Ajaz S. Hussain, Ph.D.

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Current Focus

Founder/Principal Ajaz S. Hussain Insight, Advice & Solutions LLC

President, the National Institute for Pharmaceutical Technology & Education (50%-time commitment)

Objectives

Focus on making high-quality medicines available and affordable; improving the efficiency and effectiveness of product development, manufacturing, quality assurance, and regulatory approval decision processes.

- Advisory and consulting services for the life science sector
- Complete solutions in collaboration with world-class collaborators
- Promoting research to inform public policies, rebuilding the Nations' educational infrastructure, creating opportunities for life-long learning.

Education

University of Cincinnati
1986 Ph.D. Interdisciplinary (Biopharmaceutics and Pharmacokinetics)
University of Bombay (now Mumbai)
1981 Bachelor of Pharmacy

Experience

The National Institute for Pharmaceutical Technology & Education (a not-for-profit academic organization which is primarily funded by Research Grants from US FDA)
President – elected for a 3-year term, February 2016; Executive Director, October 2014 - January 2016

NIPTE is a 501(c)(3) nonprofit academic organization dedicated to excellence in fundamental research and education in pharmaceutical science and manufacturing. Its mission is to improve human health through multi-university collaborative research by advancing quality, safety, affordability and speed to market of medicines. NIPTE is comprised of 16 top US schools of pharmacy, chemical and pharmaceutical engineering, and one medical school. Current members are Duquesne University, Illinois Institute of Technology, Long Island University, Purdue University, Rutgers University, University of Connecticut, University of Iowa, University of Kansas, University of Kentucky, University of Maryland Baltimore, University of Michigan, University of Minnesota, University of Puerto Rico, University of Rochester Medical Center, University of Texas, and University of Wisconsin.

Ajaz S. Hussain | Insight, Advice, and Solutions, LLC

Founder & President July 2013 –

A unique management consulting firm helping life science companies ensure rigor and sufficiency of scientific and regulatory evidence and to strengthen their strategies and systems for product development and regulatory submission. Mitigating risks of failure in development programs and regulatory non-compliance.

Wockhardt Ltd | Biopharmaceuticals and Pharmaceuticals

President Biotechnology & Chief Scientific Officer July 2012 – June 2013

Business strategy and development of Biosimilars product portfolio & scientific rigor and sufficiency of other development programs (New Chemical Entities and Complex Generics)

Philip Morris International | Tobacco

Chief Scientific Officer January 2013 – July 2013

Vice President Next Generation Product Assessment 2009 – 2012

Strategies and systems to successfully move forward development programs on plant-based vaccines, products for tobacco harm reduction, and ensure the credibility of scientific evidence to seek regulatory discussions and submissions.

Sandoz AG | Biopharmaceuticals and Pharmaceuticals

Vice President & Global Head of Biopharmaceutical Development 2005 – 2008

Development and/or regulatory submission of Biosimilars (in EU: Omnitrope®, Binocrit®, & Zarzio®), Follow-on Protein (in the US: Omnitrope®) and Complex Generic products (in the USA: Enoxaparin injection and Glatiramer acetate injection). These results were achieved during a critical phase for the company when it had to navigate through uncharted organizational, legal and regulatory terrains successfully.

The US Food & Drug Administration | Regulatory Agency

Deputy Director Office of Pharmaceutical Science, CDER 2000 – 2005

Several positions of increasing responsibilities at, CDER 1995 – 2000

Oversight responsibility for review assessment (Generic Drugs, Biotechnology Products, and New Drug Chemistry), research & testing and policy development. The leadership of the FDA's Process Analytical Technology (PAT) Initiative and CGMP's for the 21st Century. FDA-lead for Quality for ICH negotiations and the establishment of ICH initiative on Pharmaceutical Quality for the 21st Century (ICH Q8, Q9, and Q10). Solving difficult challenges and issues in CMC and CGMP areas, often linked to product recalls and Warning Letters or Consent Decrees.

University of Cincinnati – College of Pharmacy | Academia

Associate Professor (tenured) 1992 – 1994

Assistant Research Professor 1989 – 1991

Established a successful research program in the area of "Computer Aided Formulation Design" and the applications of artificial neural networks in modeling pharmacokinetics and pharmacodynamic data. Teaching professional and graduate students - pharmacokinetics, biopharmaceutics, advanced biopharmaceutics, and formulation design.

Ohio Northern University – College of Pharmacy | Academia

Assistant Professor 1986 – 1989

Teaching professional pharmacy students pharmaceutics, physical pharmacy, pharmacokinetics and clinical pharmacokinetics.

Significant Awards

- At FDA
    - FDA Scientific Achievement Award (2005): For unique collaborative effort among the FDA's PAT Team for developing a regulatory framework that supports innovative pharmaceutical development, manufacturing, and quality assurance.
    - Commissioner's Special Citation (2005): For successfully completing FDA's initiative on product quality regulation, leading to the implementation of new scientific and risk-based approached to pharmaceutical manufacturing and product quality.
    - CDER Award - Excellence in Communication (2000, 2001, and 2002)
    - FDA Scientific Achievement Award (2000): For development and implementation of a Biopharmaceutics Classification System to establish a mechanistic basis for correlating in vitro drug product dissolution and in vivo bioavailability.
    - CDER Award - Team Excellence (twice in 1998) – Biopharmaceutics Coordinating Committee and Biopharmaceutics Classification System Team

- CDER Award - Excellence in Mentoring (1999) Office of Clinical Pharmacology and Biopharmaceutics
- CDER Award – Leadership Excellence (1998) for exemplary leadership and guidance of important Center Initiatives and collaboration in support of science-based policy development.
- FDA Commendable Service Award (1998): For the implementation of a collaborative process, the Product Quality Research Institute, between FDA, industry, and academia to conduct product quality research to generate scientific information in support of the regulatory policy.

- Professional Associations
  - Indian Pharmaceutical Association's 2015 Dr. Venkateswarlu Memorial Lecture
  - The Medicine Makers (UK) 2015 Power List: 100 Most Influential Medicine Makers in 2015
  - Panjab University Pharmaceutical Science Oration 2014
  - Industrial Pharmacy Medal; International Pharmaceutical Federation
  - Fellow, American Association of Pharmaceutical Scientists
  - Fellow Swiss Society for Pharmaceutical Sciences
  - Fellow American Association of Indian Pharmaceutical Scientists
  - AAPS Scientific Achievement Award (Regulatory Sciences)
  - Team of the Year (FDA's PAT Team) Award by Pharmaceutical Manufacturing Magazine

- Academia
  - Robert D'Solvo Distinguished Alumni Award, University of Cincinnati
  - Visiting professorships at University of Purdue, Michigan, and Basel
  - ONU College of Pharmacy - Most Professional Professor of the Year Award

List of Publications

See http://scholar.google.com/citations?user=iQLsw6YAAAAJ&hl=en

(Accessed 4 December 2014)

Testimony to the US Senate

See http://www.help.senate.gov/imo/media/doc/Hussain1.pdf

(Accessed 4 December 2014)

List of Publications Authored or Co-Authored by Ajaz S. Hussain, Ph.D.

1. Hussain, A.S. 2016. The culture of Pharmaceutical Quality: Personnel Development. Biopharma Asia March/April 2016
2. Hussain, A.S. 2015. The culture of Pharmaceutical Quality Management System. Biopharma Asia November/December 2015
3. Hussain, A.S. 2015. The culture of Pharmaceutical Quality: Connecting the Dots. Biopharma Asia 34-38. Issue September/October 2015
4. Xiang, D., Berry, J., Buntz, S., Gargiulo, P., Cheney, J., Joshi, Y., Wabuyele, B., Wu, H., Hamed, M., Hussain, A.S. and Khan, M.A., 2009. Robust calibration design in the pharmaceutical quantitative measurements with near-infrared (NIR) spectroscopy: Avoiding the chemometric pitfalls. *Journal of Pharmaceutical Sciences*, *98*(3), pp.1155-1166.
5. Xiang, D., LoBrutto, R., Cheney, J., Wabuyele, B.W., Berry, J., Lyon, R., Wu, H., Khan, M.A. and Hussain, A.S., 2009. Evaluation of transmission and reflection modalities for measuring the content uniformity of pharmaceutical tablets with near-infrared spectroscopy. *Applied Spectroscopy*, *63*(1), pp.33-47.
6. Xie, L.I.N., Wu, H., Shen, M., Augsburger, L.L., Lyon, R.C., Khan, M.A., Hussain, A.S. and Hoag, S.W., 2008. Quality-by-design (QbD): Effects of testing parameters and formulation variables on the segregation tendency of pharmaceutical powder measured by the ASTM D 6940-04 segregation tester. *Journal of Pharmaceutical Sciences*, *97*(10), pp.4485-4497.
7. Faustino, P.J., Yang, Y., Progar, J.J., Brownell, C.R., Sadrieh, N., May, J.C., Leutzinger, E., Place, D.A., Duffy, E.P., Houn, F. and Loewke, S.A., 2008. Quantitative determination of cesium binding to ferric hexacyanoferrate: Prussian blue. *Journal of pharmaceutical and biomedical analysis*, *47*(1), pp.114-125.
8. Spencer, J.A., Gao, Z., Moore, T., Buhse, L.F., Taday, P.F., Newnham, D.A., Shen, Y., Portieri, A. and Hussain, A., 2008. Delayed release tablet dissolution related to coating thickness by terahertz pulsed image mapping. *Journal of Pharmaceutical SSSciences*, *97*(4), pp.1543-1550.
9. Wu, H., Heilweil, E.J., Hussain, A.S. and Khan, M.A., 2008. Process analytical technology (PAT): Quantification approaches in terahertz spectroscopy for pharmaceutical application. *Journal of Pharmaceutical Sciences*, *97*(2), pp.970-984.
10. Spencer, J.A., Jefferson, E.H., Hussain, A.S., Newnham, D. and Lo, T., 2007. Tablet content analysis using terahertz transmission spectroscopy. *Journal of Pharmaceutical Innovation*, *2*(1-2), pp.18-22.
11. Wu, H., Heilweil, E.J., Hussain, A.S. and Khan, M.A., 2007. Process analytical technology (PAT): Effects of instrumental and compositional variables on terahertz spectral data quality to characterize pharmaceutical materials and tablets. *International journal of pharmaceutics*, *343*(1), pp.148-158.
12. Wu, H., Khan, M.A., and Hussain, A.S., 2007. Process control perspective for process analytical technology: integration of chemical engineering practice into semiconductor

and pharmaceutical industries. *Chemical Engineering Communications*, *194*(6), pp.760-779.

13. Hussain, A.S., and Woollett, G.R. 2007 What follow-on biologics mean for the future of biotechnology industry? Biopharm. International.
14. Volpe, D.A., Faustino, P.J., Ciavarella, A.B., Asafu-Adjaye, E.B., Ellison, C.D., Yu, L.X. and Hussain, A.S., 2007. Classification of drug permeability with a Caco-2 cell monolayer assay. *Clinical Research and Regulatory Affairs*,*24*(1), pp.39-47.
15. Chen, M.L., Straughn, A.B., Sadrieh, N., Meyer, M., Faustino, P.J., Ciavarella, A.B., Meibohm, B., Yates, C.R., and Hussain, A.S., 2007. A modern view of excipient effects on bioequivalence: a case study of sorbitol. *Pharmaceutical Research*, *24*(1), pp.73-80.
16. Hussain, A.S. 2006. The Journal Of Pharmaceutical Innovation: an innovative, consensus-building tool for the 21st century. J. Pharm. Innova. 1: 9. doi:10.1007/BF02784875
17. Wokovich, A.M., Prodduturi, S., Doub, W.H., Hussain, A.S., and Buhse, L.F., 2006. Transdermal drug delivery system (TDDS) adhesion as a critical safety, efficacy and quality attribute. *European Journal of Pharmaceutics and Biopharmaceutics*, *64*(1), pp.1-8.
18. Lyon, R.C., Taylor, J.S., Porter, D.A., Prasanna, H.R. and Hussain, A.S., 2006. Stability profiles of drug products extended beyond labeled expiration dates. *Journal of Pharmaceutical Sciences*, *95*(7), pp.1549-1560.
19. Tatavarti, A.S., Fahmy, R., Wu, H., Hussain, A.S., Marnane, W., Bensley, D., Hollenbeck, G. and Hoag, S.W., 2005. Assessment of NIR spectroscopy for nondestructive analysis of physical and chemical attributes of sulfamethazine bolus dosage forms. *AAPSs PharmSciTech*, *6*(1), pp.E91-E99.
20. Wu, H., Hussain, A.S., Heilweil, E. and Khan, M.A., 2005. Measurement process prospects using THz spectroscopy for pharmaceutical applications. *AAPS J*, *7*.
21. Hussain, A., 2005. The nation needs a comprehensive pharmaceutical engineering education and research system. *Pharmaceutical Technology*,*29*(9), p.122.
22. Meyer, R.J., and Hussain, A.S., FDA's ACPS Meeting, October 2005 Awareness Topic: Mitigating the Risks of Ethanol-Induced Dose Dumping from Oral Sustained/Controlled Release Dosage Forms.
23. Yu, L.X., Raw, A.S., Ouderkirk, L.A., Hussain, A.S. and Sathe, P.M., 2004. Drug Product Performance, In Vitro. In L. Shargel and I. Kanfer eds., *Generic Drug Development: Solid Oral Dosage Forms* (pp. 187-209). Informa Healthcare.
24. Yu, L.X., Straughn, A.B., Faustino, P.J., Yang, Y., Parekh, A., Ciavarella, A.B., Asafu-Adjaye, E., Mehta, M.U., Conner, D.P., Lesko, L.J. and Hussain, A.S., 2004. The effect of food on the relative bioavailability of rapidly dissolving immediate-release solid oral products containing highly soluble drugs. *Molecular Pharmaceutics*, *1*(5), pp.357-362.
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26. Burgess, D.J., Crommelin, D.J., Hussain, A.S. and Chen, M.L., 2004. Assuring quality and performance of sustained and controlled release parenterals: EUFEPS workshop report. *AAPS PharmSci*, *6*(1), pp.100-111.
27. Watts, D.C., Afnan, A.M. and Hussain, A.S., 2004. Process analytical technology and ASTM Committee E55. *Standardization News: SN*, *32*(5), p.25.
28. Lawrence, X.Y., Lionberger, R.A., Raw, A.S., D'Costa, R., Wu, H. and Hussain, A.S., 2004. Applications of process analytical technology to crystallization processes. *Advanced Drug Delivery Reviews*, *56*(3), pp.349-369.
29. Lawrence, X.Y., Carlin, A.S., Amidon, G.L. and Hussain, A.S., 2004. Feasibility studies of utilizing disk intrinsic dissolution rate to classify drugs. *International journal of pharmaceutics*, *270*(1), pp.221-227.
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32. Lewis, E.N., Lee, E., Kidder, L., Jefferson, E., Ellison, C., Faustino, P., Lyon, R. and Hussain, A., 2003. Extending the Detection Limit for Near Infrared Spectroscopic Measurements of Heterogeneous Solids Using Focal Plane Array Detectors. *Microscopy and Microanalysis*, *9*(S02), pp.1076-1077.
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38. Yu, L.X., Amidon, G.L., Polli, J.E., Zhao, H., Mehta, M.U., Conner, D.P., Shah, V.P., Lesko, L.J., Chen, M.L., Lee, V.H., and Hussain, A.S., 2002. Biopharmaceutics

classification system: the scientific basis for biowaiver extensions. *Pharmaceutical Research*, *19*(7), pp.921-925.

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45. Lawrence, X.Y., Ellison, C.D., Conner, D.P., Lesko, L.J. and Hussain, A.S., 2001. Influence of drug release properties of conventional solid dosage forms on the systemic exposure of highly soluble drugs. *AAPS PharmSci*, *3*(3), pp.86-92.
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51. Meyer, M.C., Straughn, A.B., Mhatre, R.M., Hussain, A., Shah, V.P., Bottom, C.B., Cole, E.T., Lesko, L.L., Malinowski, H. and Williams, R.L., 2000. The effect of gelatin cross-linking on the bioequivalence of hard and soft gelatin acetaminophen capsules. *Pharmaceutical Research*, *17*(8), pp.962-966.
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