

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, Issued November 8, 2022
30. "Compositions, Methods, and Uses for Thermally Stable Multi-targeted Antigens" US patent #11,806,432, Issued Nov 7, 2023
31. "Thermostable vaccine compositions and methods of producing the same" US patent #12097291, issued September 24, 2024.

Publications

262. Thite NG, Tuberty-Vaughan E, Wilcox P, Wallace N, Calderon CP, Randolph TW. Stain-Free Approach to Determine and Monitor Cell Health Using Supervised and Unsupervised Image-Based Deep Learning. *J Pharm Sci.* 2024 May 6:S0022-3549(24)00173-4. doi: 10.1016/j.xphs.2024.05.001. Epub ahead of print. PMID: 38710387.
261. Coleman HJ, Schwartz DK, Kaar JL, Garcea RL, Randolph TW. Stabilization of an Infectious Enveloped Virus by Spray-Drying and Lyophilization. *J Pharm Sci.* 2024 Apr 21:S0022-3549(24)00141-2. doi: 10.1016/j.xphs.2024.04.012. Epub ahead of print. PMID: 38643898.
260. Greenblott, D.; Wood, C.; Zhang, J.; Viza, N.; Chintala, R.; Calderon, C.; Randolph, T. Supervised and unsupervised machine learning approaches for monitoring subvisible particles within an aluminum-salt adjuvanted vaccine formulation. *BIOTECHNOLOGY AND BIOENGINEERING* 2024, 121, 1626-1641. DOI: 10.1002/bit.28671.
259. Greenblott, D.N.; Johann, F.; Snell, J.R.; Gieseler, H.; Calderon, C.P.; Randolph, T.W. (2024) Features in Backgrounds of Microscopy Images Introduce Biases in Machine Learning Analyses. *J. Pharm. Sci.* , **2024**, *113*, 1177-1189. DOI: 10.1016/j.xphs.2024.03.003.
258. Coleman, H.; Perez, J. S.; Schwartz, D. K.; Kaar, J.; Garcea, R. L.; Randolph, T. W. Effect of mechanical stresses on viral capsid disruption during droplet formation and drying. *Colloids and Surfaces B-Biointerfaces* 2024, 233. DOI: 10.1016/j.colsurfb.2023.113661.
257. Thite, N. G.; Ghazvini, S.; Wallace, N.; Feldman, N.; Calderon, C. P.; Randolph, T. W. Interfacial Adsorption Controls Particle Formation in Antibody Formulations Subjected to Extensional Flows and Hydrodynamic Shear. *Journal of Pharmaceutical Sciences* 2023, 112 (11), 2766-2777. DOI: 10.1016/j.xphs.2023.07.010.
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
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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.

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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
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.
231. Wu, H. and Randolph, TW. Rapid Quantification of Protein Particles in High-Concentration Antibody J Pharm Sci. Volume: 108 Issue: 3 Pages: 1110-1116 Published: MAR 2019
230. Sorret LL, Monticello CR, DeWinter MA, Schwartz DK, Randolph TW. Steric Repulsion Forces Contributed by PEGylation of Interleukin-1 Receptor Antagonist Reduce Gelation and Aggregation at the Silicone Oil-Water Interface, *J Pharm Sci.* 2019 Jan;108(1):162-172. doi: 10.1016/j.xphs.2018.10.045. Epub 2018 Nov 3.
229. Qi W; Orgel S; Francon A; Randolph TW; Carpenter JF. Urea Improves Stability of Inactivated Polio Vaccine Serotype 3 During Lyophilization and Storage in Dried Formulations. *J Pharm Sci.* 2018 Aug;107(8):2070-2078.
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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.
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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.
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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.
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.
213. Jiskoot W, Kijanka G, Randolph TW, Carpenter JF, Koulov AV, Mahler HC, et al. Mouse Models for Assessing Protein Immunogenicity: Lessons and Challenges. *J Pharm Sci.* 2016 May;105(5):1567-75.
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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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- 198 Xu Y, Carpenter JF, Cicerone MT, Randolph TW 2013. Contributions of local mobility and degree of retention of native secondary structure to the stability of recombinant human growth hormone (rhGH) in glassy lyophilized formulations. *Soft Matter* 9(32):7855-7865.
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194. Gerhardt A, Bonam K, Bee JS, Carpenter JF, Randolph TW 2013. Ionic strength affects tertiary structure and aggregation propensity of a monoclonal antibody adsorbed to silicone oil-water interfaces. *Journal of Pharmaceutical Sciences* 102(2):429-440.
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