

Curriculum Vitae

Theodore W. Randolph
Professor
Department of Chemical and Biological Engineering
University of Colorado
Boulder, CO 80309

Education

1983-1987 University of California, Berkeley, Ph.D. Chemical Engineering, 1987.
1981-1983 University of Colorado, Boulder, B.S. Chemical Engineering, 1983.
1979-1981 University of Arizona, Tucson, Major: Chemical Engineering.

Professional Experience

- 1987- 1989: Chemical Engineer/ Collaborateur Scientifique, Swiss Federal Institute of Technology, Lausanne, Switzerland.
- 1989-1992: Assistant Professor, Department of Chemical Engineering, Yale University.
- 1993: Associate Professor, Department of Chemical Engineering, Yale University
- 1993: Patten Associate Professor, Department of Chemical Engineering, University of Colorado, Boulder
- 1997: Co-Director, University of Colorado Center for Pharmaceutical Biotechnology
- 1999: Professor, Department of Chemical Engineering, University of Colorado, Boulder
- 2005-present: Gillespie Chaired Professorship in Bioengineering, University of Colorado, Boulder

Awards

- Ebert Prize, American Pharmacists Association, 2023
- National Academy of Inventors, Fellow, 2022
- Ebert Prize, American Pharmacists Association, 2019
- American Association of Pharmaceutical Scientists Dale E. Wurster Research Award in Pharmaceutics, 2010
- John M. Prausnitz Award in Applied Thermodynamics, Properties and Phase Equilibria for Product and Process Design, Suzhou, China, 2010
- American Association of Pharmaceutical Scientists, Fellow, 2009
- Bayer Lectureship in Biochemical Engineering, University of California, Berkeley, 2008
- American Society of Engineering Educators Dow Lectureship Award, 2007
- Ebert Award, Best Original Investigation in 2006, American Pharmacists Association
- American Institute of Chemical Engineers, Professional Progress Award, 2005
- Boulder Faculty Assembly Research and Creative Work Award 2003
- College of Engineering and Applied Sciences Max Peters Award for Outstanding Service 2002
- Outstanding Graduate Teaching Award, Department of Chemical Engineering, 2000
- Faculty Fellowship, University of Colorado, Boulder 1999-2000
- College of Engineering and Applied Sciences Outstanding Research and Service Award, 1998
- Invited Foreign Researcher, Japanese Agency of Industrial Science and Technology, 1995
- Patten Associate Professor Chair in Chemical Engineering, University of Colorado, Boulder, 1993
- John J. Lee Junior Professorship Chair in Chemical Engineering, Yale University, 1993
- Senior Faculty Fellowship, Yale University, 1993
- National Science Foundation Presidential Young Investigator Award, 1991

Patents (US)

1. "Producing Products by Enzyme Catalyzed Reactions in Supercritical Fluids" U.S. Patent No. 4,925,790, issued May 15, 1990.
2. "Solubilization of Pharmaceutical Substances in an Organic Solvent and Preparation of Pharmaceutical Powders Using the Same", U.S. Patent #5,770,559, June 23, 1998, M.C. Manning, T.W. Randolph, E. Shefter, R.F. Falk

3. "Solubilization of Pharmaceutical Substances in an Organic Solvent and Preparation of Pharmaceutical Powders Using the Same", U.S. Patent #5,981,474, November 9, 1999, M.C. Manning, T.W. Randolph, E. Shefter, R.F. Falk
4. "Chemical reactions in water-in-carbon dioxide microemulsions and control thereof" U.S. Patent 5,814,678, September 29, 1998
5. "High Pressure Refolding of Protein Aggregates and Inclusion Bodies" U.S. Patent 6,489,450, December 3, 2002
6. "High Pressure Refolding of Protein Aggregates and Inclusion Bodies" U.S. Patent 7,064,192 June 20, 2006
7. "Microparticles of Lactide-Co-Glycolide Copolymers and Methods of Making and Using the Same", " U.S. Patent 6,319,521, November 20, 2001
8. "Preparation and Use of Photopolymerized Microparticles" " U.S. Patent 6,403,672, June 11, 2002
9. "Preparation and Use of Photopolymerized Microparticles" " U.S. Patent 6,864,301, March 8, 2005
10. "Sustained-release composition including amorphous polymer" U.S. Patent 6,613,358 September 2, 2003, and Canadian Patent No. 2,324,254, Issued January 4, 2005.
11. "Hydroxyethyl starch—containing polypeptide compositions" U.S. Patent. 6,982,080, January 3, 2006
12. "Hydroxyethyl starch—containing polypeptide compositions" U.S. Patent 7,449,444, November 11, 2008
13. "Devices and Methods for the Production of Particles" U.S. Patent 7,332,111, February 19, 2008
14. "Spray freeze dry of compositions for pulmonary administration" U.S. Patent 7,923,029, April 12, 2011
15. High-pressure inclusion body solubilization and protease clipping of recombinant fusion proteins" U.S. Patent 7,829, 681, November 9, 2010
16. "High Pressure Refolding of Protein Aggregates and Inclusion Bodies" U.S. Patent 7,767,795, Aug 3, 2010
17. "Methods for protein refolding" U.S. Patent 7,538,198, May 26, 2009
18. Spray Freeze dried Compositions for pulmonary administration, U.S. Patent 8,239,275, October 23, 2012
19. "Methods for Protein Refolding" U.S. Patent 8,329,878, Dec 11, 2012
20. "Method of preparing an immunologically-active adjuvant-bound dried vaccine composition" U.S. Patent 8,444,991, May 21, 2013.
21. "Methods for evaluating the aggregation of a protein in a suspension including organopolysiloxane and medical articles coated with organopolysiloxane containing a protein solution", U.S. Patent 8,633,034, January 21, 2014
22. "Method for reducing immunogenicity of therapeutic protein compositions", U.S. Patent 8,697,848, April 15, 2014
23. "High Pressure Refolding of Protein Aggregates and Inclusion Bodies" U.S. Patent 8,710,197, April 29, 2014
24. "High pressure refolding of monoclonal antibody aggregates". U.S. Patent 8,802,828, August 14, 2014
25. "Method of preparing an immunologically-active adjuvant-bound dried vaccine composition", U.S. Patent 8,808,710, August 19, 2014
26. "Compositions and methods for making and using thermostable immunogenic formulations with increased compatibility of use as vaccines against one or more pathogens" U.S. Patent 10,751,408, August 25, 2020
27. "Compositions, methods and uses for thermally stable multi-targeted antigens" U.S. Patent 11,273,127, March 15, 2022
28. "Compositions and methods for making and using thermostable immunogenic formulations with increased compatibility of use as vaccines against one or more pathogens" U.S. Patent 11,364,293, June 21, 2022

29. “Thermostable vaccine compositions and methods of preparing same” U.S. Patent No. 11,491,111, November 8, 2022

Publications

256. Witeof, A. E.; Meinerz, N. M.; Walker, K. D.; Funke, H. H.; Garcea, R. L.; Randolph, T. W. (2023) A Single Dose, Thermostable, Trivalent Human Papillomavirus Vaccine Formulated Using Atomic Layer Deposition. *J Pharm Sci*. DOI: 10.1016/j.xphs.2023.02.007
255. Greenblott, D. N., Zhang, J., Calderon, C. P., & Randolph, T. W. (2022). Machine Learning approaches to root cause analysis, characterization, and monitoring of subvisible particles in monoclonal antibody formulations. *Biotechnology and Bioengineering*, 1–16. <https://doi.org/10.1002/bit.28239>
254. Thite NG, Ghazvini S, Wallace N, Feldman N, Calderon CP, Randolph TW. Machine Learning Analysis Provides Insight into Mechanisms of Protein Particle Formation Inside Containers During Mechanical Agitation. *J Pharm Sci*. 2022 Jul 11:S0022-3549(22)00262-3. doi: 10.1016/j.xphs.2022.06.017. Epub ahead of print. PMID: 35835184.
253. Calderon CP, Ripple DC, Srinivasan C, Ma Y, Carrier MJ, Randolph TW, O'Connor TF. Testing Precision Limits of Neural Network-Based Quality Control Metrics in High-Throughput Digital Microscopy. *Pharm Res*. 2022 Feb;39(2):263-279. doi: 10.1007/s11095-021-03130-9. Epub 2022 Jan 26. PMID: 35080706.
252. Alyssa E Witeof, Wynton D McClary, Laura T Rea, Qin Yang, Madison M Davis, Hans H Funke, Carlos E Catalano, Theodore W Randolph. Atomic-Layer Deposition Processes Applied to Phage λ and a Phage-like Particle Platform Yield Thermostable, Single-Shot Vaccines. *J Pharm Sci*. 2022 May;111(5):1354-1362. doi: 10.1016/j.xphs.2022.01.013. Epub 2022 Jan 23.
251. Kendall B Preston, Teri Ann S Wong, Michael M Lieberman, Albert To, Chih-Yun Lai, Alex Granados, Holly Thomasson, John Misamore, Jake Yalley-Ogunro, Mehtap Cabus, Hanne Andersen, Oreola Donini, Axel T Lehrer, Theodore W Randolph. Lyophilized Filovirus Glycoprotein Vaccines: Peroxides in a Vaccine Formulation with Polysorbate 80-containing Adjuvant are Associated with Reduced Neutralizing Antibody Titers in both Mice and Non-human Primates. *J Pharm Sci* 2022 Dec;111(12):3424-3434. doi: 10.1016/j.xphs.2022.05.017. Epub 2022 May 21.
250. Movafaghi, S.; Daniels, A. I.; Kelly, M. D.; Witeof, A. E.; Calderon, C. P.; Randolph, T. W.; Goodwin, A. P. Hydrogel Coatings on Container Surfaces Reduce Protein Aggregation Caused by Mechanical Stress and Cavitation. *ACS Applied Bio Materials* **2021**, 4 (9), 6946-6953. DOI: 10.1021/acsabm.1c00622.
250. Preston, K. B.; Wong, T. A. S.; To, A.; Tashiro, T. E.; Lieberman, M. M.; Granados, A.; Feliciano, K.; Harrison, J.; Yalley-Ogunro, J.; Elyard, H. A.; et al. Single-vial filovirus glycoprotein vaccines: Biophysical characteristics and immunogenicity after co-lyophilization with adjuvant. *Vaccine* **2021**, 39 (39), 5650-5657. DOI: 10.1016/j.vaccine.2021.08.003.
249. Benkstein, K. D.; Balakrishnan, G.; Bhirde, A.; Chalus, P.; Das, T. K.; Do, N.; Duewer, D. L.; Filonov, N.; Cheong, F. C.; Garidel, P.; et al. An Interlaboratory Comparison on the Characterization of a Sub-micrometer Polydisperse Particle Dispersion. *J Pharm Sci* **2021**. DOI: 10.1016/j.xphs.2021.11.006.
248. Dong, M.; Meinerz, N. M.; Walker, K. D.; Garcea, R. L.; Randolph, T. W. Thermostability of a Trivalent, Capsomere-Based Vaccine for Human Papillomavirus Infection. *Eur J Pharm Biopharm* **2021**. DOI: 10.1016/j.ejpb.2021.08.008.
247. Hao Wu, Sanli Movafaghi, Irene M. Francino Urdániz, Tessa M. Rowe, Andrew Goodwin, and Theodore W. Randolph. Insulin Fibril Formation Caused by Mechanical Shock and Cavitation. *The Journal of Physical Chemistry B* (2021) Article ASAP DOI: 10.1021/acs.jpcc.1c01997
246. Witeof AE, Daniels AL, Rea LT, Movafaghi S, Kurtz K, Davis M, Eveland RW, Calderon CP, Randolph TW. Machine Learning and Accelerated Stress Approaches to Differentiate Potential Causes of Aggregation in Polyclonal Antibody Formulations During Shipping. *J Pharm Sci*. 2021 Jul;110(7):2743-2752. doi: 10.1016/j.xphs.2021.02.029. Epub 2021 Feb 27. PMID: 33647275.

245. Preston KB, Randolph TW. Stability of lyophilized and spray dried vaccine formulations. *Adv Drug Deliv Rev.* 2021 Jan 21; 171:50-61. PMID: 33484735.
244. Witeof AE, Daniels AL, Rea LT, Movafaghi S, Kurtz K, Davis M, Eveland RW, Calderon CP, Randolph TW. Machine Learning and Accelerated Stress Approaches to Differentiate Potential Causes of Aggregation in Polyclonal Antibody Formulations During Shipping. *J Pharm Sci.* 2021 Feb 27. PMID: 33647275.\
243. Daniels, AL, Calderon, CP, Randolph, TW. Machine learning and statistical analyses for extracting and characterizing “fingerprints” of antibody aggregation at container interfaces from flow microscopy images. *Biotechnology and Bioengineering.* 2020; 117: 3322– 3335. DOI: 10.1002/bit.27501
242. Preston, KB, Monticello, CR, Wong, TAS, To, A, Donini, O, Lehrer, AT, and Randolph, TW. Preservation of Quaternary Structure in Thermostable, Lyophilized Filovirus Glycoprotein Vaccines: A Search for Stability-Indicating Assays. *Journal of Pharmaceutical Sciences* (2020) Volume: 109 (12), 3716-3727 doi: 10.1016/j.xphs.2020.09.011
241. Gandhi, A. V.; Randolph, T. W.; Carpenter, J. F., Conjugation of Emtansine Onto Trastuzumab Promotes Aggregation of the Antibody-Drug Conjugate by Reducing Repulsive Electrostatic Interactions and Increasing Hydrophobic Interactions. *Journal of Pharmaceutical Sciences* 2019, 108 (6), 1973-1983. DOI: 10.1016/j.xphs.2019.01.029.
240. Chisholm, C. F.; Behnke, W.; Pokhilchuk, Y.; Frazer-Abel, A. A.; Randolph, T. W., Subvisible Particles in IVIg Formulations Activate Complement in Human Serum. *Journal of Pharmaceutical Sciences* 2020, 109 (1), 558-565. DOI: 10.1016/j.xphs.2019.10.041.
239. Garcea, R. L.; Meinerz, N. M.; Dong, M.; Funke, H.; Ghazvini, S.; Randolph, T. W., Single-administration, thermostable human papillomavirus vaccines prepared with atomic layer deposition technology. *Npj Vaccines* 2020, 5 (1). DOI: 10.1038/s41541-020-0195-4.
238. Her, C.; Tanenbaum, L. M.; Bandi, S.; Randolph, T. W.; Thirumangalathu, R.; Mallela, K. M. G.; Carpenter, J. F.; Elias, Y., Effects of Tubing Type, Operating Parameters, and Surfactants on Particle Formation During Peristaltic Filling Pump Processing of a mAb Formulation. *Journal of Pharmaceutical Sciences* 2020, 109 (4), 1439-1448. DOI: 10.1016/j.xphs.2020.01.009.
237. Movafaghi, S.; Wu, H.; Urdaniz, I. F. M.; Bull, D. S.; Kelly, M. D.; Randolph, T. W.; Goodwin, A. P., The Effect of Container Surface Passivation on Aggregation of Intravenous Immunoglobulin Induced by Mechanical Shock. *Biotechnology Journal* 2020, 15 (9). DOI: 10.1002/biot.202000096.
236. Snell, J. R.; Kumar, N. S. K.; Suryanarayanan, R.; Randolph, T. W., Nanobubbles in Reconstituted Lyophilized Formulations: Interaction With Proteins and Mechanism of Formation. *Journal of Pharmaceutical Sciences* 2020, 109 (1), 284-292. DOI: 10.1016/j.xphs.2019.05.005.
235. Snell, J. R.; Monticello, C. R.; Her, C.; Ross, E. L.; Frazer-Abel, A. A.; Carpenter, J. E.; Randolph, T. W., DEHP Nanodroplets Leached From Polyvinyl Chloride IV Bags Promote Aggregation of IVIG and Activate Complement in Human Serum. *Journal of Pharmaceutical Sciences* 2020, 109 (1), 429-442. DOI: 10.1016/j.xphs.2019.06.015.
234. Wu, H.; Chisholm, C. F.; Puryear, M.; Movafaghi, S.; Smith, S. D.; Pokhilchuk, Y.; Lengsfeld, C. S.; Randolph, T. W., Container Surfaces Control Initiation of Cavitation and Resulting Particle Formation in Protein Formulations After Application of Mechanical Shock. *Journal of Pharmaceutical Sciences* 2020, 109 (3), 1270-1280. DOI: 10.1016/j.xphs.2019.11.015.
233. Wu, H.; Randolph, T. W., Aggregation and Particle Formation During Pumping of an Antibody Formulation Are Controlled by Electrostatic Interactions Between Pump Surfaces and Protein Molecules. *Journal of Pharmaceutical Sciences* 2020, 109 (4), 1473-1482. DOI 10.1016/j.xphs.2020.01.023
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228. Nejadnik, MR; Randolph, TW; Volkin, DB; Schoneich, C; Carpenter, JF; Crommelin, DJA; Jiskoot, W. Post-production handling and administration of protein pharmaceuticals and potential instability issues. *J Pharm Sci.* 2018 Aug;107(8):2013-2019.
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226. Sorret, L. L.; DeWinter, M. A.; Schwartz, D. K.; Randolph, T. W., Protein-protein interactions controlling interfacial aggregation of rhIL-1ra are not described by simple colloid models. *Protein Sci* 2018.
225. Daniels, A. L.; Randolph, T. W., Flow Microscopy Imaging Is Sensitive to Characteristics of Subvisible Particles in Peginesate Formulations Associated With Severe Adverse Reactions. *J Pharm Sci* 2018.
224. Calderon, C. P.; Daniels, A. L.; Randolph, T. W., Deep Convolutional Neural Network Analysis of Flow Imaging Microscopy Data to Classify Subvisible Particles in Protein Formulations. *J Pharm Sci* 2018, 107 (4), 999-1008.
223. Randolph, T. W., Response to Comment to the Editor. *Biophys J* 2017, 113 (3), 755-756.
222. Latshaw, DC, Randolph, TW, Hall, CK. Aggregation of amphipathic peptides at an aqueous-organic interface using coarse-grained simulations. *Molecular Simulation*, 2017, 1-11.
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218. Mehta SB, Carpenter JF, Randolph TW. Colloidal instability fosters agglomeration of sub-visible particles created by rupture of gels of a monoclonal antibody formed at silicone oil-water interfaces. *J Pharm. Sci* 2016 105(8):2338-48
217. Snell JR, Zhou C, Carpenter JF and Randolph TW. Particle Formation and Aggregation of a Therapeutic Protein in Nanobubble Suspensions. *J Pharm Sci*, 2016 Oct;105(10):3057-63
216. Zhou C, Qi W, Lewis EN, Randolph TW, Carpenter JF. Reduced Subvisible Particle Formation in Lyophilized Intravenous Immunoglobulin Formulations Containing Polysorbate 20. *J Pharm Sci.* 2016, Volume 105, Issue 8, Pages 2302–2309.
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211. Christie M, Peritt D, Torres RM, Randolph TW, Carpenter JF 2015. The Role of Protein Excipient in Driving Antibody Responses to Erythropoietin. *Journal of Pharmaceutical Sciences* 104(12):4041-4055.
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209. McUmber AC, Randolph TW, Schwartz DK 2015. Electrostatic Interactions Influence Protein Adsorption (but Not Desorption) at the Silica-Aqueous Interface. *Journal of Physical Chemistry Letters* 6(13):2583-2587.
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205. Shomali M, Tanriverdi S, Freitag AJ, Engert J, Winter G, Siedler M, Kaymakcalan Z, Carpenter JF, Randolph TW 2015. Dose Levels in Particulate-Containing Formulations Impact Anti-drug Antibody Responses to Murine Monoclonal Antibody in Mice. *Journal of Pharmaceutical Sciences* 104(5):1610-1621.
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203. Mehta SB, Lewus R, Bee JS, Randolph TW, Carpenter JF 2015. Gelation of a Monoclonal Antibody at the Silicone Oil-Water Interface and Subsequent Rupture of the Interfacial Gel Results in Aggregation and Particle Formation. *Journal of Pharmaceutical Sciences* 104(4):1282-1290.
202. Freitag AJ, Shomali M, Michalakis S, Biel M, Siedler M, Kaymakcalan Z, Carpenter JF, Randolph TW, Winter G, Engert J 2015. Investigation of the Immunogenicity of Different Types of Aggregates of a Murine Monoclonal Antibody in Mice. *Pharm Res*. Feb; 32(2):430-44
201. Randolph TW, Schiltz E, Sederstrom D, Steinmann D, Mozziconacci O, Schoeneich C, Freund E, Ricci MS, Carpenter JF, Lengsfeld CS 2015. Do Not Drop: Mechanical Shock in Vials Causes Cavitation, Protein Aggregation, and Particle Formation. *Journal of Pharmaceutical Sciences* 104(2):602-611.
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Book Chapters

18. Carpenter, J.F., Chang, B.S, and Randolph, T.W., (2004), Physical Damage to Proteins During Freezing, Drying, and Reconstitution,” chapter in Lyophilization of biopharmaceuticals, H.R. Costantino and M.J. Pikal, eds, American Association of Pharmaceutical Scientists, 423-442.
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16. van de Weert, M and Randolph TW, “Physical Instability of peptides and Proteins”, in *Development of Peptides and Proteins*, M. van de Weert, Ed., CRC Press, Boca Raton, 2013.
15. Hassett, KJ, Pradyot, N., and Randolph, TW, (2013) “Formulation Approaches and Strategies for Vaccines and Adjuvants” P. Kolhe et al. (eds.), *Sterile Product Development*, AAPS Advances in the Pharmaceutical Sciences Series 6, DOI 10.1007/978-1-4614-7978-9_6,
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12. Jameel, F., Padala, C., Randolph TW, (2010) “Strategies for Bulk Storage and Shipment of Proteins”, chapter in *Formulation and Process Development Strategies for Manufacturing of a Biopharmaceutical*, F. Jameel and S. Hershenson, eds.
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7. Shahrokh, Z., Sluzky, V., Cleland, J.L., Shire, S.J., and Randolph, T.W., Eds.; (1997) Therapeutic Protein and Peptide Formulation and Delivery, *ACS Symp. Ser. 675*, American Chemical Society, Washington, D.C.
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Graduate Students Supervised

1. Austin Daniels, Ph.D., 2021, University of Colorado, Boulder, Flow imaging microscopy and machine learning methods and applications for particle morphology analysis.
2. Jared Snell, Ph.D., 2019, University of Colorado, Boulder, The Effect of Nanobubble and Nanodroplet Interfaces on Protein Stability and Aggregation in Therapeutic Protein Formulations
3. Hao Wu, Ph.D., 2019, University of Colorado, Boulder, Development of sensitive assays to understand mechanisms of protein particle and aggregates
4. Lea Sorret, Ph.D., 2018, University of Colorado, Boulder, The role of protein-protein interactions in inducing interfacial aggregation.
5. Carly Fleagle Chisholm, Ph.D. 2015, University of Colorado, Boulder, Immunogenicity of Silicone Oil in Prefilled Syringes
6. Elizabeth Russell, Ph.D. 2015, University of Colorado, Boulder, Monoclonal Antibody Aggregation in Cell Culture
7. Aaron McCumber, Ph.D. 2015, University of Colorado, Boulder, Understanding How Non-Covalent Interactions Affect Interfacial Biomolecular Dynamics
8. Alana Gerhardt, Ph.D. 2014, University of Colorado, Boulder, Synergistic Effects of Interfaces and Agitation on Particle Formation in Therapeutic Protein Formulations in Pre-filled Syringes
9. Yemin Xu, Ph.D. 2014, University of Colorado, Boulder, mechanisms of Protein Instability in Lyophilized Samples.
10. Kimberly Hassett, Ph.D. 2014, University of Colorado, Boulder, Ultrastable Glassy State Vaccines Containing Adjuvants
11. Maliheh Shomali, Ph.D. 2013, University of Colorado, Boulder, Immunogenicity of Monoclonal Antibody Therapeutics
12. Keith Britt, M.S., 2011, University of Colorado, Boulder, Excipient Effects on Monoclonal Antibody Interactions
13. Amanda Cordes, Ph.D. 2012, University of Colorado, Boulder, Stability and Formulation of Multidomain Proteins
14. Hoehne, Matthew, M.S. 2011, University of Colorado, Boulder, Adsorption of Monoclonal Antibodies to Glass Microparticles
15. David Brett Ludwig, Ph.D., 2010, University of Colorado, Boulder. Protein-silicone Oil Interactions
16. Amber Fradkin, Ph.D. 2009, University of Colorado, Boulder, Immunogenicity of Therapeutic Proteins
17. Jared Bee. Ph.D. 2009, University of Colorado, Boulder. Effects of Interfaces and Shear on Therapeutic Protein Stability
18. Ryan Crisman, Ph.D. 2009, University of Colorado, Boulder. High Pressure Crystallization of Therapeutic Proteins
19. Branden Salinas. Ph.D 2009, University of Colorado, Boulder, Therapeutic Antibody Formulation: Phase Behavior, Opalescence, Physical and Chemical stability
20. Amber Lea Clausi. Ph.D. 2007, University of Colorado, Boulder, Lyophilized vaccine Preparations Containing Aluminum Salt Adjuvants: Preparation, Immunogenicity and Stability”
21. John Alford, Ph.D. 2007, University of Colorado, Boulder, “Physical Stability of a Therapeutic Protein in High Protein Concentration Aqueous Formulations”
22. John Gabrielson, Ph.D. 2006, University of Colorado, Boulder, “Monoclonal Antibody Aggregation in Therapeutic Formulation: Size and Shape Analysis”
23. Billie-Jean Savage, Masters, 2004, University of Colorado, Boulder, “Controlled Freezing and Thawing of Cells Using a Fluidized Bed”
24. Eva Chi, Ph.D., 2004, University of Colorado, Boulder, “Protein Aggregation in Aqueous Solution- Mechanism, Thermodynamics, and Kinetics”
25. Daniel Jarmer, Ph.D. 2004, University of Colorado, Boulder, “Manipulation and Control of Particle Size Distribution During Precipitation with Compressed Antisolvents”
26. Steven Cottle, Masters, 2004, University of Colorado, Boulder, “Development of Methods and Formulation for Maintaining Aluminum Salt Adjuvant Stability and Adsorption Capacity During Freeze-Drying”

27. Michael Stoner, Ph.D., 2004, University of Colorado, Boulder, "Mechanistic Studies of Enzyme Degradation in Liquid Detergent"
28. Matthew Seefeldt, Ph.D., 2004, University of Colorado, Boulder, "High Pressure Refolding of Protein Aggregates: Efficacy and Thermodynamics"
29. Daniel Biggs, Ph.D., 2003, University of Colorado, Boulder, "Biodegradable Poly-(L-lactide) Microparticles for Pulmonary Drug Delivery with Targeting to Alveolar Macrophages: Applications in Treating Tuberculosis"
30. Jennifer L. Owens, Ph.D., 2002, University of Colorado, Boulder, "Biodegradable Microparticles for Controlled Drug Release Applications: Formation Using the Compressed Antisolvent Precipitation and Photopolymerization Process"
31. DePaz, Roberto, Ph.D., 2001, University of Colorado, Boulder, "Thermodynamics and Kinetics of Protein Degradation in Dried Solids"
32. Webb, Serena D. Ph.D., 2001, University of Colorado, Boulder, "Reconstitution of Lyophilized Therapeutic Proteins: Effects of Formulation, Processing Techniques, and Surfaces"
33. St. John, Richard J., Ph.D., 2001, University of Colorado, Boulder, "High pressure Refolding of Protein Aggregates and Inclusion Bodies"
34. Dixon, Daniel Abbas, MS, 2000, University of Colorado, Boulder, "Spray Freezing and Fluidized Bed Drying of Pharmaceutical Powders"
35. James Searles, PhD, 2000, University of Colorado, Boulder, "Calorimetric Control and Modeling of Pharmaceutical Lyophilization Processes"
36. Jon Webb, PhD, 2000, University of Colorado, Boulder, "High Pressure Crystallization, refolding, and Disaggregation of Proteins"
37. Lyman, Scott MS 1999, University of Colorado, Boulder, "Surfactant Interactions with recombinant human Interferon Beta"
38. Jing Xu, MS, 1999, University of Colorado, Boulder, "Controlled Release of Drugs in Vitreous Humor"
39. Kenneth Benjamin, MS, 1999, University of Colorado, Boulder, "Heat Transfer in Supercritical Jet Fuels"
40. Lorraine Pietrazewski, MS, 1999, "Stability of Water-in-CO₂ Emulsions"
41. Richard Falk, Ph.D., 1998, University of Colorado, Boulder, "Gas Antisolvent Precipitation Processing for Preparation of Controlled-Release Pharmaceutical Products"
42. Martin C. Heller, Ph.D., 1998, University of Colorado, Boulder, "Causes and Consequences of Polymeric Phase Separations in Protein Formulations During Lyophilization"
43. Janet deGrazia, Ph.D., 1998, University of Colorado, Boulder, "Structure in Supercritical Fluids: Reactions, Microemulsions, and Emulsions"
44. Sriram Natarayan, MS, 1996, University of Colorado, Boulder, "Ultrasonic Velocity Measurements in Supercritical Jet Fuel"
45. LaToya Shantel Jones. MS, 1996, University of Colorado, Boulder, "Surfactant Interactions with recombinant Hepatitis B Surface Antigen"
46. Claude Carlier Ph.D. 1995, Yale University "Reactions in Supercritical Fluids" (Award:Harding Bliss Award for Outstanding Best Thesis Research in Engineering and Applied Science, 1995)
47. Narendra Bam Ph.D. 1995, Yale University "Mechanisms of Stabilization of Recombinant Protein Formulations by Surfactants and Polymers"
48. Ganapathy Shankar Ph.D. 1995, Yale University "Computational and Experimental Studies of Free Radical Reactions in Supercritical Fluids"
49. Claudia Heinen, Diplomarbeit 1994, Julius-Maximilians-Universitat Wurzburg "Protein-Stabilizer Interactions During Freezing and Drying"
50. David Barbieri, MS, 1995, University of Colorado, Boulder "A Theoretical Approach to Protein Stability During the Freezing Portion of Lyophilization"
51. Eugenia Pelli, MS, 1993, Yale University.

Post-doctoral Students Supervised

Claude Carlier (1993-1995)
 Vibha Bansal (1996-1997)
 Thomas J. Anchordoquy (1996-1997)
 Corrine Cannon Lengsfeld (1998-1999)
 Stephen Cape 2001
 Sathish Hasige (2006-2008)
 Jonas Fast (2008-2009)

Wei-Jie Fan (2008-2009)
Ricardo Stephens (2008-2009)
Sanli Movafaghi (2019-2020)
Hans Funke (2018-)
Saba Ghazvini (2017-2018)