

## Curriculum Vitae

Theodore W. Randolph  
Professor  
Department of Chemical and Biological Engineering  
University of Colorado  
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## Education

1983-1987 University of California, Berkeley  
Ph.D. Chemical Engineering, 1987. Thesis advisors: Harvey W. Blanch, John M. Prausnitz.  
Thesis: "Enzyme-Catalyzed Reactions in Supercritical Fluids."

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.:Post-doctoral research position under the direction of Professor U. von Stockar.
- 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

## Publications

232. Chisholm, C. F.; Kang, T. J.; Dong, M.; Lewis, K.; Namekar, M.; Lehrer, A. T.; Randolph, T. W., Thermostable Ebola virus vaccine formulations lyophilized in the presence of aluminum hydroxide. *European Journal of Pharmaceutics and Biopharmaceutics* 2019, 136, 213-220.
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227. Pardeshi, N. N.; Zhou, C.; Randolph, T. W.; Carpenter, J. F., Protein nanoparticles promote microparticle formation in intravenous immunoglobulin solutions during freeze-thawing and agitation stresses. *J Pharm Sci* 2018.
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 Peginesatide 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.
221. Maddux, N. R.; Daniels, A. L.; Randolph, T. W., Microflow Imaging Analyses Reflect Mechanisms of Aggregate Formation: Comparing Protein Particle Data Sets Using the Kullback-Leibler Divergence. *Journal of Pharmaceutical Sciences* 2017, 106 (5), 1239-1248.
220. Chisholm, C. F.; Soucie, K. R.; Song, J. S.; Strauch, P.; Torres, R. M.; Carpenter, J. F.; Ragheb, J. A.; Randolph, T. W., Immunogenicity of Structurally Perturbed Hen Egg Lysozyme Adsorbed to Silicone Oil Microdroplets in Wild-Type and Transgenic Mouse Models. *Journal of Pharmaceutical Sciences* **2017**, 106 (6), 1519-1527.
219. Sorret, LL, DeWinter MA, Schwartz DK and Randolph TW. Challenges in predicting protein-protein interactions from measurements of molecular diffusivity. *Biophysical J.*, 2016, Vol 111(9): 1831-1842.
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.
215. Zhou C, Cleland D, Snell J, Qi W, Randolph TW, Carpenter JF. Formation of Stable Nanobubbles on Reconstituting Lyophilized Formulations Containing Trehalose, *J Pharm Sci*. 2016, Jul;105(7):2249-53.
214. Chisholm CF, Baker AE, Soucie KR, Torres RM, Carpenter JF, Randolph TW. Silicone Oil Microdroplets Can Induce Antibody Responses Against Recombinant Murine Growth Hormone in Mice. *J Pharm Sci*. 2016 May;105(5):1623-32.
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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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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.
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16. Carlier, C., and Randolph, T. W., "Dense-Gas Solvent Solute Clusters at Near-infinite Dilution: EPR Spectroscopic Evidence," *AIChE J.*, 39, No. 5, 876-884, 1993.
15. Randolph, T.W., and Carlier, C., "Pressure Control of Reactions in Supercritical Fluids: Thermodynamics and Kinetics," in Biocatalysis in Non-Conventional Media, J. Tramper, M.H. Vermue, H.H. Beeftink, and U. von Stockar, eds., Elsevier, Amsterdam, 1992.
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9. Randolph, T. W., Marison, I. W., Martens, D. E., and von Stockar, U., "Calorimetric Control of Fed-Batch Fermentations," *Biotechnol. Bioeng.*, 36, No. 7, pp. 678-684, 1990
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4. Randolph, T. W., Clark, D. S., Blanch, H. W., and Prausnitz, J. M., "Enzymatic Oxidation of Cholesterol Aggregates in Supercritical Carbon Dioxide," *Science*, 239, pp. 387-390 (1988).
3. Randolph, T. W., Blanch, H. W., Prausnitz, J. M., "Enzyme Catalyzed Oxidation of Cholesterol in Supercritical Carbon Dioxide," *AIChE J.*, Vol. 34, No. 8, pp. 1354-1360, August, 1988.
2. Randolph, T. W., Clark, D. S., Blanch, H. W., Prausnitz, J. M., "Cholesterol Aggregation and Interaction with Cholesterol Oxidase in Supercritical carbon Dioxide," *Proc. Natl. Acad. Sci., USA*, Vol. 85, pp. 2979-2983, May, 1988.
1. Randolph, T. W., Blanch, H. W., Prausnitz, J. M., and Wilke, C. R., "Enzymatic Activity in a Supercritical Fluid," *Biotechnol. Lett.* 7, 325 (1985).

#### **Patents**

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”***, US 6,319,521, November 20, 2001
8. ***“Preparation and Use of Photopolymerized Microparticles”*** US Patent 6,403,672, June 11, 2002
9. ***“Preparation and Use of Photopolymerized Microparticles”*** US Patent 6,864,301, March 8, 2005
10. ***“Sustained-release composition including amorphous polymer”*** United States 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 No. 6,982,080, January 3, 2006
12. ***“Hydroxyethyl starch—containing polypeptide compositions”*** U.S. patent No. 7,449,444, November 11, 2008
13. ***“Devices and Methods for the Production of Particles”*** U.S. patent No. 7,332,111, February 19, 2008
14. ***“Improved Protein Disaggregation and Refolding Using High Pressure”*** European Patent 1434789 A, March 26, 2008
15. ***“High-Pressure Refolding of Protein Aggregates and Inclusion Bodies”***. European Patent 1095056 B
16. ***“Spray freeze dry of compositions for pulmonary administration”*** US 7,923,029, April 12, 2011
17. ***High-pressure inclusion body solubilization and protease clipping of recombinant fusion proteins”*** US Patent 7,829,681, November 9, 2010
18. ***“High Pressure Refolding of Protein Aggregates and Inclusion Bodies”*** U.S. Patent 7,767,795, Aug 3, 2010
19. ***“Methods for protein refolding”*** US Patent 7,538,198, May 26, 2009
20. ***Spray Freeze dried Compositions for pulmonary administration***, US 8,239,275, October 23, 2012
21. ***“Methods for Protein Refolding”*** US Patent 8,329,878, Dec 11, 2012
22. ***“Method of preparing an immunologically-active adjuvant-bound dried vaccine composition”*** 8,444,991, May 21, 2013.
23. ***“Methods for evaluating the aggregation of a protein in a suspension including organopolysiloxane and medical articles coated with organopolysiloxane containing a protein solution”*** US patent 8,633,034, January 21, 2014
24. ***“Method for reducing immunogenicity of therapeutic protein compositions”*** US patent 8,697,848, April 14, 2014
25. ***“Method of preparing an immunologically-active adjuvant-bound dried vaccine composition”*** US Patent 8,808,710, August 19, 2014
26. ***“High pressure refolding of monoclonal antibody aggregates”*** US Patent 8,802,828, August 12, 2014
27. ***“High pressure refolding of protein aggregates and inclusion bodies”*** US Patent 8,710,197, April 29, 2014

#### **Industrial Boards**

Co-director, Medical and Scientific Advisory Board, RxKinetix, Inc. 10/97-4/99  
 Member, Scientific Advisory Board, AktivDry, Inc. 01/02-  
 Member, Scientific Advisory Board, Integrated Biosystems, Inc. 1998-  
 Member, Board of Directors, University Technology Corporation, 2000-2002



Founder and Scientific Advisory Board Director, BaroFold, Inc., 2002-  
Founder, CEO, VitriVax, Inc. 2015-

### **Awards, Memberships, Editorial Boards**

- Ebert Award, Best Original Investigation in 2018, American Pharmacists Association
- NIH Study Section member, Vaccines for Microbial Diseases 2015-2019
- 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
- Editorial Board Member, *Journal of Pharmaceutical Sciences*
- Outstanding Graduate Teaching Award, Department of Chemical Engineering, 2000
- Faculty Fellowship, University of Colorado, Boulder 1999-2000
- Editorial Board Member, *Current Pharmaceutical Biotechnology*
- 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
- 1990 Yale Nominee for the David and Lucille Packard Fellowship Award
- William H. Peterson Award from the American Chemical Society Division of Microbial and Biochemical Technology for Best Student Paper, 1987 Annual Meeting of the ACS.
- Outstanding Teaching Assistant Award, Department of Chemical Engineering, University of California, Berkeley, Fall, 1984.
- George Gregson Scholarship for Academic Excellence, Department of Chemical Engineering, University of Arizona, 1979-1981.
- Member, Tau Beta Pi National Engineering Honor Society
- Member, Omega Chi Epsilon National Chemical Engineering Honor Society
- Member, American Institute of Chemical Engineers
- Member, American Association for the Advancement of Science
- Member, American Association of Pharmaceutical Scientists

### **Graduate Students Supervised**

- 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
- Lea Sorret, Ph.D., 2018, University of Colorado, Boulder, The role of protein-protein interactions in inducing interfacial aggregation.
- Carly Fleagle Chisholm, Ph.D. 2015, University of Colorado, Boulder, Immunogenicity of Silicone Oil in Prefilled Syringes
- Elizabeth Russell, Ph.D. 2015, University of Colorado, Boulder, Monoclonal Antibody Aggregation in Cell Culture
- Aaron McCumber, Ph.D. 2015, University of Colorado, Boulder, Understanding How Non-Covalent Interactions Affect Interfacial Biomolecular Dynamics
- 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

- Yemin Xu, Ph.D. 2014, University of Colorado, Boulder, mechanisms of Protein Instability in Lyophilized Samples.
- Kimberly Hassett, Ph.D. 2014, University of Colorado, Boulder, Ultrastable Glassy State Vaccines Containing Adjuvants
- Maliheh Shomali, Ph.D. 2013, University of Colorado, Boulder, Immunogenicity of Monoclonal Antibody Therapeutics
- Keith Britt, M.S., 2011, University of Colorado, Boulder, Excipient Effects on Monoclonal Antibody Interactions
- Amanda Cordes, Ph.D. 2012, University of Colorado, Boulder, Stability and Formulation of Multidomain Proteins
- Hoehne, Matthew, M.S. 2011, University of Colorado, Boulder, Adsorption of Monoclonal Antibodies to Glass Microparticles
- David Brett Ludwig, Ph.D., 2010, University of Colorado, Boulder. Protein-silicone Oil Interactions
- Amber Fradkin, Ph.D. 2009, University of Colorado, Boulder, Immunogenicity of Therapeutic Proteins
- Jared Bee. Ph.D. 2009, University of Colorado, Boulder. Effects of Interfaces and Shear on Therapeutic Protein Stability
- Ryan Crisman, 2009, University of Colorado, Boulder. High Pressure Crystallization of Therapeutic Proteins
- Branden Salinas. Ph.D 2009, University of Colorado, Boulder, Therapeutic Antibody Formulation: Phase Behavior, Opalescence, Physical and Chemical stability
- Amber Lea Clausi. Ph.D. 2007, University of Colorado, Boulder, Lyophilized vaccine Preparations Containing Aluminum Salt Adjuvants: Preparation, Immunogenicity and Stability”
- John Alford, Ph.D. 2007, University of Colorado, Boulder, “Physical Stability of a Therapeutic Protein in High Protein Concentration Aqueous Formulations”
- John Gabrielson, Ph.D. 2006, University of Colorado, Boulder, “Monoclonal Antibody Aggregation in Therapeutic Formulation: Size and Shape Analysis”
- Billie-Jean Savage, Masters, 2004, University of Colorado, Boulder, “Controlled Freezing and Thawing of Cells Using a Fluidized Bed”
- Eva Chi, Ph.D., 2004, University of Colorado, Boulder, “Protein Aggregation in Aqueous Solution- Mechanism, Thermodynamics, and Kinetics”
- Daniel Jarmer, Ph.D. 2004, University of Colorado, Boulder, “Manipulation and Control of Particle Size Distribution During Precipitation with Compressed Antisolvents”
- 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”
- Michael Stoner, Ph.D., 2004, University of Colorado, Boulder, “Mechanistic Studies of Enzyme Degradation in Liquid Detergent”
- Matthew Seefeldt, Ph.D., 2004, University of Colorado, Boulder, “High Pressure Refolding of Protein Aggregates: Efficacy and Thermodynamics”
- 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”
- 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”
- DePaz, Roberto, Ph.D., 2001, University of Colorado, Boulder, “Thermodynamics and Kinetics of Protein Degradation in Dried Solids”
- Webb, Serena D. ,2001, University of Colorado, Boulder, “Reconstitution of Lyophilized Therapeutic Proteins: Effects of Formulation, Processing Techniques, and Surfaces”
- St. John, Richard J., Ph.D., 2001, University of Colorado, Boulder, “High pressure Refolding of Protein Aggregates and Inclusion Bodies”
- Dixon, Daniel Abbas, MS, 2000, University of Colorado, Boulder, “Spray Freezing and Fluidized Bed Drying of Pharmaceutical Powders”
- James Searles, PhD, 2000, University of Colorado, Boulder, “Calorimetric Control and Modeling of Pharmaceutical Lyophilization Processes”
- Jon Webb, PhD, 2000, University of Colorado, Boulder, “High Pressure Crystallization, refolding, and Disaggregation of Proteins”
- Lyman, Scott MS 1999, University of Colorado, Boulder, “Surfactant Interactions with recombinant human Interferon Beta”

- Jing Xu, MS, 1999, University of Colorado, Boulder, "Controlled Release of Drugs in Vitreous Humor"
- Kenneth Benjamin, MS, 1999, University of Colorado, Boulder, "Heat Transfer in Supercritical Jet Fuels"
- Lorraine Pietrazewski, MS, 1999, "Stability of Water-in-CO<sub>2</sub> Emulsions"
- Richard Falk, Ph.D., 1998, University of Colorado, Boulder, "Gas Antisolvent Precipitation Processing for Preparation of Controlled-Release Pharmaceutical Products"
- Martin C. Heller, Ph.D., 1998, University of Colorado, Boulder, "Causes and Consequences of Polymeric Phase Separations in Protein Formulations During Lyophilization"
- Janet deGrazia, Ph.D., 1998, University of Colorado, Boulder, "Structure in Supercritical Fluids: Reactions, Microemulsions, and Emulsions"
- Sriram Natarayan, MS, 1996, University of Colorado, Boulder, "Ultrasonic Velocity Measurements in Supercritical Jet Fuel"
- LaToya Shantel Jones. MS, 1996, University of Colorado, Boulder, "Surfactant Interactions with recombinant Hepatitis B Surface Antigen"
- 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)
- Narendra Bam Ph.D. 1995, Yale University "Mechanisms of Stabilization of Recombinant Protein Formulations by Surfactants and Polymers"
- Ganapathy Shankar Ph.D. 1995, Yale University "Computational and Experimental Studies of Free Radical Reactions in Supercritical Fluids"
- Claudia Heinen, Diplomarbeit 1994, Julius-Maximilians-Universitat Wurzburg "Protein-Stabilizer Interactions During Freezing and Drying"
- David Barbieri, MS, 1995, University of Colorado, Boulder "A Theoretical Approach to Protein Stability During the Freezing Portion of Lyophilization"
- Eugenia Pelli, MS, 1993, Yale University.

#### **Post-doctoral Students Supervised**

Claude Carlier (1993-1995)  
 Vibha Bansal (1996-1997)  
 Thomas J. Anchordoquy (1996-1997)  
 Corrine Connon Lengsfeld (1998-1999)  
 Stephen Cape 2001  
 Sathish Hasige (2006-2008)  
 Jonas Fast (2008-2009)  
 Wei-Jie Fan (2008-2010)  
 Ricardo Stephens (2008)  
 Benjamin Barthel, (2015-2016)  
 Nathaniel Maddux, (2016-2017)  
 Saba Ghazvini, (2017-2018)  
 Sanli Movafaghi(2019-)