Amy Kimzey, Ph.D., DABT

SENIOR MANAGING SCIENTIST

DIRECTOR, PHARMACEUTICALS PRACTICE

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Amy Kimzey is a Senior Managing Scientist and Director of ToxStrategies Pharmaceuticals practice and is located in Massachusetts. She is a board-certified toxicologist with 20 years of toxicology and drug discovery experience in the pharmaceutical industry, with both large pharmaceutical companies and small start-ups. She has experience as a project-team liaison on multidisciplinary discovery and development project teams, with accountability for designing discovery and development toxicology screening and testing paradigms appropriate to the project stage, therapeutic area, and disease setting.

Dr. Kimzey also specializes in writing regulatory submissions (pre-INDs, INDs, IBs, briefing books, carcinogenicity risk assessments, reproductive toxicity assessments and NDAs), due diligence evaluations, and toxicology monographs for drug impurities and excipients; conducting drug target safety evaluations and both early- and late-stage toxicology risk evaluations; interpreting *in vitro* and *in vivo* assay results; and designing toxicology programs to maximize value with minimum investment. With a background in biochemistry, Dr. Kimzey understands target pathways, underlying biological mechanisms of disease states, and the biological mechanisms of toxicity.

Dr. Kimzey also has toxicology expertise with oncology, immune-oncology, radiotherapeutics, severe hematologic disease, pain, neurology, and rare disease products, and designing and monitoring non-GLP and GLP toxicology studies. She has also managed nonclinical studies and complex study events, including infusion reactions, for studies utilizing a variety of administration routes including, but not limited to, intravenous, subcutaneous, intrathecal, and oral.

EDUCATION AND DEGREES EARNED

1999 Ph.D., Chemistry, with specialization in Biochemistry, University of Colorado, Boulder

1993 B.S., Biochemistry, Oregon State University, Corvallis

CERTIFICATIONS

2011–Present Diplomate, American Board of Toxicology (DABT)

PROFESSIONAL ASSOCIATIONS

2008–Present Society of Toxicology

2017–Present American College of Toxicology

2009–Present Boston Area Pharmaceutical Toxicology Group

1999–Present American Society for Biochemistry and Molecular Biology

1993–Present American Chemical Society

SELECTED PROFESSIONAL EXPERIENCE

Regulatory Submissions

Multiple regulatory submissions, including INTERACTs, pre-INDs, INDs, Type C meetings, and BLAs/NDAs, and regulatory submission documents, including Investigator Brochures, meeting briefing books, clinical hold responses, carcinogenicity and reproductive risk assessment and waivers, and carcinogenicity SPAs. Responsible for interpreting and summarizing toxicology data, as well as executing literature evaluations for nonclinical data interpretation and risk assessment required to put the data into the appropriate toxicology context. Responsible for writing product-specific white papers to address regulatory concerns.

Pharmaceutical Toxicology

Served as the lead toxicology representative on cross-functional drug development program teams, with responsibility for designing and executing scoping and regulatory toxicology programs for monoclonal antibodies and other biologics, as well as small molecules, with responsibilities including:

- Designing, placing, and monitoring nonclinical studies outsourced to CROs, including reviewing, editing, finalizing, and incorporating reports into regulatory submissions.
- Managing multiple toxicity concerns arising during the studies, including, but not limited to, infusion reactions and other causes of animal distress/premature mortality.
- Reporting study findings and associated benefit-risk evaluations of potential drug safety signals and trends to the study teams and to management.
- Overseeing multiple projects simultaneously, accruing substantial experience in prioritizing work and successfully meeting deadlines.

In addition, performed evaluations of the nonclinical toxicology risks of potential in-licensing candidates.

Scientific Literature Analysis & Risk Evaluation

Composed multiple carcinogenesis and reproductive toxicology risk assessments for regulatory submission as well as special protocol assessment documents for carcinogenicity study dose selection.

Responsible for developing toxicology risk assessments/monographs of excipients and impurities in the context of the specific clinical route of administration, including non-standard routes such as ocular and intrathecal. Provided species-specific risk assessments and permissible daily exposure calculations of potential excipients in non-clinical formulations.

Responsible for evaluating the chemical risks of potential and actual small-molecule chemical series in close collaboration with project chemists; produced dozens of chemical risk evaluations, including comprehensive evaluations for chemical series with high-risk functional groups.

Primary scientist responsible for developing risk evaluations on the impact of inhibiting potentially druggable target genes and biological pathways, based on analysis of existing medical literature and/or databases and other publicly available information.

Drug Discovery Toxicology

Successfully represented the preclinical drug safety organization as a liaison on cross-disciplinary discovery project teams, responsible for designing early safety strategies to advance lead compounds through the selection process and into formal GLP development.

Biochemistry & Cell Biology

Defined a component of the regulatory mechanism of HTLV-I (Human T-Cell Leukemia Virus Type I) protein transcription by examining the complex interactions between the multiprotein HTLV-I Tax / CREB complex and its DNA site, utilizing classical biochemical and molecular biology techniques.

Developed multiple biochemistry and cell biology assays appropriate for a fast-paced, small biotechnology company.

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. Boca Raton, FL: CRC Press.

Kimzey AL, Piche M-S, Wood M, Weir AB, Lansita J. 2018. 11.19 — Immunophenotyping in drug development. In: Comprehensive Toxicology, 3rd Ed., Vol 11. Elsevier Science. pp. 399–427.

SELECTED PUBLICATIONS

Basarab GS, Doig P, Eyermann CJ, Galullo V, Kern G, **Kimzey A**, Kutschke A, Morningstar M, Schuck V, Vishwanathan K, Zhou F, Gowravaram M, Hauck S. 2020. Antibacterial spiropyrimidinetriones with N-linked azole substituents on a benzisoxazole scaffold targeting DNA gyrase. J Med Chem 63(20):11882–11901.

Sibley K, Chen J, Koetzner L, Mendes O, **Kimzey A**, Lansita J, Boulos RA. 2019. A 14-day repeat dose oral gavage range-finding study of a first-in-class CDI investigational antibiotic, in rats. Sci Rep 9(1):158.

Mease K, **Kimzey A**, Lansita J. 2017. Biomarkers for nonclinical infusion reactions in marketed biotherapeutics and considerations for study design. Curr Opin Toxicol 4(June):1–15.

Basarab GS, Doig P, Galullo V, Kern G, **Kimzey A**, Kutschke A, Newman JP, Morningstar M, Mueller J, Otterson L, Vishwanathan K, Zhou F, Gowravaram M. 2015. Discovery of novel DNA gyrase inhibiting spiropyrimidinetriones: Benzisoxazole fusion with n-linked oxazolidinone substituents leading to a clinical candidate (ETX0914). J Med Chem 58(15):6264–6282.

Basarab GS, Kern GH, McNulty J, Mueller JP, Lawrence K, Vishwanathan K, Alm RA, Barvian K, Doig P, Galullo V, Gardner H, Gowravaram M, Huband M, **Kimzey A**, Morningstar M, Kutschke A, Lahiri SD, Perros M, Singh R, Schuck VJ, Tommasi R, Walkup G, Newman JV. 2015. Responding to the challenge of untreatable gonorrhea: ETX0914, a first-in-class agent with a distinct mechanism-of-action against bacterial Type II topoisomerases. Sci Rep 5:11827.

Bao L, **Kimzey AL**, Sauter G, Sowadski JM, Lu KP, Wang DG. 2004. Prevalent overexpression of prolyl isomerase pin1 in human cancers. Am J Path 164(5):1727–1737.

Kimzey AL, Weitz KK, Guengerich FP, Zangar RC. 2003. Hydroperoxy-10,12-octadecadienoic acid stimulates cytochrome P450 3A protein aggregation by a mechanism that is inhibited by substrate. Biochem 42(43):12691–12699.

Zangar RC, **Kimzey AL**, Okita JR, Wunschel DS, Edwards RJ, Kim H, Okita RT. 2002. Cytochrome P450 3A conjugation to ubiquitin in a process distinct from classical ubiquitination pathway. Molec Pharmacol 61(4):892–904.

Kimzey AL, Dynan WS. 1999. Identification of a human T-cell leukemia virus Type I tax peptide in contact with DNA. J Biol Chem 274(48):34226–34232.

Kimzey AL, Dynan WS. 1998. Specific regions of contact between human T-cell leukemia virus Type I tax protein and DNA identified by photocross-linking. J Biol Chem 273(23):13768–13775.

SELECTED PRESENTATIONS AND ABSTRACTS

Kimzey A, Mihalchik A, Bottomley A, Wood M. Development of an occupational exposure limit (OEL) and permissible daily exposure (PDE) limit to support manufacturing of an intermediate antibody using read-across. Poster P413, American College of Toxicology (ACT) 47th Annual Meeting, San Antonio, TX, November 2026.

Kimzey A. Carcinogenicity risk assessments and waiver examples. CRL Biotech, Carlsbad, CA, September 2024.

Kimzey A, Welsh B, Wood M. Case studies demonstrating the process and challenges of deriving exposure-based limits for Impurities in pharmaceutical drug products administered directly to the CNS. American College of Toxicology 42nd Annual Meeting, Virtual, 2021.

Kimzey AL, Welsh BT, Chesney AR, Fonck C, O'Neill C, Wood ML. Derivation of a health-based exposure limit for cesium using non-clinical and clinical data. American College of Toxicology 41st Annual Meeting, Virtual, 2020.

Chesney A, Welsh B, **Kimzey A**, Lansita J. The process and challenges of deriving exposure-based limits for toxicological risk assessment for components and impurities present in cell therapy products with case studies. Abstract 2773, Society of Toxicology 59th Annual Meeting, Virtual, March 2020.

Welsh BT, **Kimzey AL**, Lansita J. The process and challenges of deriving exposure-based limits for components and impurities present in pharmaceutical drug products with case studies for an excipient, a potential genotoxic impurity, an immunomodulator, and a pediatric drug. American College of Toxicology 38th Annual Meeting, Palm Springs, CA, November 2017.

Mease KM, **Kimzey AL**, Lansita JA. Managing immune mediated infusion reactions in nonclinical studies. American College of Toxicology 38th Annual Meeting, Palm Springs, CA, November 2017.

Mease K, **Kimzey A**, Lansita J. 2017. Failed dose formulation analysis during a GLP study — Now what? Abstract 1720, Society of Toxicology 56th Annual Meeting, Baltimore, MD, March 2017.

Scott C, Ehmann D, **Kimzey A**, Dragan Y. Assessing selectivity of covalent irreversible β-lactams and β-lactamase inhibitors using activity-based protein profiling. Abstract 1137, Society of Toxicology 51st Annual Meeting, San Francisco, CA, March 2012.

Prior H, Noakes J, Slater I, Kelly S, Smith M, Marks L, **Kimzey A**, Roberts R, Valentin JP. Inclusion of microchip transponder body temperature measurements in rat toxicology studies. Abstract 2263, Society of Toxicology 51st Annual Meeting, San Francisco, CA, March 2012.