# KELVIN H. LEE – Gore Professor

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**EDUCATION:**

***Ph.D.* Chemical Engineering (minor in Biology)** *4/95*
California Institute of Technology

***M.S.* Chemical Engineering** *4/93*
California Institute of Technology

***B.S.E.* Chemical Engineering and Certificate in Engineering Biology** *6/91*
Princeton University

**PROFESSIONAL EXPERIENCE:**

**National Institute for Innovation in Manufacturing Biopharmaceuticals**

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| Institute Director | 1/17-present |

**University of Delaware**

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| Gore Professor of Chemical & Biomolecular Engineering | 8/07-present |
| Senior Research Scientist, ChristianaCare Health System | 9/11-present |
| Director, NSF IGERT: Systems Biology of Cells in Engineered Environments | 7/12-present |
| Director, Delaware Biotechnology Institute | 9/08-1/17 |

**Cornell University**

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| Professor School of Chemical & Biomolecular Engineering | 4/07–8/07 |
| The Samuel C. and Nancy M. Fleming Professor of Molecular and Cell Biology | 2005-2007 |
| Director of the Institute for Biotechnology and Life Science Technologies | 2005-2007 |
| Director of the New York State Center for Life Science Enterprise | 2005-2007 |
| Director, Cornell Proteomics Program | 2001-2005 |
| Faculty Director, Cornell Proteomics and Mass Spectrometry Facility | 2003-2005 |
| Associate Professor, School of Chemical and Biomolecular Engineering | 4/03–4/07 |
| Assistant Professor, School of Chemical and Biomolecular Engineering | 11/97–4/03 |

**Education / Training**

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| Postdoctoral Scholar, Biology Division, California Institute of Technology | 9/95–10/97 |
| Graduate Research Asst. and Research Fellow, Inst. Biotech.<br>Swiss Federal Institute of Technology (Zürich, Switzerland) | 4/93-9/95 |
| Graduate Research Asst., Chemical Engineering/Molecular Biotech.<br>California Institute of Technology | 9/91-4/93 |

**HONORS**

· National Science Foundation Graduate Fellowship (1991-1994)
· DuPont Young Professor (1999-2002)
· National Science Foundation CAREER Award (1999-2003)
· Invited participant in NSF New Century Scholars workshop, Stanford CA Aug 1-6, 1999

· Invited participant in the National Academy of Engineering Third German-American Frontiers of Engineering Symposium, Bremen, Germany April 13-15, 2000
· J.P. and Mary Barger '50 College of Engineering Excellence in Teaching Award 2000
· MIT *Technology Review* Top 100 Innovators in the World in Business & Technology 2002
· Jay Bailey Young Investigator Best Paper Award in *Metabolic Engineering* 2002
· Camille Dreyfus Teacher-Scholar Award 2003
· Invited participant in the National Academy of Engineering Frontiers of Engineering Symposium, Irvine CA September 17-20, 2003
· Cornell Provost's Ronay and Richard Menschel Award for Distinguished Scholarship 2004.
· Distinguished Professor, NYS Office of Science, Technology and Academic Research 2004.
· Samuel C. and Nancy M. Fleming Professor of Molecular and Cell Biology 2005.
· Gore Professor of Chemical Engineering 2007.
· Invited participant in the National Academy of Engineering Japan-American Frontiers of Engineering Symposium, Kobe Japan November 15-17, 2008.
· Inaugural Winner of the *Biochemical Engineering* Journal Young Investigator Award, 2009.
· Elected Fellow of American Institute of Medical and Biological Engineers, 2010.
· Elected Fellow of American Association for the Advancement of Science, 2011.
· Inaugural Winner of the American Electrophoresis Society Award, 2011.
· *Bioprocess International* Upstream Collaboration of the Decade Finalist, 2012.
· Professional Progress Award for Outstanding Progress in Chemical Engineering, AIChE, 2013.
· Delaware Scientist of the Year, Delaware Bioscience Association, 2016.
· Biotechnology and Bioengineering Elmer Gaden Award for Outstanding Publication, 2017.
· ACS BIOT Marvin Johnson Award in Microbial and Biochemical Technology. 2018.

## RESEARCH ACTIVITIES

**Key accomplishments**

Lead the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), a Manufacturing USA institute dedicated to biopharmaceutical manufacturing with 5 year, $250M+ commitment to advance manufacturing readiness levels 4-7 technologies and the American biomanufacturing workforce. Viewed as the national leader in industry, academic, government issues around biopharmaceutical manufacturing.

Co-leads the Advanced Mammalian Biomanufacturing Innovation Center (AMBIC), a public-private consortium supported by NSF to address manufacturing readiness levels 2-4 technologies in upstream biopharmaceutical manufacturing.

Leads the international CHO (Chinese hamster ovary) cell genome community committed to sequencing, sharing, and standardizing genomes relevant to the biopharmaceutical industry.

Developed novel technologies for quantitative proteomic analysis - methods that are widely used in a variety of contexts.

Developed the first biochemical test for antemortem diagnosis of Creutzfeldt-Jakob disease and other prion diseases. The test is widely used in the clinical diagnosis of CJD around the world.

Developed the first new set of molecular diagnostic proteins for Alzheimer's disease diagnosis. These molecular diagnostics are being evaluated today.

## Peer-Reviewed Journal Publications since 2014

103) Levy N, Valente K, Choe LH, Lee KH, Lenhoff A (2014). Identification and Characterization of Host Cell Protein Product-Associated Impurities in Monoclonal Antibody Bioprocessing. *Biotechnol. Bioeng.* 111: 904-912. doi: 10.1002/bit.25158. PMID: 24254318

104) Baik JY, KH Lee (2014). miRNA Expression in CHO: Nature Knows Best. Biotechnology J. 9:459-460. PMID: 24519876 doi: 10.1002/biot.201300503

105) Wuest, DM, KH Lee (2014). Amyloid-β concentration and structure influences the transport and immunomodulatory effects of IVIG. J. Neurochem. 130: 136-144. doi: 10.1111/jnc.12678 PMID: 24517534

106) Yuk IM, Zhang JD, Ebeling M, Werz S, Gomez N, Berrera M, Meiringer C, Shao Z, Swanberg J, KH Lee, Luo J, and B Szperalski (2014). Effects of Copper on CHO Cells: Insights from Gene Expression Analyses. Biotechnology Progress. 30: 429-442. DOI: 10.1002/btpr.1868 PMID: 24403277

107) Tuerk A, KH Lee (2014). The Evolving Engineer. AIChE Journal 60: 1956-1963.

108) Shayan G, Adamiak B, Choe LH, Relkin NR, and KH Lee (2014). Longitudinal Effects of Intravenous Immunoglobulin on Alzheimer's Cerebrospinal Fluid Proteome. Electrophoresis 35: 1821-1827. PMID: 24756957

109) Baik JY, and KH Lee (2014). Toward Product Attribute Control: Developments From Genome Sequencing. Current Opinion in Biotechnology. 30: 40-44. PMID: 24874795

110) Kremkow B and KH Lee (2015). Sequencing Technologies for Animal Cell Culture Reseach. Biotechnology Letters. 37: 55-65.

111) Valente K, Lenhoff A, and KH Lee (2015). Expression of Difficult-to-Remove Host Cell Protein Impurities During Extended Chinese Hamster Ovary Cell Culture and Their Impact on Continuous Bioprocessing. *Biotech. Bioeng.* 112 (6), 1232-1242.

112) Min L, Choe LH, and KH Lee (2015). Improved protease digestion conditions for membrane protein detection. *Electrophoresis*. 36:1690-8. doi: 10.1002/elps.201400579. PMID: 2588427

113) Kremkow B, Baik JY, MacDonald ML, and KH Lee (2015). "CHOgenome.org 2.0: Genome resources and website updates". Biotechnology Journal. 10: 931-938.

114) Venkataramanan KP, Min L, Jones SW, Hou S, Ralston MR, Lee KH and ET Papoutsakis (2015). "Complex and extensive post-transcriptional regulation revealed by integrative proteomic and transcriptomic analysis of metabolite stress response in *Clostridium acetobutylicum*". Biotechnology for Biofuels Biology. 8:81. doi: 10.1186/s13068-015-0260-9. PMID: 26269711 PMCID: PMC4533764

115) Choi YS, Lee KH (2015). Multiple reaction monitoring assay based on conventional liquid chromatography and electrospray ionization for simultaneous monitoring of multiple cerebrospinal fluid biomarker candidates for Alzheimer's disease. *Arch. Pharm. Res.* doi 10.1007/s12272-015-0663-y. PMID: 26404792

116) Levy N, Valente K, Lee KH, Lenhoff A (2016). "Host cell protein impurities in chromatographic polishing steps for monoclonal antibody purification". *Biotechnol Bioeng.* 113(6):1260-72. doi: 10.1002/bit.25882 PMID: 26550778

117) Heintz KA, Bregenzer ME, Mantle JL, Lee KH, West JL, JH Slater (2016). Fabrication of Three-Dimensional Biomimetic Microfluidic Networks in Hydrogels. Adv. Healthc. Mater. 5: 2153-2160. 10.1002/adhm.201600351. PMID: 27239785 PMCID: PMC5014628.

118) Baik, JY, Lee KH (2016). Toward improved host cell protein impurity assessment. Biotechnology J. 11: 998-999. doi: 10.1002/biot.201600223. PMID: 27331371

119) Levy, A, Lee KH, TE Hanson (2016). *Chlorobaculum tepidum* modulates amino acid composition in response to energy availability, as revealed by a systematic exploration of the energy landscape of phototrophic sulfur oxidation. Appl Environ Microbiol. 82: 6431-6439. PMID: 27565613 PMCID: PMC5066360

120) Mantle J, Min L, Lee KH (2016). Minimum Transendothelial Electrical Resistance Thresholds for the Study of Small and Large Molecule Drug Transport in a Human in Vitro Blood-Brain Barrier Model. Molecular Pharmaceutics.13:4191-4198. PMID: 27934481

121) Harcum S, Lee KH (2016). CHO Cells Can Make More Protein. Cell Syst. 3:412-413. PMID: 27883886

122) Baik JY, Lee KH (2017). A framework to quantify karyotype variation associated with CHO production instability. Biotechnol Bioeng. 114:1045-1053. PMID: 27922175

123) Chiu J, Valente KN, Levy NE, Min L, Lenhoff AM, Lee KH (2017). Knockout of a difficult-to-remove CHO host cell protein, lipoprotein lipase, for improved polysorbate stability in monoclonal antibody formulations. Biotechnol Bioeng. 114:1006-1015. PMID: 27943242 PMCID: PMC5360534

124) Lertsuwan K, Choe LH, Marwa I, Lee, KH, Sikes, R (2017). Identification of Fibulin-1 as a Human Bone Marrow Stromal (HS-5) Cell-Derived Factor that Induces Human Prostate Cancer Cell. *Prostate*. Prostate. 77:729-742. PMID: 28168724

125) Lee KH, Springs S, Carbonell RG (2017). National Institute to Accelerate Innovation in Biopharmaceutical Manufacturing. BioProcess International. 15(9)i:12-16.

126) Rehmann, Matthew; Skeens, Kelsi; Kharkar, Prathamesh; Maverakis, Emanual; Lee, Kelvin; Kloxin, April (2017). Tuning and predicting mesh size and protein release from step growth hydrogels. Biomacromolecules 18:3131-3142. PMID: 28850788

127) Valente K*, Levy N*, Lee KH, Lenhoff AM (2018). Applications of Proteomic Methods for CHO Host Cell Protein Characterization in Biopharmaceutical Manufacturing. Current Opinion in Biotechnology 2018, 53:144–150. PMID: 29414072

128) Weintraub W and Lee KH (2018). Advances in Cardiovascular Care: How to Stimulate Innovation While Controlling Cost. Accepted. JACC: Basic to Translational Science. 3, 114-118. PMID: 30062198

129) Baik JY, Lee KH (2018). Growth rate changes in CHO host cells are associated with karyotypic heterogeneity. Biotechnology Journal. 13(3):e1700230. doi: 10.1002/biot.201700230. PMID: 28865132

130) Kremkow B, Lee KH (2018). Glyco-Mapper: A Chinese hamster ovary (CHO) genome-specific glycosylation prediction tool. Metabolic Engineering. 47:134-142. doi: 10.1016/j.ymben.2018.03.002. PMID: 29522825

131) Sawicki, L, Choe L, Wiley K, Lee KH, Kloxin AM (2018). Isolation and identification of protein secreted by cells cultured within synthetic hydrogel-based matrices. Accepted. ACS Biomaterials Science & Engineering. 4(3):836-845. doi: 10.1021/acsbiomaterials.7b00647. PMID: 29552635 PMCID: PMC5850091

132) Greene DG, Traylor SJ, Guo J, Choe LH, Modla S, Xu X, Singh N, Lock LL, Ghose S, Li ZJ, Lee KH, Wagner NJ, Lenhoff AM (2018). Mechanisms of precipitate formation during the purification of an Fc-fusion protein. Biotechnology and Bioengienering 115: 2489-2503. doi: 10.1002/bit.26746. PMID: 29896879 PMCID: PMC6185765

133) Rupp O*, MacDonald ML*, Li S, Dhiman H, Griep S, Heffner K, Hernandez I, Brinkrolf K, Polson S, Kingham B, Samoudi M, Betenbaugh M, Goesmann A, Lewis NE, Borth N, Lee KH (2018). A reference genome of the Chinese hamster based on a hybrid assembly strategy. Biotechnology and Bioengineering. 115: 2087-2100. DOI: 10.1002/bit.26722. PMID: 29704459 PMCID: PMC6045439.

134) Mantle JL, Lee, KH (2018). A differentiating neural stem cell-derived astrocytic population mitigates the inflammatory effects of TNF-α and IL-6 in an iPSC-based blood-brain barrier model. Neurobiology of Disease **119**: 113-120. PMID: 30075293 DOI: 10.1016/j.nbd.2018.07.030. PMID: 30075293

135) MacDonald M, Hamaker N, Lee KH (2018). Bioinformatic analysis of Chinese hamster ovary host cell protein lipases. AIChE Journal. 64: 4247-4254. doi.org/10.1002/aic.16378

136) Ruano-Salguero R, Lee KH (2018). Efflux Pump Substrates Shuttled to Cytosolic or Vesicular Compartments Exhibit Different Permeability in a Quantitative Human Blood-Brain Barrier Model. Molecular Pharmaceutics. **15**:5081-5088. doi: 10.1021/acs.molpharmaceut.8b00662. PMID: 30212633

137) Dahodwala H, Lee KH (2018). The Fickle CHO: A review of the causes, implications and potential alleviation of the CHO cell line instability problem. Accepted. Current Opinion in Biotechnology. 60:128-137. doi: 10.1016/j.copbio.2019.01.011

138) Hamaker N, Lee KH (2018). Site-specific Integration Ushers in a New Era of Precise CHO Cell Line Engineering. Current Opinion in Chemical Engineering. 22:152-160. 10.1016/j.coche.2018.09.011

139) Mantle JL, Lee KH (2018). IgG transport increases at the blood-brain barrier during Alzheimer's disease and neuroinflammation. Accepted