

Sarfaraz K. Niazi, Ph.D., SI, FRSB, FPAMS, FACB
20 Riverside Drive, Deerfield, Illinois 60015. USA
Phone: +1-312-298-0000; Fax: +1-312-297-1100; email: niazi@niazi.com

Expertise:

- **Pharmaceutical Preformulation**
- **Pharmaceutical Formulations**
- **Commercial Manufacturing**
- **Bioequivalence Testing**
- **Biological Products Formulation**
- **Clinical Testing**
- **Statistical Modeling**
- **Bioprocess Technology**
- **New Chemical Entities**

Education:

- 1974: Ph.D., Pharmaceutical Sciences, University of Illinois, Chicago, IL
- 1970: MS, Pharmaceutical Sciences, Washington State University, Pullman, Washington
- 1969: B. Pharm., Karachi University, Pakistan
- 1968: Diploma Marketing, Institute of Business Administration, Karachi, Pakistan
- 1966: BSc., Karachi University, Pakistan

Professional:

Patent Agent, US Patent and Trademark Office, 2002-present. Prosecuted 200+ patents.

Positions:

Academic:

- 1972-1988: Instructor to Tenured Associate Professor at University of Illinois College of Pharmacy, Chicago, Illinois.
- 2000-Present: Visiting and Foreign Professor, HEJ Research Institute, Karachi, Pakistan.
- 2004-present: Visiting Professor, National University of Science and Technology, Islamabad, Pakistan.
- 2012-Present: Visiting Professor, University of Houston College of Pharmacy.
- 2015-Present: Adjunct Professor of Biopharmaceutical Sciences, University of Illinois College of Pharmacy

Corporate:

- 1988-1995: Director Technical Affairs, Abbott International.
- 1995-Present: Founder and Executive Chairman, Pharmaceutical Scientist, LLC, Chicago, IL.
- 2003-2017: Founder and Executive Chairman, Adello Biologics, LLC (formerly Therapeutic Proteins Inc.), the first and fully integrated biosimilar products company in US, now owned by Kashiv Biosciences.

- 2017-present: Founder and Executive Chairman, Karyo Biologics, LLC, a virtual biosimilar products development company with several products in clinical approval stage with FDA.

Professional

- 2002-present: United States Patent and Trademark Office, Patent Agent.

Recognitions, Awards, and Contributions

- Civil Award by the President of Pakistan (Sitara-e-Imtiaz) for contribution to biotechnology.
- Fellowship of Royal Society of Biology, Pakistan Academy of Medical Sciences, American Society of Clinical Biochemistry.
- Forbes Magazine's Cover Pages:
 - "The Most Interesting Man Revolutionizing The Health World" 2014
 - "Scientist Invented A New Pathway To Approve Biosimilars, And The FDA Is Listening." 2019
- Invited contributor to BPCIA as advisor to the US Congress
- Invited advisor to President Obama.
- Advisor to US FDA on Biosimilars Guidance and Bioequivalence Testing
- Volwiler Fellow Abbott Laboratories (tenured)
- US Pharmacopoeia: advisor on Biosimilar Monographs, teaching faculty
- Inductee as US Entrepreneur Hall of Fame.
- University of Illinois Alumni of the Year
- TOKTEN Fellow for US Aid under PL-480 program.
- March of Dimes grant reviewer.
- Editorial boards of scientific journals.
- Radio host for Voice of America since 2008.
- Advisor to Higher Education Commission of Pakistan on intellectual property management since 2012
- Pro bono service to scientist in the developing countries to secure US patents.
- Invited speaker 500+ engagements worldwide.
- Innovation of the Year, Sponsored by Honeywell; Global Generics and Biosimilars Awards 2014: <https://www.generics-bulletin.com/media/19636/Winners-for-Website1.jpg>
- Finalists Best Upstream Technology Application 2012: TPI Single-use technology for production of bacterial proteins, Bioprocess International (<http://www.bioprocessintl.com/bioprocess-international-2016-awards/past-winners-of-bioprocess-international-awards/>).

Achievements

- Created the first line of generic products for Abbott Laboratories, solid dosage forms, suspensions, liquids.
- Assisted 10+ companies worldwide to establish biosimilar development and manufacturing.

- Convinced FDA to withdraw its Biosimilars Statistical Modeling Guidance and suggested replacement with a rational approach (August 2018).
- Convinced FDA to declare that comparative clinical efficacy trials are not appropriate (May 2019).
- Trained new hires as FDA inspectors in cGMP compliance.
- Trained 46 graduate students: MS. Ph.D.
- 100+ US patents; largest solo inventor of bioprocessing patents; NCE, NBE, drug delivery, natural products, drug testing, wine aging, automobile safety, disease management, and other technologies.
- Developed a fourth-dimension analytical similarity testing to achieve fingerprint-like similarity for biosimilars.
- Developed a biodistribution PK model recommended by FDA in 2019 to establish interchangeability (May 2019)
- Developed an ISO 9 bioreactor used to file the first BLA of a biosimilar.
- First handbook authored on biosimilars. Largest number of books on biosimilars.
- First book on FDA views on biosimilarity; dedicated to Dr. Woodcock.
- Coordinated dozens of FDA audits of generic and biological manufacturers, secured first FDA approval of a product from ME countries.
- Advised dozens of regulatory authorities on creating guidelines: Indonesia, Canada, Japan, US and Australia.
- Consultant to investment bankers, VC groups and private investors on value proposition analysis in the field of pharmaceutical and biopharmaceuticals.
- Served as expert witness in IP and pharmaceutical cases.
- Taught physicians in the US on the regulatory pathways and safety features of biosimilars on behalf of large pharma companies.
- Founded the first US biosimilars company—raised \$500 Million [largest funding of startup biotech in US history].
- Chicago Marathon runner 2014.

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Sarfaraz K. Niazi - Wikipedia

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Sarfaraz Khan Niazi (Urdu: سرفراز خان نیازی) was born in Lucknow, India in 1949; he migrated to Karachi, Pakistan in 1962, and to the United States in 1970. He is an expert in biopharmaceutical manufacturing and has worked in academia and in industry, and as an entrepreneur.

[Employment](#) · [Honorary Teaching](#)

- <https://bioprocessintl.com/2019/january-february-2019/january-february-bioprocess-insider/>
- <https://bioprocessintl.com/bioprocess-insider/global-markets/biosimilars-big-pharmas-imminent-exit-in-sight-says-expert/>
- <https://bioprocessintl.com/2018/january-february-2018/january-february-editor/>
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- <https://www.centerforbiosimilars.com/news/citizen-petition-asks-fda-to-withdraw-contentious-biologic-naming-guidance>
- <https://www.centerforbiosimilars.com/news/biosimilar-regulatory-roundup-march-2019>
- <https://www.centerforbiosimilars.com/contributor/sarfaraz-niazi/2018/12/the-fda-biosimilar-action-plan-making-biologics-more-accessible>
- <http://gabi-journal.net/rationalizing-fda-guidance-on-biosimilars-expediting-approvals-and-acceptance.html>
- <https://www.forbes.com/sites/nicolefisher/2018/07/25/one-mans-mission-to-fix-the-fdas-biosimilar-problem/#1d8b19792380>
- <https://www.forbes.com/sites/nicolefisher/2014/08/30/the-most-interesting-man-revolutionizing-the-health-world/#442d379f20ba>
- <https://www.europeanpharmaceuticalreview.com/article/70987/obstacles-success-biosimilars-us-market/>
- <http://gabionline.net/Biosimilars/Research/Impact-of-proposed-changes-to-FDA-approach-to-biosimilars>

Publications

Books (Partial List): (<https://isbnsearch.org/search?s=Sarfaraz+Niazi>); 170 ISBNs

- Textbook of Biopharmaceutics and Clinical Pharmacokinetics, J Wiley & Sons, New York, NY, 1979; ISBN-13: 9789381075043
- The Omega Connection, Esquire Press, Illinois, 1982; ISBN-13: 9780961784102
- Adsorption and Chelation Therapy, Esquire Press, Illinois; 1987. ISBN-9780961784140
- [Attacking the Sacred Cows: The Health Hazards of Milk](#), Esquire Press, Illinois; 1988; ISBN-13: 9780961784119
- Endorphins: The Body Opium, Esquire Press, Illinois; 1988; ISBN 9780961784126
- Nutritional Myths: The Story No One Wants to Talk About, Esquire Press, Illinois. ISBN 9780961784133
- Wellness Guide. Ferozsans Publishers. Pakistan 2002. ISBN 9789690017932

- Love Sonnets of Ghalib: Translations, Explication and Lexicon, Ferozsons Publishers, Lahore, Pakistan 2002 and Rupa Publications, New Delhi, India 2002; ISBN-13: 9788171675968
- Filing Patents Online, CRC Press, Boca Raton, Florida, 2003; ISBN-13: 9780849316241
- Pharmacokinetic and Pharmacodynamic Modeling in Early Drug Development in Charles G. Smith and James T. O'Donnell (eds.), The Process of New Drug Discovery and Development (2nd ed.). New York: CRC Press, 2004; ISBN-13: 978-0849327797.
- Handbook of Biogeneric Therapeutic Proteins: Manufacturing, Regulatory, Testing and Patent Issues, CRC Press, Boca Raton, FL, 2005; ISBN-13: 9780971474611
- Handbook of Preformulation: Chemical, Biological and Botanical Drugs, Informa Healthcare, New York, NY, 2006; ISBN-13: 9780849371936
- Handbook of Bioequivalence Testing. New York: Informa Healthcare, 2007; ISBN-13: 978-0849303951
- Handbook of Pharmaceutical Manufacturing Formulations, Volume 6 Second Edition: Sterile Products, Informa Healthcare, New York, NY, 2009; ISBN-13: 9781420081305
- Handbook of Pharmaceutical Manufacturing Formulations, Volume 1 Second Edition: Compressed Solids, Informa Healthcare, New York, NY, 2009; ISBN-13: 9781420081169
- Handbook of Pharmaceutical Manufacturing Formulations, Volume 2 Second Edition: Uncompressed Solids, Informa Healthcare, New York, NY, 2009; ISBN-13: 9781420081183
- Handbook of Pharmaceutical Manufacturing Formulations, Volume 3 Second Edition: Liquid Products, Informa Healthcare, New York, NY, 2009; ISBN-13: 9780849317484
- Handbook of Pharmaceutical Manufacturing Formulations, Volume 4 Second Edition: Semisolid Products, Informa Healthcare, New York, NY, 2009 ISBN-13: 9781420081268;
- Handbook of Pharmaceutical Manufacturing Formulations, Volume 5 Second Edition: Over the Counter Products, Informa Healthcare, New York, NY, 2009; ISBN-13: 978-1420081282
- Textbook of Biopharmaceutics and Clinical Pharmacokinetics. Hyderabad, India: The Book Syndicate, 2010. ISBN 978-93-8107-504-3
- Wine of Passion: Love Poems of Ghalib, Ferozsons (Pvt) Ltd., Lahore, Pakistan, 2010; ISBN-13: 9780971474611
- Disposable Bioprocessing Systems, CRC Press, Boca Raton, FL, 2012; ISBN-13: 9781439866702
- Handbook of Bioequivalence Testing. Second Edition, New York, NY: Informa Healthcare, 2014 ISBN-13: [9781482226379](#)
- There is No Wisdom: Selected Love Poems of Bedil. Translations from Darri Farsi, Sarfaraz K. Niazi and Maryam Tawoosi, Ferozsons Private (Ltd), Lahore, Pakistan, 2015 ISBN 978969025036

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