

Kerstin K. (Kiki) Leuther, PhD

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PROFESSIONAL PROFILE

- Focus on Research to advance compassionate, innovative care that empowers people with chronic disease to live life as they hope to.
- Manage strategic projects with an emphasis on research and business initiatives that require cross-functional coordination.
- In-depth knowledge of all phases of pharmaceutical product development including R&D and commercial phases, broad scientific expertise, and a strong background in strategic and operational leadership.
- Experience in building and leading effective teams and creating constructive approaches to address strategic opportunities and challenges.
- Experience leading global and domestic alliances working with private and public companies, startups to large multinational companies.
- Experience with scientific and business due diligence activities, including negotiation of license agreements and partnership contracts.
- Facilitate high-impact and at times sensitive corporate and alliance matters with a high degree of professionalism, discretion, integrity, and respect.
- As part of executive and senior management, interact with Board of Directors to review company strategies, objectives, metrics, milestones, timelines, and results.
- Manage multiple objectives, priorities, and resources to maximize success in each project.
- Striving to do some good in the world.

KEY SKILLS

- Clinical Research
- Drug and Medical Device Development
- R&D and Corporate Operations
- Project, Portfolio, and Alliance Management
- Strong Communicator

RESEARCH AND PROFESSIONAL EXPERIENCE

2/2020 – Present Senior Research Scientist | Director, Extramural Grant Program Satellite Healthcare Inc.

Research to advance compassionate, innovative care that empowers people with kidney disease to live life as they hope to.

- Design, develop, and execute quantitative and qualitative clinical research in areas that matter most to people living with kidney disease and those who care for them.
- Scientific due diligence projects to evaluate new technologies in the nephrology space.
- Process and workflow development for clinical research department.
- Research intake, evaluation, and company approval for in-house R&D, contract research, and research collaborations.
- Research liaison for R&D legal and compliance matters, including nondisclosure agreements, business associate agreements, research collaboration contracts, grant funding, and clinical trial agreements.
- Intern mentorship.

5/2013 – Present Partner Full Spectrum Biotechnology Consulting

Flexible and practical consulting services for corporate and R&D strategy and operations, alliance management, and project / portfolio management for biotechnology, pharmaceutical, and medical device companies.

6/2013 – 5/2018 VP, R&D Operations and Alliance Management Edison Pharmaceuticals, Inc. / BioElectron Technology Corporation

Research to develop treatments for mitochondrial diseases which are frequently inherited, primarily affect children, and commonly result in severe neurological impairment and death. Mitochondrial diseases share the common feature of defects in DNA that encode proteins critical to the process of regulating the flow of electrons known as redox control, which is essential to the generation and regulation of energy.

- Responsible for cross-functional team management and coordination of company-wide R&D operations.
- Led alliance management activities for partnered drug development projects. Responsible for tracking adherence to provisions in a global License and Collaboration Agreement with Sumitomo Dainippon Pharma Co. Ltd.
- Responsible for authoring, review, and revision of partnership agreements, pharmacovigilance agreements, supply agreements, and quality agreements.
- Participated in authoring, review, revision, and submission of regulatory documents including pre-IND documentation, IND submissions, Investigator's Brochures, Development Safety Update Reports (DSURs), orphan designation applications, Rare Pediatric Disease Designation Applications, IND information amendments, FDA and EMA meeting correspondence, and NDA documents.

6/1998 – 4/2013 Affymax, Inc.

Played a critical role in a number of drug discovery, development, and commercialization projects, including leadership of the alliance and project management function for development and commercialization of peginesatide (Omontys®).

2013 Executive Director, Operations and Alliance Management Chief of Staff to the CEO

- Responsible for the central coordination of corporate activities in operations and strategic planning for Affymax.

- Manage strategic projects with a primary focus on business initiatives that require cross-functional coordination.

1/2009 – 2/2013 Executive Director, Alliance and Project Management

- Led Product Team for Affymax lead product, peginesatide (Omontys®).
- Led global alliance teams for partnered product.
- Provided project management leadership to product Launch Team.
- Provided project and alliance management leadership to NDA teams for novel product candidate, resulting in NDA submission, positive FDA advisory committee, and FDA approval.
- Member of portfolio evaluation / corporate development team evaluating new pipeline opportunities.

7/2006 – 12/2008 Senior Director, Alliance and Project Management

- Led alliance and project management department.
- Led internal development team for novel product candidate, peginesatide, for the treatment of anemia in adult patients with CKD on dialysis.
- Managed partner alliances, both strategic execution as well as day to day operations.
- Primary alliance liaison for partnership with Takeda Pharmaceutical Company Ltd. on lead product candidate:
 - Helped identify strategic opportunities to maximize value for partnered program.
 - Provided infrastructure, set project objectives, and developed communication channels and decision-making procedures, to ensure successful outcomes for product partnership with Takeda.
 - Streamlined scientific, business, and contractual aspects of the partnership.

8/2004 – 6/2006 Director, Project Management

- Responsible for building and leading cross-functional project teams to facilitate and manage the timely and efficient execution of R&D project plans.
- Develop, monitor, and communicate objectives and timelines for internal as well as external research.
- Help manage IB, IND, CTA, IRB, and REC document writing, review, and assembly for IND/CTA and IRB/EC submissions.
- Contribute to investigational drug partnering, strategic positioning of Affymax, and pipeline expansion.

6/2002 – 7/2004 Associate Director, Project Management

- Project Team Lead of the cross-functional investigational drug Development Team responsible for all aspects of Affymax's EPO receptor agonist R&D.
- Team Lead of the cross-functional Oncology Project Team responsible for the strategic planning and operation of the oncology projects at Affymax, including Affymax's G-CSF receptor agonist program.
- Team Lead of the Target Selection Team, responsible for selection of new drug targets, and prioritization of targets.

11/2000 – 6/2002 Senior Scientist, Biology

- Participated in the creation of a new systems-based research program at Affymax. Contributed to the selection of the program's first target class (protein tyrosine phosphatases) and first validated target (PTP1B).
- Identified and tested mammalian cell lines as disease models. Evaluated new pharmacophores in cellular models.

9/1999 – 11/2000 Staff Scientist II

- Helped implement an in vivo analytics program at Affymax.
- Initiated projects to discover new drug delivery methods.

6/1998 – 9/1999 Staff Scientist I

- Discovered and developed novel technologies in genomics (multiplexed genotyping, SNP detection and analysis).
- Enabled novel solid-phase PCR method for direct genotyping with human genomic DNA.

1993 – 1998 Stanford University School of Medicine

Department of Structural Biology (Dr. Roger D. Kornberg)

Postdoctoral work on structural studies of eukaryotic transcription complexes. Initiated, designed, and successfully completed research in electron crystallography. Active member of the team solving the X-ray crystal structure of RNA polymerase II. This research was part of the work recognized with the 2006 Nobel Prize in Chemistry to Roger Kornberg. Authored and received grants for this work.

Department of Medicine (Dr. Gilbert Chu)

Postdoctoral work on structural studies of DNA-dependent protein kinase (DNA-PK), a large DNA repair enzyme.

1991 - 1993 UT Southwestern Medical Center

Co-inventor in the development of a simple method for protein and peptide purification using a site-specific protease (TEV protease). Collaborated with Life Technologies (now Thermo Fisher Scientific) on commercialization of this protease.

1988 - 1993 Duke University and UT Southwestern Medical Center

Graduate Program in Biochemistry, Genetics and Development (Dr. Stephen Johnston)

Applied molecular biology, biochemistry, and yeast genetics to study interactions of proteins that control gene expression. Generated numerous mutations in transcriptional regulatory proteins and evaluated their altered functions in vitro and in vivo.

PhD Thesis: Leuther K.K. (1993) Genetic, biochemical, and biophysical analysis of the transcriptional activator GAL4 and its interaction with the negative regulator GAL80. University of Texas Southwestern Medical Center, Dallas, TX.

EDUCATION

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| 1993 | PhD in Biochemistry, Genetics, and Development
University of Texas, Southwestern Medical Center, Dallas, TX |
| 1988 | BA Summa Cum Laude in Biology, University of Jamestown, Jamestown, ND |

PROFESSIONAL TRAINING

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| 2021 | Global Health Training Center ICH Good Clinical Practice (GCP) E6 (R2) |
| 2021 | Advanced Renal Education Program Home Dialysis: A Patient's Journey Through Transitional Care |

2021	Lifeline Vascular Care: Critical Thinking for Access Preservation
2020	Institute for Healthcare Improvement (IHI) Certificate in Quality & Safety
2020	Pfiedler Education: Foundations of Peritoneal Dialysis Nursing
2011	Affymax Leadership Development Initiative, Center for Creative Leadership
2009	Developing the Strategic Leader, Center for Creative Leadership
2008	Executive Education for Women: Next Generation Bioscience Leaders, Smith-Keck Graduate Institute
2004	Project Management in the Research-Based Pharmaceutical Industry, Pharmaceutical Education and Research Institute (PERI)

EXPERTISE AND SKILLS

- Clinical Research
- R&D Strategy
- Drug and Medical Device Development
- Corporate Operations
- Project, Portfolio, and Alliance Management
- Strong Communicator
- Scientific Due Diligence
- Process and Workflow Development

HONORS AND AWARDS

2018	Alumni Hall of Fame, University of Jamestown
2014	The United States President's Volunteer Service Award, Gold Level. In recognition and appreciation of commitment to strengthening our Nation and for making a difference through volunteer service.
2011	Best Team Spirit Award, Affymax Inc.
1999	Special Achievement Award (honoring top two Staff Scientists), Affymax
1996-1998	Grant Funding: Senior Postdoctoral Fellowship of the American Cancer Society
1994-1996	Grant Funding: Postdoctoral Fellowship of the Cancer Research Fund of the Damon Runyon Cancer Research Foundation
1993	Nominata Award for research achievements and academic excellence (awarded to one graduate student each year), UT Southwestern Medical Center
1988	College Fellow in Biology, University of Jamestown
1986-1988	Foreign Exchange Scholarship, University of Jamestown

VOLUNTEERING

2007 - Present **California County of Santa Clara, Parks Department**
Equestrian and Hiker Trail Watch Volunteer: Trail patrol and maintenance, event support.

2018 – 2020 VITAS Healthcare

Hospice Volunteer: Friendly visits to hospice patients, their families, and their caregivers. Provided dog-assisted visits for emotional support as needed.

ADDITIONAL INFORMATION

Bilingual proficiency in English and German.

Dual Citizenship USA and Germany.

PUBLICATIONS

Angell Y.M., Bhandari A., De Francisco M.N., Frederick B.T., Green J.M., Leu K., **Leuther K.**, Sana R., Schatz P.J., Whitehorn E.A., Wright K., Holmes C.P. (2009) Discovery and optimization of a TRAIL R2 agonist for cancer therapy. *Adv Exp Med Biol.*;611:101-3. https://link.springer.com/chapter/10.1007/978-0-387-73657-0_45

Fan Q., **Leuther K.K.**, Holmes C.P., Fong K.L., Zhang J., Velkovska S., Chen M.J., Mortensen R.B., Leu K., Green J.M., Schatz P.J., Woodburn K.W. (2006) Preclinical evaluation of Hematide, a novel erythropoiesis stimulating agent, for the treatment of anemia. *Exp Hematol.* Oct;34(10):1303-11. [https://www.exphem.org/article/S0301-472X\(06\)00329-8/fulltext](https://www.exphem.org/article/S0301-472X(06)00329-8/fulltext)

Stead R.B., Lambert J., Wessels D., Iwashita J.S., **Leuther K.K.**, Woodburn K.W., Schatz P.J., Okamoto D.M., Naso R., Duliege A.M. (2006) Evaluation of the safety and pharmacodynamics of Hematide, a novel erythropoietic agent, in a phase 1, double-blind, placebo-controlled, dose-escalation study in healthy volunteers. *Blood.* Sep 15;108(6):1830-4. <https://ashpublications.org/blood/article/108/6/1830/22675/Evaluation-of-the-safety-and-pharmacodynamics-of>

Brewerton S. C., Dore A. S., Drake A. C., **Leuther K. K.**, Blundell T. L. (2004). Structural analysis of DNA-PKcs: modeling of the repeat units and insights into the detailed molecular architecture. *J. Struct. Biol.* 145(3):295-306. <https://www.sciencedirect.com/science/article/abs/pii/S1047847703002971?via%3Dihub>

Shapero, M. H.* , **Leuther, K. K.***, Nguyen, A., Scott, M., and Jones, K. W. (2001). SNP Genotyping by multiplexed solid-phase amplification and fluorescent minisequencing. *Genome Research* 11:1926-1934 *M.H.S. and K.K.L. contributed equally to this work. <https://genome.cshlp.org/content/11/11/1926.long>

Leuther, K. K., Hammarsten, O. J., Kornberg, R. D., and Chu, G. (1999). Structure of DNA-dependent protein kinase: implications for its regulation by DNA. *EMBO J.* 18:1114-1123. <https://www.embopress.org/doi/full/10.1093/emboj/18.5.1114>

Myers, L. C., **Leuther, K. K.**, Bushnell, D. A., Gustafsson, C. M., and Kornberg, R. D. (1997). Yeast RNA polymerase II reconstituted with purified proteins. *Methods (Orlando)* 12:212-216. <https://www.sciencedirect.com/science/article/pii/S1046202397904734?via%3Dihub>

Leuther, K. K., Bushnell, D. A., and Kornberg, R. D. (1996). Two-dimensional crystallography of transcription factor IIB- and IIE- RNA polymerase II complexes: Implications for start site selection and initiation complex formation. *Cell* 85:773-779. [https://www.cell.com/cell/fulltext/S0092-8674\(00\)81242-8?returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0092867400812428%3Fshowall%3Dtrue](https://www.cell.com/cell/fulltext/S0092-8674(00)81242-8?returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0092867400812428%3Fshowall%3Dtrue)

Parks, T. D., **Leuther, K. K.**, Howard, E. D., Johnston, S. A., and Dougherty, W. G. (1994). Release of proteins and peptides from fusion proteins using a recombinant plant virus proteinase. *Analytical Biochemistry* 216:413-417. <https://www.sciencedirect.com/science/article/abs/pii/S0003269784710608?via%3Dihub>

Leuther, K. K., Salmeron, J. M., and Johnston, S. A. (1993). Genetic evidence that an activation domain of GAL4 does not require acidity and may form a β -sheet. *Cell* 72:575-585. [https://www.cell.com/cell/pdf/0092-8674\(93\)90076-3.pdf?returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2F0092867493900763%3Fshowall%3Dtrue](https://www.cell.com/cell/pdf/0092-8674(93)90076-3.pdf?returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2F0092867493900763%3Fshowall%3Dtrue)

Van Hoy, M. *, **Leuther, K. K. ***, Kodadek, T., and Johnston, S. A. (1993). The acidic activation domains of the GCN4 and GAL4 proteins are not α -helical, but form β -sheets. *Cell* 72:587-594. *M.V.H. and K.K.L. contributed equally to this work. [https://www.cell.com/cell/pdf/0092-8674\(93\)90077-4.pdf?returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2F0092867493900774%3Fshowall%3Dtrue](https://www.cell.com/cell/pdf/0092-8674(93)90077-4.pdf?returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2F0092867493900774%3Fshowall%3Dtrue)

Leuther, K. K. and Johnston, S. A. (1992). Nondissociation of GAL4 and GAL80 *in vivo* after galactose induction. *Science* 256:1333-1335. https://www.science.org/doi/10.1126/science.1598579?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed

Salmeron, J. M., **Leuther, K. K.**, and Johnston, S. A. (1990). GAL4 mutations that separate the transcriptional activation and GAL80-interactive functions of the GAL4 protein. *Genetics* 125:21-27. <https://academic.oup.com/genetics/article/125/1/21/6000734?login=false>

PATENTS

Duliege, A-M., Stead, R., **Leuther, K.**, Woodburn, K., Naso, R. (2012). Erythropoietin receptor peptide formulations and uses. US Patent 8,324,159.

Duliege, A-M., Stead, R., **Leuther, K.**, Woodburn, K., Naso, R. (2011). Erythropoietin receptor peptide formulations and uses. US Patent 7,919,461.

Duliege, A-M., Stead, R., **Leuther, K.**, Woodburn, K., Naso, R. (2011). Erythropoietin receptor peptide formulations and uses. US Patent 7,906,485.

Duliege, A-M., Stead, R., **Leuther, K.**, Woodburn, K., Naso, R. (2009). Erythropoietin receptor peptide formulations and uses. US Patent 7,550,433.

Angell, Y. M., Bhandari, A., DeFrancisco, N., Frederick, B., Green, J. Leu, K. **Leuther, K.**, Sana, R., Whitehorn, E., Schatz, P., Holmes, P. (2009). Compounds and Peptides that bind the TRAIL receptor, WIPO Patent Application WO/2009/002947.

Jones, K., **Leuther, K. K.**, Shapero, M. H. (2002). High throughput polymorphism screening in nucleic acid samples. *Eur. Pat. Appl.*, EP 1256632A3.