Curriculum Vitae

Afshan N. Hashmi, PhD, C(ASCP),RAC,

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Author: http://afshanhashmi.com/ General: http://www.drafshanhashmi.com/ Author of Four blogs: "India Business Innovations" (http://indiabusinessinnovations.wordpress.com/) and

"Connecting with the Dignitaries"

(http://connectingdignitaries.wordpress.com/)

The Modern Mughal Mentality Blog

(Best-Selling Author Dr.Afshan N. Hashmi - The Modern Mughal Mentality Blog

(afshanhashmi.com)

The Outbreak of A Monstrous Infection Blog

(Best-Selling Author Dr.Afshan N. Hashmi - The Outbreak of A Monstrous Infection Blog (afshanhashmi.com)

My Current Radio and TV Show on W4WN Radio and Talk4TV http://www.afshanhashmi.com/dr.afshan hashmis radio show on w4wn

My Current Radio and TV Show on K4HD Radio and TaLK4TV:

My Current TV Show:

 $\frac{http://www.afshanhashmi.com/dr.afshan\ hashmi\ as\ tv\ host\ on\ gtv/}{\text{(GTV show retired in June 30 2021)}}$

SUMMARY OF QUALIFICATIONS

Best-selling and Hot #1 new Release Author in a category on Amazon.

TV and Radio Personality.

Publishing, Regulatory, business development, and scientific professional with more than 10 years experience. PhD in Biochemistry, certification from American Society for Clinical Pathology (ASCP) - Technologist in Chemistry, and Regulatory Affairs Certified (RAC) US. Extensive experience with scientific research and publication, as well as an in-depth knowledge of regulatory requirements of the U.S. Food and Drug Administration (FDA). Demonstrated ability to perform complex and routine clinical chemistry tests and procedures. Excellent oral and written communication skills with proven track record communicating complex scientific and regulatory information to diverse, multinational audiences.

WORK EXPERIENCE

2/19-Present;

Managing Member of Dr. Afshan Hashmi Consulting Group, LLC

Publishing, Regulatory, Business Development and Scientific Consultant. I host two Radio plus TV shows one on K4HD Radio and Talk4TV and the other on W4WN Radio and Talk4TV. Both Shows each have 300 million listeners and syndicated worldwide

Wrote a best-selling book in a category on Amazon in USA . The book is called **The Outbreak of A Monstrous Infection**"

About the Book

A monstrous infection is spreading worldwide. Is this a simple infection or a deliberate attempt to ruin the human population, or bio-terrorism? What is this global infection and who is spreading this? To know that, read this suspense-filled book by an Amazon best-selling and hot #1 new-release author of a previous book called The Modern Mughal Mentality: New Strategies to Succeed in India and the Global Marketplace. In the author's second book, a sizzling science-fiction story, a crime is investigated by the FBI in collaboration with the Central Bureau of Investigation (CBI) of India.

The book is available worldwide wherever books are sold in print, audio and online formats. Have got lot of media coverage and my Author website will tell you in more detail about it (http://afshanhashmi.com/)

12/10-2/19; Regulatory, Business Development and Scientific Consultant. Wrote a best-selling and Hot #1 New book in a category on Amazon both in USA. The book was best-selling on Amazon in India also in a category.. The book is called **The Modern Mughal Mentality-**New Strategies to Succeed in India and the Global Marketplace

About the Book

The Modern Mughal Mentality transforms hardships and difficulties into success stories by introducing the *Jugaad* Management Principle Business Model, which can be applied to any business, anywhere.

For the purpose of this book, the term *Jugaad* will be defined as "obtaining your objectives by maximizing resources through thinking out of the box."

Following this new business model will inspire all types of companies around the world, no matter how big or small, to create innovative mentalities, products, and strategies. *The Modern Mughal Mentality* reveals ways in which companies everywhere can benefit from this new business model.

It also reveals ways in which western companies can learn to be successful in India. Executives of multinational corporations, government officials, and even American and global small business owners who have no plans to do business in India will benefit from the innovative and revolutionary approach to maximizing resources that *The Modern Mughal Mentality* delivers.

Multi-sector success stories illustrate the various components of the *Jugaad* Management Principle Business Model. Specific questions in the "Modern Mughal Mentality Exercises" at the end will guide the reader through putting the *Jugaad* Management Principle Business Model to work for their business.

Implementing the model can lead to increased profit, maximized resources, and a more efficient way of dealing with today's turbulent economy. *The Modern Mughal Mentality* also identifies international opportunities in various industries – providing practical solutions to take the guesswork out of the equation.

The Modern Mughal Mentality's four chapters reveal how the same mentality, which has enabled India to enjoy economic success in today's turbulent times can radically transform any business. The *Jugaad* Management Principle Business Model can be used to maximize resources and increase profitability in many sectors. Success stories, important lessons to remember, and opportunities for growth in both India and around the world are given. The "Modern Mughal Mentality Exercises" at the end leads the reader to think creatively and use **The Modern Mughal Mentality** to create innovative and cost-effective solutions to problems on their own. Regardless of where the reader lives, or what type of business they run, they will be able to improve their bottom line by implementing these changes.

Photo galleries of magical moments that led to the birth of *The Modern Mughal Mentality* give the readers of my book an opportunity to see some of my special moments and provide them another unique way to connect to this book.

The book is available worldwide wherever books are sold in print, audio and online formats. Have got lot of media coverage and my Author website will tell you in more detail about it (http://afshanhashmi.com/)

Also developed an online course related to my book.

1/07-11/10; PRESIDENT; Global Regulatory and Business Solutions, LLC; Rockville, MD

President of a company providing business development, market entry, and regulatory affairs expertise.

OPERATIONS MANAGEMENT: Managed day-to-day operations of company with clients worldwide. Developed new business strategies to generate sales. Prepared press releases and other marketing materials. Maintained comprehensive client records; managed company budget. Prioritized assignments to meet deadlines and effectively managed time, data and resources.

REGULATORY AFFAIRS AND BUSINESS DEVELOPMENT CONSULTANT: Developed regulatory strategy for clients according to the regulatory requirements of the US Food and Drug Administration.

Prepared customized business proposals for clients to support market entry of a wide range of products specializing in U.S. and emerging markets such as India, United Arab Emirates, Bahrain, and Qatar. Dr. Hashmi also specializes in providing Lectures and Seminars on "Doing Business in India" including culture training and she is passionate about sharing her knowledge with others. Maintain extensive professional network in public and private that are required to launch initiatives.

REGULATORY AFFAIRS MANAGEMENT: Served as liaison between potential clients and business partners; coordinated introductions and initial meetings to provide a wide range of regulatory services for client companies to bring cutting-edge medical technologies to the competitive market.

MARKET RESEARCH: Identified potential partners and evaluated outsourcing opportunities for clinical trials and manufacturing.

SCIENTIFIC RESEARCH AND REVIEW: Performed scientific review to support intellectual property filings. Conducted scientific literature review and analyzed research data to remain up-to-date on most trends and discoveries.

DELEGATION: Global Regulatory and Business Solutions, LLC was part of USIBC (US India Business Council) Health Mission to India November 12-15 2007.

Global Regulatory and Business Solutions, LLC was part of Montgomery County, Maryland's Business Mission to India from November 11-17 2007.

MEMBER OF TECH COUNCIL OF MARYLAND: In Tech Council of Maryland: Dr. Afshan Hashmi was a member of MdBio CSO/CMO Forum; MdBio Program Committee and International Committee.

KEY ACCOMPLISHMENTS:

- Successfully collaborated with a client to gather information to support filing of a Patent Cooperation Treaty (PCT) application, allowing client to file for a patent in multiple countries simultaneously. Reviewed scientific portion of application; used this information to then help client develop licensing agreement to distribute a new technology.
- Coordinated meetings and accommodations for a U.S. business delegation in India.
- Provided entrepreneurship training and career advice to students in India. Led interactive Q&A sessions among student groups.

6/05-4/06; CONSULTING LIAISON; ToxLogic LLC, Potomac, MD

Served as primary company liaison to companies located in Asia and US. Served as liaison between potential client companies and ToxLogic LLC. Supported company's business development activities by communicating orally and in writing with potential clients, providing regulatory strategic planning and advice. Advised representatives of international food and drug companies of compliance requirements for products exported to the U.S. Traveled internationally to support business development and gave oral presentations to diverse

audiences.

4/01 -7/03; Human Genome Sciences, Inc., Rockville, Maryland

RESEARCH ASSOCIATE, Department of Bioanalytical Sciences

- Developed methods for Immunogenicity and PK Assays. Trained to work in GMP/GLP, expertise in regulatory and ICH guidelines. Qualification of these Bioanalytical methods.
- Tested clinical samples for both PK and Immunogenicity assays.
- Wrote SOPs and presented data at group meetings.

RESEARCH ASSOCIATE, Analytical Sciences Group, PLM Manager

- In-charge of Waters HPLC Qualification and Scheduling of HPLCs.
- Conducted analytical method development by reversed-phase HPLC, ion-exchange HPLC and SDS-PAGE and tested GMP samples by these HPLC. Performed qualification and validation of these analytical methods and also wrote SOPs for these methods.

12/99-4/01; MEDICAL TECHNOLOGIST

Rapid Response Laboratory; University of Maryland Medical Center, Baltimore, MD

Tested human blood, urine, and stool samples. Accessioned and processed specimens in Clinical Lab. Tested samples using a wide variety of testing techniques and analytical tools, including Urinalysis, Atlas, Microscopes, Digital Refractometer, T.S. Meter, Gastroccult Blood and pH, Buffer Blood and pH, Stool Blood, Scalp pH, CX7, Dimension, Ektachem 500 and 700, Glycohemoglobin Assay, Hemoglobin A+ F Assay, Blood Gases, Axsym, Toxicology, Rapimat, Clintex 50 and 200, Biorad Auto Dilutor, and Laboratory Information System (Cerner).

1/99-12/99; Maryland State Department of Health and Mental Hygiene; Laboratories Administration, Baltimore, MD

PUBLIC HEALTH SCIENTIST, Lead Laboratory PUBLIC HEALTH SCIENTIST, Newborn Screening Laboratory

Conducted routine laboratory testing of specimens taken from newborns to screen for public health concerns such as hereditary metabolic disorders. Also, tested other human blood samples for elevated blood levels of lead.

1/93-1/94; POSTDOCTORAL FELLOW, Division of Physiology, Department of Environmental Health Sciences, School of Hygiene and Public Health; Johns Hopkins University, Baltimore, MD

9/92-11/92; RESEARCH ASSISTANT; University of Maryland Cancer Center, Baltimore, MD

Learned tissue culture technique and worked on multiple drug resistance of Chinese hamster lung ADX cell line and drug sensitive cell line DC3F.

TECHNICAL SKILLS

- Tested clinical trial samples by immunoassays and performed analytical and bioanalytical tests under GMP environment.
- Able to conduct scientific literature review and performed experiments with radioactive compounds labeled with 3H and 125 I.
- Knowledge and understanding of protein and clinical chemistry techniques and of CLIA and homebrew diagnostic assays and medical reimbursement: Polyacrylamide Gel Electrophoresis (Disc and Slab Gel Electrophoresis simple as well as Gradient), Densitometer, Western Blotting and Immunoblotting, ELISA, Electroelution, Accessioning and processing of specimens in Clinical Labs, Urinalysis, Atlas, Microscopes, Digital Refractometer, T.S. Meter, Gastroccult Blood and pH, Buffer Blood and pH, Stool Blood, Scalp pH,

CX7, Dimension, Ektachem 500 and 700, Glycohemoglobin Assay, Hemoglobin A+ F Assay, Blood Gases, Axsym, Toxicology, Rapimat, Clintex 50 and 200, Biorad Auto Dilutor, Laboratory Information System (Cerner), Atomic Absorption, Blood Lead Testing, Guthrie Microbial Assay, Microbial agar Plate Making, Punch Indexer Machine, Colorimetry, Ultraviolet and Visible Spectroscopy, High speed Centrifugation, Ultra-centrifugation, Scintillation Counter, Thin Layer Chromatography, Total Fatty Acid Analysis, Lipid Extraction and its Quantitative Estimation in Biological Samples.

EDUCATION

Johns Hopkins University, Montgomery County Campus, Rockville, Maryland

 Educated in Regulatory Affairs, in the Zanvyl Krieger School of Arts and Sciences, Advanced Academic Programs, Department of Biotechnology, Fall 2004 semester. Course work: Regulatory Processes for Domestic and Global Biotechnology Products.

University of Maryland (Baltimore), School of Medicine, Department of Medical and Research Technology **Categorical Course in Clinical Chemistry**, 1997

Aligarh University, Aligarh, India

PhD - Biochemistry, 1991

Dissertation Title: Studies on the Effect of Phenylhydrazine on Red Blood Cell Membrane

M.Phil - Biochemistry, (a pre-PhD requirement), 1988

Dissertation Title: Organization of Membrane Proteins in Normal and Abnormal Erythrocytes (Effect of Phenylhydrazine)

M.Sc. - Biochemistry, 1985

B.S. (Honors) - Chemistry, 1983

CERTIFICATIONS (current)

Regulatory Affairs Certified RAC (US) April 2, 2005

American Society for Clinical Pathology (ASCP) - Technologist in Chemistry

AWARDS

- On December 1, 2008, Dr. Afshan Hashmi received the 'Ibn Sina Public Health Award' in recognition of her contributions in the field of Public Health Science and Entrepreneurship. from the AIDS Cell of the Ibn Sînâ Academy of Medieval Medicine & Sciences, Aligarh, (UP), India.
- On November 21,2008 an 'Award of Excellence' by AMU Ladies Club, Aligarh, (UP), India.
- On April 14,2008, Dr. Afshan Hashmi's company, Global Regulatory and Business Solutions, LLC, was awarded Certificate of Appreciation by the County Executive, The Honorable Isiah Leggett of Montgomery County in recognition and appreciation for being one of Montgomery County's outstanding companies chosen for visits during Business Appreciation Week. Dr. Hashmi was also presented with an 'I am Montgomery' pin with signature of The Honorable Isiah Leggett.
- Also on April 14, 2008 another Certificate of Appreciation was presented to Dr. Afshan Hashmi's company, Global Regulatory and Business Solutions, LLC, by the Mayor of the City of Rockville, The Honorable Susan Hoffmann and Executive Director of Rockville Economic Development, Inc., Sally Sternbach in recognition of company's contributions to Rockville's economy and participation in Rockville Business Appreciation Week, April 14-18, 2008.
- Dr. Afshan Hashmi, President of Global Regulatory and Business Solutions, LLC, was awarded a Certificate
 of Appreciation on March 10, 2008 by the County Executive of Montgomery County, Maryland, The

Honorable Isiah Leggett, for serving as a member of Montgomery County's November 2007 business mission to India.

- Worked on a project entitled Specificity of Cardiac Troponin I Antibodies during the Categorical Course in Clinical Chemistry. Presented this work in the "Senior Showcase 1997" of the Department of Medical and Research Technology at the University of Maryland.
- Passed with "Excellence" the clinical rotation part of the Categorical Course in Clinical Chemistry. The
 portfolio prepared during this rotation and for the Professional Development Course (MEDT 309) was
 recognized by the department for its excellence and serves as a model for other students.
- Awarded Junior and Senior Research Fellowships by the Indian Council of Medical Research, May 1987 to November 1991. Worked in the area of membrane biology.
- Awarded an Aligarh University Medal for earning the "First Position" in the M.SC. Biochemistry Program.
- Awarded the university's "Science Merit Scholarship" as a result of a written competitive test for the academic session 1983-1985. Scholarship was given for the pursuit of a two-year M.Sc. biochemistry program.

PUBLICATIONS, CONFERENCE PRESENTATIONS AND SPEAKER ENGAGEMENTS

- Speaker in Sir Syed Day Celebrations of Aligarh Alumni Association of Washington DC, on October 17, 2010. Spoke on the topic "Towards New Horizon Our Alma mater Aligarh Muslim University-A report of major initiatives 2007-2010."
- Poster Presentation in Eight Annual Convention of Federation of Aligarh Alumni Associations, held between July 17-19,2009, Boston, MA,USA. Poster was entitled" Franchising in India with a focus on AMU, Aligarh (UP), India."
- Phenylhydrazine Causes Sulfhydryl Oxidation and Protein Aggregation in Hemoglobin Free Erythrocyte Membranes, Biochemistry and Molecular Biology International, October 1996, Vol. 40. No. 3, pages 543-550.
- Paper entitled: Modulation of Muscarinic Agonist Binding by Cations and Guanine Nucleotides during Aging [communicated during working at Hopkins to American Lung Association/ American Thoracic Society (ALA/ATS) International Conference held in Boston, Massachusetts, USA], from May 22 to 25 1994.
- Attended the International Conference of the ALA/ATS held in San Francisco, California, USA from May 16 to 19, 1993.
- Paper entitled: Phenylhydrazine- stimulated Oxidation of the Human Erythrocyte Membrane Lipids, accepted in Second International Symposium on Clinical, Biochemical and Molecular Aspects of Fatty Acid Oxidation held in Philadelphia, Pennsylvania, USA from November 3-6, 1991.
- Paper entitled: Antioxidants and Phenylhydrazine- mediated Alterations in Human Erythrocyte Membrane, accepted in UNESCO/ COSTOM Workshop on Lipid- Soluble Antioxidants in Biochemistry of Nutrition and Environmental Health organized by UNESCO Global Network for Molecular and Cell Biology (MCBN) and Confederation of Scientific and Technological Associations in Malaysia (COSTOM), in collaboration with Institut Kimia, Malaysia (IKM) held at Penang, Malaysia from September 20 to 22 1991. Registration No. 1005/1006.
- Paper entitled: Effects of Phenylhydrazine on Human Erythrocyte and Erthrocyte Membrane, accepted in Oxidative Damage and Repair, (The 5th Biennial Meeting of the International Society for Free Radical Research), hosted by the Oxygen Society, sponsored by the Institute for Toxicology, University of Southern California, USA held in Pasadena, California, USA from November 14-20, 1990 (Abst. No. 9.23).
- Presented a paper entitled: Effects of Phenylhydrazine on Human Erythrocyte Membrane, in the International Symposium on Biological Oxidation System, organized by the College of Agriculture and

Environmental Resource Research Institute, Pennsylvania State University, PA, USA and Indian Institute of Science, Bangalore, held at Bangalore India from October 23 to 26, 1989 (Abstr. No. 185).

PROFESSIONAL TRAINING

Regulatory Affairs Professionals Society (RAPS)

Attended the Annual RAPS Conference and Exhibition, October 2010 Attended a workshop: Regulatory Manager Boot Camp, October 2010

Attended the Annual RAPS Conference and Exhibition, September 2009 Attended a workshop on: Regulatory Essentials: Japan, September 2009

Attended the Annual RAPS Conference and Exhibition, September 2007 Attended a workshop on: Essentials of Canadian RA, September 2007

Attended the Annual RAPS Conference and Exhibition, October 2006 Attended a workshop on: Effective Medical Writing, October 2006

Attended the Combination Products: Key issues for each stage of the combination product Lifecycle and working Effectively with FDA Webcast Series July 2005

Attended the Annual RAPS Conference and Exhibition, October 2005 Attended a workshop on: The Essentials: EU Regulatory Affairs, October 2005

Attended the Annual RAPS Conference and Exhibition, October 2004 Attended a workshop on: Principles & Practices of US Regulatory Affairs, September 2004

Attended the Prepare for the RAC (US) Exam Webcast Series, March 2005:

Module 1: Strategic Planning, Design and Development, Review Areas Included: Product Classification, Regulatory Pathways/Regulatory Options, Documentation, Testing Requirements/ Compliance

Module 2: Premarketing/Regulatory Review and Manufacturing/Quality System, Review Areas Included: Regulatory Authorities, Vendors and Subcontractors, Submission/Listing/Registration/Obtaining Approval, Documentation, SOPs, Training, Regulatory Compliance

Module 3: Marketing/Post Approval and Interfacing, Review Areas Included: Advertising, Promotion and Labeling, Postmarketing Surveillance/ Vigilance, Distribution, Postmarketing/ Maintenance, Crisis Management, Interfacing with Regulatory Agencies, Inspections, Government and Public Relations.

- Attended FDLI's 49th Annual Conference: Celebrating the Centennial of the 1906 Pure Food and Drugs Act ,Washington DC, April 2006
- Attended conference: United States-Mexico Chamber of Commerce: 10th Annual US- Mexico Congressional Border Issues Conference, Washington DC, March 2006
- Attended seminar on: Qualification of HPLC Instruments, by Waters, March 2002.
- Attended seminar on: Understanding Column Selection for Reversed- Phase Chromatography, by Waters, October 2001.

PERSONAL ATTRIBUTES

- Well-organized, self-motivated, always sees tasks to completion
- Adaptable to challenges under contrasting working environments and time constraints
- Strong analytical skills. Creative in resolving problems and adverse issues
- Works well independently as well as contributes to a team effort

- Excellent interpersonal skills. Quick to establish relationships with others
- Skilled communicator. Proficient in both oral and written communications

COMPUTER SKILLS

Microsoft Office (Word, Excel, PowerPoint, Access, Outlook, Publisher); Adobe Acrobat professional, Bioanalytical and Analytical softwares. Attended a special course "Presentation Skills Using PowerPoint" given by CompUSA.

VOLUNTEER

Dr. Afshan Hashmi volunteered in "Maximum India" festival held from March 1-20, 2011, at the Kennedy Center in Washington DC.

Dr. Afshan Hashmi Volunteered in Presidential campaign of President-Elect Donald J. Trump.

Speaker's Bureau: http://drafshanhashmi.com/id16.html

CITIZENSHIP

United States of America
