Comprehensive Professional Vitae

Name: Seongkyu Yoon
Department: Chemical Engineering

College: Engineering Rank: Professor

Field: Systems & Synthetic Biology, Drug Delivery, Process Systems Engineering, Regulatory Sciences

EDUCATION AND ACADEMIC QUALIFICATIONS

Education

Master of Business Administration	2007-2017
Babson College, F.W. Olin Graduate School of Business, Wellesley, MA	
Doctor of Philosophy, Dept of Chemical Engineering	1996 - 2001
McMaster University, Hamilton, ON, Canada	
Master of Science, Dept of Chemical and Biomolecular Eng.	1988 - 1990
Korea Advanced Institute of Science and Technology, Daejeon, Korea	
Bachelor of Eng, Dept of Chemical and Biomolecular Eng.	1984 - 1988
Yonsei University, Seoul, Korea	

• Academic Experience

University of Massachusetts Lowell	
Professor, Department of Chemical Eng.	2018 – Current
Associate Professor, Department of Chemical Eng.	2016 - 2018
Assistant Professor, Department of Chemical Eng.	2010 - 2016

PROFESSIONAL ACTIVITIES

• Professional Experiences

National Academy of Sciences, Committee on Identifying Innovative Technologies in Pharmaceutical Manufacturing Dec 2019- Dec. 2021

US Food and Drug Administration

Center for Drug Evaluation and Research/OTR, Visiting Professor, Jun 2019 – Aug 2019 ORISE Research Fellow, 2014, 2015, 2016

University of Massachusetts Lowell, MA USA

2010-Current

Assistant/Associate/Professor, Department of Chemical Engineering; NSF/AccelNet/IBioNe (International Biomanufacturing Network), Co-PI

NSF/IUCRC Advanced Mammalian Biomanufacturing Innovation Center (AMBIC) UMass

Lowell, Site Director, 2016-Current

Director of Biomanufacturing Innovation Institute, 2015-Current

Co-Director of Massachusetts Biomanufacturing Center, 2010-Current

Biogen Biopharmaceutical, Cambridge MA Manufacturing Sciences Group Lead	2005-2010
Umetrics Data Analytics (now Satorius Data Analytics) Sr. Application Staff	2001-2005
LG Chemical, Seoul, S. Korea (Former Hyundai) Sr. Process Control Engineer	1990-1996

• Professional Association Participation

Membership in Professional Societies

- 1) Technical Committee of NIIMBL (2017-Current)
- 2) Executive Director, Korean American Bio-Industry Council (2012-Current)
- 3) Member, American Association of Cancer Research (AACR) (2010 Current)
- 4) Member, Massachusetts Separation Society (MASS SEP) (2010-Current)
- 5) Member, Process Analytical Technology Roundtable (PPAR) (2009-Current)
- 6) Member, International Society of Pharmaceutical Engineer (ISPE) (2005 Current)
- 7) Member, American Chemistry Society (ACS) (2005 Current)
- 8) Member, International Chemometrics Society (ICS) (2001 Current)
- 9) Member, American Institute of Chemical Engineers (AIChE) (2001 Current)
- 10) Member, Korean Scientist and Engineer Association (2001- Current)
- 11) Member, Korean American Society in Biotech and Pharmaceuticals (2001-Current)

Editor of journals

- 1) Editorial Board, Preparative Biochemistry and Biotechnology (2015 Current)
- 2) Board, International Forum of Process Analytical Technology (2017 Current)
- 3) Guest Editor, Processes (2015, 2020)
- 4) Editor, Journal of Chemical Technology and Biotechnology (2014 Current)
- 5) Editorial Board, Journal of Pharmaceutical Processing (2013 Current)
- 6) Editorial Board, AIMS Medical Science (2013 Current)

Conference, workshop and training Organized

- 1) NSF/IUCRC AMBIC Biannual Meeting, Wilmington DE, June 2022
- 2) NSF/IUCRC AMBIC Biannual Meeting, Virtual, Jan 2022
- 3) NSF/IUCRC AMBIC Biannual Meeting, Lowell MA, July 2021
- 4) Industry short course: "Bioprocess Data Analytics and Machine Learning", MIT, MA, Jun 29-30, 2021
- 5) Industry short course: "Statistical 101 and Quality Control for Biopharmaceutical", Virtual, May 17-19, 2021
- 6) Industry short course: "Viral Vector for Gene Therapy Manufacturing", Virtual, March 9-11, 2021
- 7) Industry short course: "Industrial Lyophilization Training", Virtual, Feb 8-10, 2021

- 8) Industry short course: "Bioprocess Data Analytics and Machine Learning", MIT, MA, Oct 12-14, 2020
- 9) NSF/IUCRC AMBIC Biannual Meeting (Virtual), June 2020
- 10) Industry short course coordinator: "Advanced Industrial Bioprocessing", Lowell MA, Aug 5-9, 2019
- 11) NSF/IUCRC AMBIC Biannual Meeting, College Park, MD, Dec 2019
- 12) NSF/IUCRC AMBIC Biannual Meeting, Cambridge MA, June 2019
- 13) NSF/IUCRC AMBIC Biannual Meeting, St, Louis MO, Dec 10-12, 2018
- 14) Session Chair/Co-Chair: "Biomanufacturing", IFPAC 2019, North Bethesda, MD, Feb. 2019
- 15) NSF/IUCRC AMBIC Biannual Meeting, South San Francisco, June 18-20, 2018
- 16) Industry short course coordinator: "Continuous Chromatography", Lowell MA, Oct 17, 2018
- 17) Industry short course coordinator: "QbD/PAT in Biopharmaceutical", Lowell MA, Oct 24, 2018
- 18) Industry short course coordinator: "Advanced Industrial Bioprocessing", Lowell MA, Aug 6-10, 2018
- 19) Conference Chair and Coordinator: "Biomanufacturing Innovation", Biomanufacturing Annual Summit, Boston MA, Sep 9-10, 2018
- 20) Session Chair/Co-Chair: "Biomanufacturing", IFPAC 2018, North Bethesda, MD, Feb. 2018
- 21) Industry short course coordinator: "Advanced Bioprocessing", Biopharmaceutical Summit Boston MA, May 24-26, 2017
- 22) Conference Chair and Coordinator: "Beyond monoclonal antibody", Biomanufacturing Annual Summit, Boston MA, May 22-23, 2017
- 23) Session Chair/Co-Chair: "Biomanufacturing", IFPAC 2017, North Bethesda, MD, Feb. 2017
- 24) Session Chair/Co-Chair: "Biomanufacturing", AIChE 2016 Annual Meeting, San Francisco CA, Nov, 2016 Industry short course coordinator: "Integrated Continuous Bioprocessing", Biopharmaceutical Consortium, Lowell MA, May 18-20, 2016 (15 people attended)
- 25) Conference Chair and Coordinator: "Future Biomanufacturing", Biomanufacturing Science and Technology Consortium Annual Summit, Boston MA, May 23-24, 2016 (140 people attended)
- 26) Industry short course coordinator: "PAT and QbD in Biopharmaceutical", Biopharmaceutical Consortium, Lowell MA, May 20-22, 2015 (15 people attended)
- 27) Conference Chair and Coordinator: "Raw material variability and its process control in Bioprocessing", Biopharmaceutical Consortium Annual Summit, Lowell MA, May 18-19, 2015 (100 people attended)
- 28) Training Coordinator: "Quality by Design (QbD) training" Osong Medical Innovation Foundation, Clinical Drug Manufacturing Center, Osong, Korea, Sep, 2014 (30 people attended)
- 29) Industry short course coordinator: "PAT and QbD principles in Bioprocessing", Biopharmaceutical Consortium, Lowell MA, May 27-28, 2014 (25 people attended)
- 30) Conference Chair and Coordinator: "PAT and QbD in Biopharmaceutical", Biopharmaceutical Consortium Annual Summit, Lowell MA, May 29-30, 2014 (140 people attended)

- 31) Training Coordinator: "Process Analytical Technology (PAT) training" Osong Medical Innovation Foundation, Clinical Drug Manufacturing Center, Osong, Korea, Oct 27-28, 2013 (40 people attended)
- 32) Workshop Coordinator: "Training Technology Leader", Professional Science Master (PSM) workshop for Korean Professors, Lowell MA, June 17-19, 2013
- 33) Industry short course coordinator: "Continuous Bioprocessing", Biopharmaceutical Consortium, Lowell MA, May 29-30, 2013 (25 people attended)
- 34) Conference Chair and Coordinator: "Continuous Bioprocessing", Biopharmaceutical Consortium Annual Summit, Lowell MA, May 15, 2013 (140 people attended)
- 35) Conference organizing committee and session chair: Metabolomics and Systems Biology, Chicago, Apr 8-10, 2013
- 36) Advisory board member and session chair: P2P (Process to Product), International Bioprocess Conference, Washington DC, Oct 12-13, 2012
- 37) Session Chair/Co-Chair: "Process monitoring, Life Sciences modeling sessions", AIChE 2011 Annual Meeting, Pittsburg, PA, Oct, 16-21, 2012
- 38) Conference Chair and Coordinator: "Biopharmaceutical Challenges and Innovation", Biopharmaceutical Consortium Annual Summit, Lowell MA, Mar. 9, 2012 (135 people attended)
- 39) Session Chair/Co-Chair: "Process monitoring, Life Sciences modeling sessions", AIChE 2011 Annual Meeting, Minneapolis, MN, Oct, 16-21, 2011
- 40) Advisory board member and session chair: P2P (Process to Product), International Bioprocess Conference, Washington DC, Oct 14, 2011
- 41) Advisory board member and session chair: P2P (Process to Product), International Bioprocess Conference, Bethesda, MD, Oct 18, 2010

Honors and awards

- 1) MBI (Model Based Innovation) Award 2019, Winner
- 2) MBI (Model Based Innovation) Award 2018, Runners-Up:
- 3) Robert and Gail Ward Endowed Professorship in Biomedical Material Sciences (2016-2018)
- 4) FDA ORISE Fellow (2014, 2015, 2016)
- 5) Special advisory board of Korean Ministry of Food and Drug Safety (2014)
- 6) CPC/FOCAPD, Travel Award (\$10,500) (2012, 2014, 2016)
- 7) Global Pharmaceutical Leader (GPKOL) of Korean Health Industry Development Institute (KHIDI) (2013)
- 8) CCE XIII, Travel Award (\$2,600) (2012)
- 9) UMass Medical, CTTS Annual Retreat Best Poster Award (May 2011)
- 10) McMaster University Scholarship (1996-2001)
- 11) Sherman Scholarship for excellent teaching & research, McMaster Univ. (1999)
- 12) Korean-Canadian Scholarship Foundation, Canada (1997)
- 13) Excellent Engineer Award of the Year, Hyundai Petrochemical Co. (1995)
- 14) Korean government scholarship for Graduate Study (1988-1990)
- 15) Yonsei University Journalism Scholarship (1986-1988)

RESEARCH

Summary of Grants and Contracts awarded to Dr. Yoon Since September 2010

Grant	No of Grants	Amount	
Active	18	\$	4,244,070
Completed	50	\$	8,449,540
In-Kind	9	\$	2,108,000
Total	76	\$	14,901,610

2. Academic & Professional Publications

• Refereed journal papers

2022

- [1] Hadley, B, K. Behere, V. Canning, J. Heimbach, S. Yoon, R, Gerber, R. Beri (2022), Evaluation of a Glycosylation Control Strategy for Monoclonal Antibodies through an Integrated Statistical and Experimental Approach, **Biotechnology & Bioengineering (In Revision).**
- [2] Trunfio, N., J. Liu, H. Lee, and S. Yoon* (2022), Chemometric based image processing and delineation for the intraoperative mapping of nonmelanima skin cancer, IEEE Transactions on Biomedical Engineering, **TBME-01636-2017 (In Revision)**
- [3] Namjoon Kim, Prokash Paul, Nicholas Trunfio, Garry Handelman, Jaeyeon Kim, *Lanyan Fang*, Seongkyu Yoon (2022), Bioequivalence Assessment of Generics and Biosimilars: Evaluation guidelines and regulatory consideration, **International Journal of Pharmaceutics (FDA Approval Pending)**
- [4] Prokash Paul, Namjoon Kim, Seo-Young Park, Garry Handelman, Jaeyeon Kim, and, Yoon, S.*, (2022), Advances and challenges of population PK/PD modeling of long-acting injectable, **Journal of Pharmacology (Submitted)**
- [5] Prokash Paul, Namjoon Kim, Garry Handelman, Jaeyeon Kim, and, Yoon, S. *, (2022), Qualitative Analysis of Complex Pharmacokinetics of Generic and Reference Listed Long-Acting Injectable Products, International Journal of Pharmaceutics (FDA Clearance Pending)
- [6] Yuri Svirkin, Jaeweon Lee, Richard Marx, Seongkyu Yoon, Nelson Landrau, Md Abul Kaisar, Bin Qin, Jin H. Park, Khondoker Alam, Darby Kozak, Yan Wang, Xiaoming Xu, Jiwen Zheng, Benjamin Rivnay. Ampptericin B release rate is the link between drug status in the liposomal bilayer and toxicity, Asian Journal of Pharmaceutical Sciences, 2022, https://doi.org/10.1016/j.ajps.2022.04.007
- [7] Kazarin, P., Kessler, W., Gong, E. *et al.* A Compact Model for Lyophilizer Equipment Capability Estimation. *AAPS PharmSciTech* **23**, 14 (2022). https://doi.org/10.1208/s12249-021-02167-8

2021

[8] Kuang, B., Dhara, V.G., Hoang, D., Jenkins, J., Ladiwala, P., Tan, Y., Shaffer, S.A., Galbraith, S.C., Betenbaugh, M.J. and Yoon, S., 2021. Identification of novel inhibitory metabolites and impact verification on growth and protein synthesis in mammalian cells. *Metabolic engineering communications*, 13, p.e00182.

- [9] Kazarin, P., Kessler, W., Gong, E., Yoon, S., Liu, H., Marx, R., Bogner, R. and Alexeenko, A., 2022. A Compact Model for Lyophilizer Equipment Capability Estimation. *AAPS PharmSciTech*, 23(1), pp.1-15.
- [10] Morris, C., Madhavarao, C.N., Yoon, S. and Ashraf, M., 2021. Single in-line biomass probe detects CHO cell growth by capacitance and bacterial contamination by conductivity in bioreactor. *Biotechnology Journal*, 16(12), p.2100126
- [11] Bogner, R., Gong, E., Kessler, W., Hinds, M., Manchanda, A., Yoon, S., Liu, H., Marx, R., Zhao, J., Sharma, P. and Bhambhani, A., 2021. A Software Tool for Lyophilization Primary Drying Process Development and Scale-up Including Process Heterogeneity, I: Laboratory-Scale Model Testing. *AAPS PharmSciTech*, 22(8), pp.1-16.
- [12] Liu, H., Meyer, R., Flamm, M. *et al.* Optimization of Critical Quality Attributes in Tablet Film Coating and Design Space Determination Using Pilot-Scale Experimental Data. *AAPS PharmSciTech* **22**, 17 (2021). https://doi.org/10.1208/s12249-020-01884-w
- [13] Caitlin Morris, Yong Suk Lee, Seongkyu Yoon, Adventitious agent detection methods in bio-pharmaceutical applications with a focus on viruses, bacteria, and mycoplasma, Current Opinion in Biotechnology, Volume 71, 2021, 105-114, https://doi.org/10.1016/j.copbio.2021.06.027.
- [14] Hoang, Duc, Shaun Galbraith, Bingyu Kuang, Amy Johnson, and Seongkyu Yoon. "Characterization of Chinese Hamster Ovary Cell Culture Feed Media Precipitate." *Biotechnology progress*.
- [15] Graham, Ryan J., Adil Mohammad, George Liang, Qiang Fu, Bingyu Kuang, Ashli Polanco, Yong Suk Lee, R. Kenneth Marcus, and Seongkyu Yoon. "Effect of iron addition on mAb productivity and oxidative stress in CHO culture." *Biotechnology progress*.
- [16] Graham, Ryan J., Stephanie A. Ketcham, Adil Mohammad, Evan Paregol, Seongkyu Yoon, Guozhang Zou, Tongzhong Ju, Patrick J. Faustino, Muhammad Ashraf, and Chikkathur N. Madhavarao. "Zinc supplementation modulates intracellular metal uptake and oxidative stress defense mechanisms in CHO cell cultures." *Biochemical Engineering Journal* 169 (2021): 107928.
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- [19] Behere K., S. Yoon (2020), Chromatography Bioseparation Technologies and In-Silico Modelings for Continuous Production of Biotherapeutics, Journal of Chromatography A., https://doi.org/10.1016/j.chroma.2020.461376
- [20] Polanco, A, Kuang, B., S. Yoon, Bioprocess Technologies that Preserve the Quality of iPSCs", Trends in Biotechnology https://doi.org/10.1016/j.tibtech.2020.03.006
- [21] Huang, Z, Galbraith, S., S. Yoon (2020), Effects of process parameters on tablet critical quality attributes in continuous tablet direct compression: A case study of integrating data-driven statistical model and first-principle flowsheet model" Pharmaceutical Development and Technology 1-12, https://doi.org/10.1080/10837450.2020.1805760

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- [23] Huang, Z, S. Yoon (2020), Integration of time-series transcriptomic data with genome-scale CHO metabolic models for mAb engineering. Processes, 8(3), 331; https://doi.org/10.3390/pr8030331
- [24] Huang, Zhuangrong, Jianlin Xu, Andrew Yongky, Caitlin S. Morris, Ashli L. Polanco, Michael Reily, Michael Borys, Zheng Jian Li, and Seongkyu Yoon. "CHO cell productivity improvement by genome-scale modeling and pathway analysis: Application to feed supplements." *Biochemical Engineering Journal* (2020), /doi.org/10.1016/j.bej.2020.107638
- [25] Huang, Z, S. Yoon (2020), Identifying metabolic features and engineering targets for productivity improvement in CHO cells by integrated transcriptomics and genome-scale metabolic model, Biochemical Engineering Journal, https://doi.org/10.1016/j.bej.2020.107624
- [26] Morris, C., Polanco, A., Yongky, A. *et al.* Bigdata analytics identifies metabolic inhibitors and promoters for productivity improvement and optimization of monoclonal antibody (mAb) production process. *Bioresour. Bioprocess.* 7, 31 (2020). https://doi.org/10.1186/s40643-020-00318-6
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- [33] YHV Soong, N Liu, S Yoon, C Lawton, D Xie, Cellular and metabolic engineering of oleaginous yeast *Yarrowia lipolytica* for bioconversion of hydrophobic substrates into high-value products Engineering in Life Sciences 19 (6), 423-443

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- [35] Galbraith, Shaun C., Huolong Liu, Bumjoon Cha, Seo-Young Park, Zhuangrong Huang, and Seongkyu Yoon. "Modeling and simulation of continuous powder blending applied to a continuous direct compression process." *Pharmaceutical development and technology* 23, no. 10 (2018): 1097-1107
- [36] RJ Graham, H Bhatia, S Yoon, Consequences of trace metal variability and supplementation on Chinese hamster ovary (CHO) cell culture performance: A review of key mechanisms and considerations, Biotechnology and Bioengineering 116 (12), 3446-3456
- [37] DN Powers, Y Wang, EJ Fratz-Berilla, SR Velugula-Yellela, B Chavez, and S, Yoon, Real-time quantification and supplementation of bioreactor amino acids to prolong culture time and maintain antibody product quality, Biotechnology Progress 35 (6), e2894,
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- [39] B Rivnay, J Wakim, K Avery, P Petrochenko, JH Myung, D Kozak, S Yoon, Critical process parameters in manufacturing of liposomal formulations of amphotericin B, International journal of pharmaceutics 565, 447-457
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- [41] SC Galbraith, B Cha, Z Huang, S Park, H Liu, RF Meyer, MH Flamm, and S. Yoon, Integrated modeling of a continuous direct compression tablet manufacturing process: A production scale case study, Powder Technology 354, 199-210
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- [64] Galbraith, S.C. Zhuangrong Huang, Bumjoon Cha. Hurley Liu, Huolong, and S. Yoon*, (2017), Flowsheet modeling of a continuous direct compression tableting process at production. FOCAPD Conference Proceeding

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Book chapters

- [1] HW Lee, H Bhatia, SY Park, MH Kamga, T Reimonn, S Sha, Z Huang, and S. Yoon (2019), Process Analytical Technology and Quality by Design for Animal Cell Culture, Cell Culture Engineering: Recombinant Protein Production, 365-390
- [2] Yoon, S., S. Galbraith, H. Liu, B. Cha, (2018), Flowsheet modeling of a continuous direct compaction process, Computer Aided Chemical Engineering 41, 121-139 edited by Singh and Yuan, Elsevier
- [3] S. Yoon* (2014), Basic principles and application trend of Quality By Design in "Roadmap to Becoming Biopharmaceutical Leader", Editors: Korean FDA, 2014 (in Korean)
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• Invention disclosures & patents: 4

- 1) Patent on Inhibitory Metabolites (Inventor: Seongkyu Yoon)
- 2) Provisional Patent on Continuous Perfusion Media and Process Control (Inventor: Seongkyu Yoon)
- 3) UML-2013-16 on New method of media formulation and optimization for bio- therapeutic development (Inventor: Seongkyu Yoon) Turned down
- 4) Distributed perfusion bioreactor system for continuous culture of biological cells US Patent 10,214,718 (Inventors: O Berteau, Y Seongkyu, D Sergeant, T Poskin)
- 5) Provisional Patent on Estimation of Viable Cell Density During Late Growth Phase of CHO Cell Culture Using Dielectric Spectroscopy (Inventor: Seongkyu Yoon and Haewoo Lee) Turn down
- 6) Provisional Patent (M&E Ref. 118082-00801) on Distributed perfusion bioreactor system for continuous culture of biological cells (Inventors: Olivier Berteau, Apicells; David Sergeant: Ipratech; Seongkyu Yoon: UMass Lowell
- 7) WP-2317 Sustainable Green Vinyl Ester Resin (GVER) for Renewable Resources (Inventor: Akshay Kokil, Priyank Shah, Seongkyu Yoon, Robert Kovar, Yongwoo Lee)

• Conferences presentation and invited talks

- [1] Yoon, S. (2022), Identification and Control of Novel Waste Inhibitory Metabolites In CHO Cell-Cultures, ESACT2022, Lisbon Portugal
- [2] Morris, Caitlin, and Yoon, S. (2022) Single in-line biomass probe detects CHO cell growth by capacitance and bacterial contamination by conductivity in bioreactor, ESACT2022, Lisbon Portugal
- [3] Fu, Qiang and Yoon, S. (2022) Design space determination and process optimization of critical quality attributes in AAV gene therapy manufacturing, ESACT2022, Lisbon Portugal

- [4] Graham, RJ. *and S. Yoon (2020)*. "Trace metal variability in culture media can impair CHO culture performance by enhancing mechanisms of oxidative stress." American Chemical Society National Meeting, August 2020, San Francisco, CA.
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- [6] Graham, RJ. *and S. Yoon.* (2019). "Zinc enhances β-glucuronidase secretion from CHO cells by suppressing apoptosis." American Chemical Society National Meeting, April 2018, Orlando, FL.
- [7] <u>Yoon</u>, (2019), Biomanufacturing Sciences Challenges and Opportunities South Dakoda University of Mines and Science
- [8] Sha, <u>Yoon</u>, (2019), An Investigation of Nucleotide Sugar Dynamics Under the Galactose Supplementation in CHO Cell Cultures, GlycoBioTech 2019, Jan 28-30, Berlin Germany
- [6] <u>Caitlin Morris, S. Yoon</u>, (2019), Manufacturing Platform, Flowsheet Modeling, and Optimization of Continuous Viral Vaccine Production Process Golden Research Conference on Biotherapeutics and Emerging Technology, Galveston, TX.
- [7] <u>Sha</u>, Yoon, (2018), RNA-seq data reveals transcriptomic regulation in Chinese Hamster Ovary cell culture, New Orleans, ACS
- [8] <u>Galbraith</u>, Yoon (2018), Media Formulation Optimization Based on Multi-Scale Modeling of Heterogeneity in Mammalian Cell Culture Process, New Orleans, ACS
- [9] S. Yoon (2018), Biomanufacturing Innovation in Biopharmaceutical Industry, IFPAC, Feb. 2018 (Invited Talk)
- [10] <u>S. Yoon</u> (2017), Continuous Pharmaceutical Manufacturing, FDA Workshop, Silver Spring MA, Oct 31, 2017 (Invited Talk)
- [11] <u>S. Yoon</u> (2017), Systems Biotechnology in Biomanufacturing Innovation, RAFT (Recent Advances in Fermentation Technology), Oct 30, 2017, Ft. Myers FL (Invited Talk)
- [12] <u>S. Yoon</u> (2017), What, how, why quality metrics, US FDA's quality metrics initiative, Global Biotechnology Conference 2017, Jun 2017, Seoul, Korea (Invited Talk)
- [13] <u>S. Yoon</u> (2017), How can systems biotechnology add values to biopharmaceutical development and manufacturing? BMS Invited Speaker Series, June 2017, Devens, MA, USA (Invited Talk)
- [14] <u>S. Yoon (2017)</u>, Missing Opportunities of Multivariate Modeling in Pharmaceutical Sectors, IFPAC 2017, 31th International Forum Process Analytical Technology, Feb 2017, North Bethesda MD, USA
- [15] <u>S. Yoon</u> (2017), How can systems biotechnology add values to biopharmaceutical development and manufacturing? Soonchun University, July 2017, Soonchin, Korea (Invited Talk)
- [16] <u>Galbraith S. G.</u>, and S. Yoon (2017), "Flowsheet Modeling of a Continuous Direct Compression Process at Production Scale", ADCHEM/APC 2017, Jan 2017, Scottdale, AZ
- [17] <u>Liu</u>, H. and S. Yoon (2017), "Three-compartmental population balance model and experimental validation of a continuous twin-screw wet granulation process", ADCHEM/APC 2017, Jan, 2017 Scottdale, AZ.
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- [21] <u>S. Yoon</u> (2016), "Biomanufacturing Sciences and Technology Consortium Challenges and Update", 2016 AIChE Annual Meeting, Nov 8-13, San Francisco, CA.
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- [25] <u>S. Yoon</u> (2016), "Control and Estimation of N-Glycosylation for Biotherapeutics Manufacturing", Cell Culture Engineering, May 9-13, Palm Springs CA.
- [26] <u>K. Behere</u> and S. Yoon (2016), "Evaluation of a continuous chromatography process through process modeling and resin lifetime study", IFPAC, DC.
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- [28] <u>H. Hemlata</u> and S. Yoon (2016), "Genomics Based Methodology of Cell-Culture Media Formulation for Improved Bio-Therapeutic Productivity and Quality Consistency", IFPAC, DC.
- [29] J. L. Staudenmann, and <u>S. Yoon</u> (2016), "NIST/AMTech Program and BSTC Consortium", Feb 2016, IFPAC, DC.
- [30] S. Yoon (2016), "Quality Metrics, Challenges, and Tools", IFPAC, DC.
- [31] <u>S. Galbraith</u> and S. Yoon (2016), "Blender Modeling in a Continuous Direct Compaction Process using a Tanks in Series Method", Feb. 2016 IFPAC, DC.
- [32] <u>H. Hemlata</u> and S. Yoon (2015), "Genomics Based Methodology of Cell-Culture Media Formulation for Improved Bio-Therapeutic Productivity and Quality Consistency", ICB2 Conference, Berkeley CA.
- [33] <u>K. Behere</u> and S. Yoon (2015), "Evaluation of a continuous chromatography process through process modeling and resin characterization", ICB2 Conference, Berkeley CA.
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- [37] S. Yoon (2016), "Systems Biotechnology in Biomanufacturing," Rutgers University, NJ.

- [38] <u>S. Yoon</u> (2015), "Regulatory expectation and industrial practices on continuous validation and process performance qualification", 2015 Global Biotechnology Conference, June 30, Songdo, Korea 29 July 3
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- [40] <u>S. Sha</u>, Kurt Brorson, Erik Read, Cyrus Agarabi, Scott Lute, and Seongkyu Yoon (2015), "Investigation of intracellular pathway perturbation leading to antibody glycosylation variation under varied cell culture conditions", IFPAC, VA, Jan 25-28
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- [44] <u>S. Yoon</u>, (2014), "How to assess intracellular characteristics of CHO cells? Systems Biotechnology Approach", Monthly Technology Seminar, Bristol-Myer-Squipp, Hopkinton, MA Dec 2014 (Invited)
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- [46] <u>S. Yoon</u>, (2014), "Robust Optimization Design Space Exploration and Examination", 2014 QbD International Forum, Korea Biotech Industry Association, Seoul Korea, Sep 2014 (Invited)
- [47] <u>S. Yoon</u>, (2014), "QbD Roadmap Multivariate statistics applications in biopharmaceutical development and manufacturing", Shire HGT, Lexington MA, June 2014 (Invited)
- [48] <u>S. Yoon</u>, (2014), "Assessment, Monitoring and In-Process Control of Critical Raw Material Variability in Mammalian Cell-Culture", Biomanufacturing & Process Innovation Leaders Summit, June 10-12, Boston MA (Invited)
- [49] <u>S. Yoon</u>, (2014), "Opportunities of multivariate statistics applications in biopharmaceutical development and manufacturing", AAPS, National Biotechnology Conference, May 19-21, San Diego CA 2014 (Invited)
- [50] S. Yoon, (2014), "How to unveil intracellular characteristics of CHO cells? Metabolic Analysis and Glycosylation Modeling of CHO Cells with Raw Material Variability", University of Massachusetts, BiogenIdec, Cambridge, MA, March 2014 (Invited)
- [51] <u>S. Yoon</u>, (2014), "Intracellular characteristics and glycosylation reaction network model", University of Massachusetts, Cell-Culture Engineering Conference, Quebec Canada, May 2014 (Poster Presentation)
- [52] <u>S. Yoon</u>, (2014), "Intracellular characteristics and glycosylation reaction network model", University of Massachusetts, Mass Biologics, West Roxbury, MA, March 2014 (Invited)
- [53] <u>S. Yoon, (2014)</u>, "Intracellular characteristics of Chinese Hamster Ovary Cells", IFPAC, DC, Jan 21-25 (Invited)

- [54] <u>S. Yoon</u>, (2014), "Simulation and Optimization of Continuous Downstream Process in Biopharmaceutical Manufacturing", PEPTALK, Palm Springs, CA, Jan 13-17, 2014 (Invited)
- [55] <u>S. Yoon</u>, (2013), "Spectral Technology Application in Biologics", Eastern Analytical Symposium, Summit NJ, November 2013 (Invited)
- [56] <u>N. Trunfio</u>, H. Lee and S. Yoon, (2013), "Raw material characterization for mammalian cell-cultures using spectral technologies", Eastern Analytical Symposium, Summit NJ., November 2013
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- [58] <u>S. Yoon</u>, (2013), "Monitoring and Control in Pilot Scale Biologics Production", Bioprocessing Summit 2013, Boston MA, August 19-23, 2013
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- [61] S. Yoon. O. Berteau and H. Hemlata (2013), "Systems approach for media formulation and optimization", ESACT 2013, France, June 21-24
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- [64] <u>S. Yoon</u> (2013), "Manufacturing Sciences in Biopharmaceutical Industry", 3rd International Symposium on Research, Development and Manufacturing of Biopharmaceuticals in Global Market, Osong Medical Innovation Foundation, Korea, 2013 (Invited Talk)
- [65] <u>S. Yoon (2013)</u>, "Intracellular Metabolic Flux Analysis of CHO cells Supplemented with Wheat Hydrolysates for Improved mAb Production and Cell-growth", Quality by Design International Workshop, Osong Medical Innovation Foundation, Korea, Oct 2013 (Invited Talk)
- [66] <u>S. Yoon</u> (2013), "Assessment, monitoring and in-process control of critical raw material variability in mammalian cell-culture", 2013 Raw material characterization IBC Summit, San Diego CA, 2013
- [67] <u>S. Yoon</u> (2013), "Improved Estimation of Viable Cell Density using Dielectric Spectroscopy", 2013 Aber Instrument Webinar, Feb 4, 2013
- [68] <u>H. Lee</u> and S. Yoon (2013), "Advanced Real-time Monitoring of Cell Growth in Therapeutic Protein Production using Dielectric Spectroscopy and Chemometrics", IFPAC, Baltimore MD, 2013
- [69] <u>S. Yoon</u> (2012), "Converting data into value multivariate data analysis in biopharmaceutical", Lonza Biologics, Portsmouth NH (Invited talk)
- [70] H. Lee and <u>S. Yoon (2012)</u>, "Variability management and in-process control of critical raw materials in mammalian cell-cultures," 2012 Process to Product Summit, DC Oct 31-1 2012

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- [72] M. Kamga, and S. Yoon (2012), Application of Process Analytical Technology in Protein Purification: Use of Second & Fourth Derivative Ultra Violet (UV) for Making Real-Time Pooling Decisions in Chromatography, PREP 2012, July 2012, Cambridge MA
- [73] <u>A. Bawn</u>, H. Lee, S. Yoon (2012), "Batch quality control of monoclonal antibody product (MAb) in mammalian cell-culture", *2012 ASEE Northeast Section Conference*, Lowell, MA, April 2012. (No record)
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- [75] M. Kamga, H. Lee and S. Yoon (2012), Modeling and binding capacity estimation of hydrophobic interaction chromatography, Biopharmaceutical Summit 2012, March 2012, Lowell MA
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- [81] <u>S. Dutta</u> and S. Yoon (2012), Systematic media optimization of CHO cells for biosimilar development, Biopharmaceutical Summit 2012, March 2012, Lowell MA
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- [83] <u>H. Lee</u> and S. Yoon (2012), Complementary data fusion for raw materials in mammalian cell-culture, CEC XIII, April 2012, Scottsdate, AZ (No slide)
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- [85] <u>H Lee and S. Yoon (2011)</u>, Breast Cancer Growth Modeling, AIChE Annual conference, Oct 2011, Minneapolis, MN (No slide)
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- [93] <u>S. Yoon (2011)</u>, Trends in Biopharmaceutical micro and macroscopic views, Korean Scientist and Engineer Association, MIT, Cambridge, MA
- [94] <u>A. Gupta</u> and S. Yoon (2011), Ozone based cleaning technology, Sustainable Remediation Conference, June 1, 2011, Amherst, MA
- [95] H. Lee and S. Yoon (2011), "Feature selection of mass spectroscopy for robust ovarian cancer diagnosis", 2nd Annual Clinical and Translational Science Research Retreat, May 12 2011, Worcester MA (Selected as the best poster)
- [96] N. Trunfio, Victor Neel, Anna Yaroslavsky, and Seongkyu Yoon (2011), Image processing and delineation for the intra-operative mapping of nonmelanoma skin cancer, 2011 Massachusetts Undergraduate Research Conference, Amherst, MA (No slide)
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UNIVERSITY AND COMMUNITY ACIVITIES

• University, College and Department Committees:

Committee	Term	Frequency of	Accomplishment	Role
		Meeting		
Biomedical	2015 -	On-going	Hiring	Member
Engineering and	Current		research/adjunct	
Biotechnology Personal			faculty	
Committee			-	

Non-tenure track hiring committee	2010-current	Every week in the semester	Reviewed all applications and Identified finalists	Member
Tenure track hiring committee	2010-current	Every week in the semester	Reviewed applications and identified finalists	Member
Graduate Committee	2010 - Current	Ad-hoc	Qualification exam and PhD degree requirement proposal Preparation	Member
Biomedical Minor Committee	2011 Fall	Ad-hoc	Developing proposal draft	Member
Graduate Qualification Exam Improvement	2012 Spring	Ad-hoc	Developing new qualification exam proposal	Member
Faculty senate	2014 – 2017	Once a month	Voting on University's GPAC/UPAC Proposals	Member
Pharmaceutical Science Graduate Committee	2014 – Current	Ad-hoc	Pharmaceutical Science Program	Member

• Biopharmaceutical Industry Community:

Conferences, workshops, training program organizer for professional community

Professional Community Activities	Location, Date	Results
NSF/IUCRC AMBIC Biannual Meeting	(Hybrid) 2021	
NSF/IUCRC AMBIC Biannual Meeting	(Virtual) 2020	
NSF/IUCRC AMBIC Biannual Meeting	College Park MD, Dec, 2019	
NSF/IUCRC AMBIC Biannual Meeting	St, Louis MO, Dec 10-12, 2018	
NSF/IUCRC AMBIC Biannual Meeting	South San Francisco, June 18-20, 2018	
Industry short course coordinator:	Lowell MA, Oct 17, 2018	
"Continuous Chromatography",		
Industry short course coordinator:	Lowell MA, Oct 24, 2018	
"QbD/PAT in Biopharmaceutical",		
Industry short course coordinator:	Lowell MA, Aug 6-10, 2018	
"Advanced Industrial Bioprocessing",		
Conference Chair and Coordinator:	Boston MA, Sep 9-10, 2018	
"Biomanufacturing Innovation",		
Biomanufacturing Annual Summit		
Session Chair/Co-Chair:	North Bethesda, MD, Feb.	
"Biomanufacturing", IFPAC 2018	2018	
Industry short course coordinator:	May 24-26, 2017	
"Advanced Bioprocessing",		

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6th Biopharmaceutical Summit –	May 22-23, 2017	21 speakers, 25 posters, 140
Beyond mAbs	Boston, MA	professionals attended from 50
Biopharmaceutical Summit Training -	May 24 26 2017	companies Advanced Industrial Bioprocessing
Coordinator	May 24-26, 2017 Boston MA	Training, 17 People attended
5th Biopharmaceutical Summit – Future	May 23-24, 2016	26 speakers, 30 posters, 150
Biomanufacturing	Lowell MA	professionals attended from 50
Biomanufacturing	Lowell WA	companies
Biopharmaceutical Summit / Training -	May 18-20, 2016	Continuous Bioprocessing
Coordinator	Lowell MA	Training, 10 People attended
Biopharmaceutical Summit – Training	May 25-27, 2016	Fundamental of PAT & QbD in
Biopharmaceureur summing	Lowell MA	Biopharmaceutical, 10 People
	Edwen iii i	attended
Multivariate Statistics – Training	Jun-Aug 2015, FDA	Fundamental of PAT & QbD in
		Biopharmaceutical, 12 FDA staff
		attended
4th Biopharmaceutical Summit - Raw	May 18-19, 2015	25 speakers and panelists, 18
material variability	Lowell MA	posters, 100 professionals
		attended from 35 companies
Biopharmaceutical Summit – Training	May 20-22, 2015	Fundamental of PAT & QbD in
	Lowell MA	Biopharmaceutical, 15 People
		attended
3rd Biopharmaceutical Summit - PAT	May 29-30, 2014	21 speakers and panelists, 30
and QbD	Lowell MA	posters, 145 professionals
		attended from 50 companies
Biopharmaceutical Summit – Training	May 27-28, 2014	Fundamental of PAT & QbD
	Lowell MA	in Biopharmaceutical, 25 People
		attended
2nd Biopharmaceutical Summit -	May 15 2013	13 speakers and panelists, 15
Continuous Bioprocessing	Lowell MA	posters, 145 professionals attended
		from 50 companies. Chancellor
		and provost came to give welcome
D' 1 10 /m	36 12 14 2012	talks.
Biopharmaceutical Summit / Training -	May 13-14, 2013	Continuous Bioprocessing
Coordinator PSM (Professional Science Master)	Lowell MA June 17-21, 2013	Training, 25 People attended
	Lowell MA	PSM workshop for Korean Professors
workshop – Training Technology Leaders of Korea Coordinator	Lowell MA	Professors
PAT Training	Oct 27, 2013	2 days of training for 40
1711 Hanning	Seoul Korea	biopharmaceutical engineers
1st Biopharmaceutical Summit -	March 9 2012 Lowell MA	20 speakers and panelists, 22
Biopharmaceutical Challenges and	Water 9 2012 Lowell WA	posters, 150 professionals
Innovations		attended from 60 companies
11110 (4410)		including FDA, Massachusetts
		Life Sciences Center, most big
		biopharmaceuticals; Chancellor
		and MLSC CEO came to give
		welcome talks.
Founded Biopharmaceutical Product	Univ. of	
and Quality Consortium with UMass	Massachusetts Lowell	
S&T funding		
- Assembled steering committee		
- Assembled advisory board		
- Started cell-line development		
Started cert file development	J	

project for biosimilar	

INSTRUCTION RELATED ACTIVITY

• Students graduated with thesis, project or independent study

- 1) Ashli Polanco (Transferred PhD in Jan 2018 in Completed in May 2022, Now at Biogen), Elucidating the combined metabolic effects of Zinc and copper supplementation on CHO cell culture
- 2) William Stuart (Started PhD in September 2012 and converted as part-time student in 2013, Completed in May 2022 Completer in May 2022), Inhibition of embryonic ectoderm development as a novel mechanism for fetal hemoglobin induction in sickle cell disease
- 3) Ryan Graham (Started PhD in September 2017, and completed in Dec 2020, Now at Genentech), CHO Trace-Metal Characterization
- 4) Bingyu Kuang (Started PhD in September 2016, and completed in Dec 2021, Now at Abbie), Inhibitory Metabolites Identification and Control
- 5) Nivedita Shirpurkas (Started MS in Sep 2016 and Completed in Dec 2020 in Chemical Engineering, now at Takeda)
- 6) Zhuangrong Huang (Started PhD in September 2013, and completed in Dec 2019, Now at BMS), CHO Genome Scale Modeling
- 7) Mark Henry Kamga (Started PhD in September 2015, and completed in Dec 2019, Now at Thermofisher), CHO Epigenetic characteristics
- 8) Sha Sha (Started PhD in September 2013, and completed in Dec 2018, Now at Ultrazenyx), CHO Glycosylation
- 9) Ashwitha Rajagopal, (Started MS in Sep 2017 in Biological Sciences, and completed in May 2018, Now at BMS)
- 10) Alessandro Mora (Started PhD in September 2012 as part-time PhD, full time at Abbott), Metabolic Flux Analysis for mammalian cell-culture, Completed in Dec 2017, Now at)
- 11) Hemlata Hemlata (Started PhD in January 2013, Completed in Dec 2017, Now at Takeda), Systems approach for media formulation and Optimization
- 12) Seoyoung Park (Started PhD in September 2013, Completed in Dec 2017, Now at Sungkuenkwan Univ as re), Metabolomics of CHO cell Culture
- 13) Nicholas Trunfio (Started PhD in September 2013, Completed in Dec 2017, now at FDA), Cell Network
- 14) Ketki Behere, PhD, Downstream process development for continuous bioprocessing, (Completed in April 2017, Now at BMS)
- 15) Thomas Reimonn, Honors Thesis, Dynamic Metabolic Flux Balance Modeling of Hybridoma Cell-Culture (Completed in May 2015, Now MD/PhD at UMass Medical School)
- 16) MarkHenry Kamga, Master of Science, Hydrophobic Interaction Chromatography Modeling and Characterization, (Completed in Dec 2012. Now enrolled in PhD program after 3 years of works)
- 17) Andrew Bawn, Master of Science, Characterization of Raw material impact to Cell Growth, MS, (Completed in Dec 2012, now at Joule Unlimited, now at Abbive)
- 18) Nicholas Trunfio, Undergraduate project on Image Processing of Skin Cancer using Multivariate Statistical Method, 2012

- 19) Sumit Dutta, Master of Science, Cell line development, 2012 (Graduated in 2012 December, now at Pfizer)
- 20) Karina Riojas, Master of Science, Chemometrics analysis of mammalian cell-culture (Graduated in 2013 May, now at Takeda)
- 21) Ketki Dashkar, Master of Science, Chromatography modeling (Graduated in 2014 May, now at Biogen)
- 22) Omer Karpuz (Started in September 2011 and transferred in May 2012 to Yildiz Technical University, Turkey)

• Current graduate students -9 PhD candidates, 0 Master Students

- 1) Yongdan Wang (Started PhD in May 2020)
- 2) Soyoung Park (Started PhD in May 2020)
- 3) Richard Marx (Started PhD in May 2019)
- 4) Qiang Fu (Started PhD in May 2019)
- 5) Yongsuk Lee (Started MS in 2018 and transferred to PhD in Sep 2019)
- 6) George Liang (Started PhD in Sep 2019)
- 7) Caitlin Morris (Started PhD in May 2018)
- 8) Duc Huong (Started PhD in Sep 2018)
- 9) Zhao Wang (Started PhD in Jan 2018)

• FDA ORISE Fellowship

- 1) Jaewan Lee, 2021-2022
- 2) George Liang, 2020-2021
- 3) Caitlin Morris, 2019-2020
- 4) Ryan Graham, 2017, 2018 Summer
- 5) Bingyu Kuang, 2017 Summer
- 6) MarkHenry Kamga, 2015 Summer, 2016 Summer
- 7) Hemlata Hemlata, 2016 Summer
- 8) Nicholas Trunfio, 2016 Summer/Fall, 2017 Spring/Summer/Fall
- 9) Sha Sha, 2014 Summer, 2015 Summer

• Post-doctoral fellows/Research Engineer – 8 Fellows

- 1) Dr. Prokash Paul (Feb 2016 2018, Full-time)
- 2) Dr. Shaun Galbraith (March 2015 Jan 2020: Full-time; Jan 2020 Current: Part Time)
- 3) Dr. Huolong Liu (April 2015 May 2020, Full Time), AstraZeneca
- 4) Dr. Bumjoon Cha (October 2015 Aug. 2017, Full Time), Samsung Biologics
- 5) Dr. Namjoon Kim (January 2013 Aug 2020, Part-time), MilliporeSigma
- 6) Dr. Mohammd Masuri (November 2015 Feb 2016, Full-time), Now at Amgen (Cambridge, MA)
- 7) Dr. Nate Kingsbury (March 2016 Sep 2016, Full-time). Now at Millipore (San Diego, CA)
- 8) Dr. Haewoo Lee (Aug 2010 Oct 2013, Now at DGMIF (Daegu Kyungbuk Medical Innovation Foundation as Sr. Research Staff))

Saonskyn Joon

Jul 15, 2022

Signature Date Filed