapid release of capsaicin for the treatment of postsurgical pain. Poster at American Association of Pharmaceutical Scientists, AAPS PHARMSCI 360, Boston, MA, October 2022.

Grover A, Sankaranarayanan S, Mathur V, Suri P, Andrews-Zwilling Y, **Mease K**, Taylor LK, Cahir-McFarland E, Keswani S, Yednock T. Poster: Pharmacokinetics and target engagement of intravitreal administration of ANX007, an anti-C1q antibody fragment, in nonhuman primates. Invest Ophthalmol Vis Sci 62(8):219, 2021.

Mease KM, Kimzey AL, Lansita JA. Managing immune mediated infusion reactions in nonclinical studies. American College of Toxicology annual meeting, Palm Springs, CA, 2017.

Mease KM, Kimzey AL, Lansita JA. Failed dose formulation analysis during a GLP study — Now what? Society of Toxicology annual meeting, Baltimore, MD, 2017.

Taub ME, **Mease K**, Sane RS, Watson CA, Chen L, Ellens H, Hirakawa B, Reyner EL, Jani M, Lee CA. Dioxin is not a substrate for organic anion transporting polypeptide transporters OATP1A2, OATP1B1, OATP1B3, and OATP2B1 but is a substrate for a sodium dependent transporter expressed in HEK293 cells. International Society for the Study of Xenobiotics, Atlanta, GA, 2011.

Sane RS, Podila L, Mathur A, **Mease K**, Taub ME, Tweedie D, Huang Q, Elgadi M, Nehmiz G, Steinmann G. Mechanisms of isolated unconjugated hyperbilirubinemia induced by the HCV NS3/4A protease inhibitor BI 201335. The International Liver Conference (EASL), Berlin, Germany, 2011.

Mease K, Podila L, Sane RS, Taub ME. A practical strategy to evaluate the role of multiple transporters involved in the bidirectional transport of an investigational compound. Gordon Research Conference – Drug Metabolism. 2010.

Mease K, Podila L, Sane RS, Taub ME. A practical strategy to evaluate the role of multiple transporters involved in the bidirectional transport of an investigational compound. The Holderness School, Holderness, NH, and American Association of Pharmaceutical Scientists, Transporter Workshop, Bethesda, MD, 2011.

Mease K, Sane RS, Taub ME. Multiple OATP transporters contribute to the active uptake of BI-D into transiently-transfected HEK 293 Cells. Gordon Research Conference — Drug Metabolism. The Holderness School, Holderness, NH, 2009.

Mease K, Sane RS, Taub ME. Deconvoluting the contribution of multiple efflux transporters in monolayer permeability studies: Consideration of multiple in vitro methods in tandem. Drug Metabolism Reviews 41, Supplement 3, 2009.

CONTINUING EDUCATION

CRL Biotech Symposium, Better Science with Fewer Animals, September 2023

CRL Biotech Symposium, Demystifying the Late Stages of Nonclinical Development of Biotherapeutics, September 2019

SOT, Detecting Cancer Risk in Drugs: Design, Conduct, and Interpretation of Carcinogenicity Studies for Regulatory Approvals, March 2017

ACT, How to be a Toxicology Project Leader, November 2015

University of California, Davis, Entrepreneurship Academy, September 2014

ACT, Pathology for the Non-Pathologist, May 2014