CURRICULUM VITAE: BADRUL ALAM CHOWDHURY, MD, PHD

Citizenship:	Unites States of America
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PRESENT POSITIONS:

Principal, BC Pharma Consulting, Limited Liability Company, Potomac, Maryland, USA, April 2026 to the present.

EDUCATION:

High School/College:	Faujdarhat Cadet College, Chittagong, Bangladesh. Secondary School Certificate (School Final), 1973. Higher Secondary Certificate (College Final), 1975.
Medical School:	University of Dhaka, Dhaka Medical College, Dhaka, Bangladesh. November 1976 to November 1982. MB, BS. 1982.
Graduate School:	Memorial University of Newfoundland, St. John's, Newfoundland, Canada. May 1985 to April 1988. Ph.D., Immunology. 1988.
Residency:	Wayne State University School of Medicine and The Detroit Medical Center, Detroit, Michigan. July 1988 to June 1991. Internal Medicine.
Fellowship:	National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland. July 1991 to June 1995. Allergy and Immunology.

BOARD CERTIFICATION:

American Board of Internal Medicine, 1992.
American Board of Allergy and Immunology, 1995.

QUALIFYING AND LICENSING EXAMINATIONS:

Foreign Medical Graduate Examination in the Medical Sciences (FMGEMS), USA, 1985.

Medical Council of Canada Evaluating Examination (MCCEE) for Graduate of Foreign Medical Schools, Canada, 1986.

Federation Licensing Examination (FLEX), USA, 1986.

MEDICAL LICENSURE:

Maryland	No. D 0039214	Obtained on October 25, 1989	Active
Michigan	No. 4301053022	Obtained on June 30, 1990	Inactive
Tennessee	No. MD 0000026418	Obtained on July 24, 1995	Inactive
District of Columbia	No. MD 30776	Obtained on March 2, 1998	Active
Pennsylvania	No. MD-066652-L	Obtained on October 5, 1998	Inactive

CLINICAL AND HOSPITAL AFFILIATIONS:

Member of the Medical Staff, Walter Reed Army Medical Center, Washington, D.C., May 2000 to June 2009.

Member of the Medical Staff, Kaiser Permanente, Mid-Atlantic Permanente Medical Group, P.C., Maryland, April 1988 to April 2004.

PREVIOUS PROFESSIONAL POSITIONS AND APPOINTMENTS:

Rotating Intern, Dhaka Medical College Hospital, Dhaka, Bangladesh, November 1982 to November 1983.

General Practitioner, Ministry of Health, Government of Iran, January 1984 to January 1985.

Graduate Assistant, Faculty of Medicine, Memorial University of Newfoundland, St. John's, Canada, May 1985 to April 1988.

Resident, Department of Internal Medicine, Wayne State University School of Medicine and the Detroit Medical Center, Detroit, Michigan, July 1988 to June 1991.

Medical Staff Fellow, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland, July 1991 to June 1995.

Assistant Professor, Department of Medicine, Division of Allergy and Immunology, University of Tennessee College of Medicine, Memphis, Tennessee, July 1995 to July 1997.

Staff Physician, Department of Veterans Affairs Medical Center and The University of Tennessee Affiliated Hospitals, Memphis, Tennessee, July 1995 to July 1997.

Medical Officer, Division of Pulmonary Drug Products, Center for Drug Evaluation and Research, US Food and Drug Administration, Rockville, Maryland, August 1997 to July 1999.

Medical Team Leader, Division of Pulmonary and Allergy Drug Products, Center for Drug Evaluation and Research, US Food and Drug Administration, Rockville, Maryland, July 1999 to March 2003.

Director (Acting), Division of Pulmonary and Allergy Drug Products, Center for Drug Evaluation and Research, US Food and Drug Administration, Rockville, Maryland, July 2002 to March 2003.

Member of the Medical Staff, Washington Hospital Center, Washington, D.C., July 1988 to August 2000.

Assistant Professor of Clinical Medicine, The George Washington University School of Medicine and Health Sciences, Washington, DC, December 1999 to March 2001.

Assistant Professor of Medicine, Uniformed Services University of the Health Sciences, Bethesda, Maryland, September 2000 to June 2005.

Consultant, Department of Allergy and Immunology, Walter Reed Army Medical Center, Washington, DC, May 2000 to June 2012.

Director, Division of Pulmonary, Allergy, and Rheumatology Products, Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring, Maryland, July 2002 to April 2018.

AstraZeneca Pharmaceuticals, April 2018 to the November 2019

Senior Vice President, Chief Physician-Scientist, Respiratory Inflammation and Autoimmunity (RIA), Late Stage Development, BioPharmaceuticals R&D, AstraZeneca, Gaithersburg, Maryland, USA, April 2019 to November 2019.

Senior Vice President, R&D AstraZeneca Medimmune; Head of Respiratory Inflammation and Autoimmunity (RIA) Innovative Medicine Early Development at Medimmune; Member of Medimmune Leadership Team (MLT); Gaithersburg, Maryland, USA, April 2018 to April 2019.

Independent Director, WuXi MedImmune/AstraZeneca Biopharmaceutical Co Limited, Causeway Bay, Hong Kong, January 2019 to November 2019.

Independent Director, Proteostasis Incorporated, Boston, Massachusetts, USA, May 2019 to December 2020.

Chief Medical Officer, Savara Pharmaceuticals, Austin, Texas, and, Langhorne, Pennsylvania, USA; and at Horsholm, Denmark, November 2019 to the September 2022.

Chief Life Science Officer, Smoke-Free Products, Philips Morris International (PMI), Lausanne and Neuchatel, Switzerland, September 2022 to April 2026. Member, PMI's Senior Management Leadership Team, Lausanne, Switzerland, September 2022 to April 2026.

HONORS AND AWARDS:

Third position in the Higher Secondary Certificate (College Final) Examination, 1975.

First position in University of Dhaka, Bangladesh, in the First Professional MB, BS Examination of 1979; and second position in University in the Second, Third, and Final Professional MB, BS Examinations of 1980, 1981, and 1982.

Honors in Pharmacology, Forensic Medicine and Toxicology, Pathology and Microbiology, and Surgery during the MB, BS course.

Dhaka Medical College Gold Medal on being selected the best graduate of 1982.

Second Prize, Wyeth Graduate Student Award by the Canadian Society for Nutritional Sciences, 1986.

Glaxo Wellcome Allergy Research Award, 1997.

Team Excellence Award 1999; Center for Drug Evaluation and Research, US Food and Drug Administration. For work on pediatric exclusivity protocols that will produce health benefits for pediatric patients.

Team Excellence Award 2000; Center for Drug Evaluation and Research, US Food and Drug Administration. For conducting scientifically supported evaluation of the problem of foreign volatile ingress into low-density polyethylene containers.

Team Excellence Award 2002; Center for Drug Evaluation and Research, US Food and Drug Administration. For excellence in conducting a timely, comprehensive review of the safety databases for three prescription antihistamines proposed for possible switch to over-the-counter marketing status.

Special Recognition Award 2002; Center for Drug Evaluation and Research, US Food and Drug Administration. For the exceptional performance in the review of the pediatric safety data for Clarinex Syrup and Clarinex Reditabs.

Volunteer Clinical Faculty Award, 2004, American Academy of Allergy, Asthma and Immunology and the Training Program Directors Executive Committee, for 5 years of service as Volunteer Clinical Faculty member in the training of Allergy and Immunology Fellows at Walter Reed Army Medical Center.

Special Recognition Award 2006; Center for Drug Evaluation and Research, US Food and Drug Administration. For excellence in developing the Compliance Policy Guide for Unapproved Drugs.

Team Excellence Award 2007; Center for Drug Evaluation and Research, US Food and Drug Administration. For significant effort and exemplary team performance assuring that compounded inhalation drugs comply with the Act and educating the public about the risks of these products.

Outstanding Service Award 2007; Center for Drug Evaluation and Research, US Food and Drug Administration. For outstanding service to the US Government in leading the FDA's participating in the Montreal Protocol for the protection of the ozone layer in 2006.

The Stratospheric Ozone Protection Award 2007; United States Environmental Protection Agency. For leadership in ensuring a successful transition away from essential use of CFC metered dose inhalers.

Center Director's Special citation 2011; Center for Drug Evaluation and Research, US Food and Drug Administration. For the publication of peer reviewed articles in the New England Journal of Medicine on LABA safety.

Center Director's Special citation 2011; Center for Drug Evaluation and Research, US Food and Drug Administration. For complicated review of large database, presentation at Advisory Committee Meeting, and writing peer review articles on indacaterol inhalation powder NDA for COPD.

Meritorious Honor Award 2011, Department of State, United States of America. For outstanding effort to implement a domestic transition out of CFCs, and to ensure global progress in the development and commercialization of CFC-free alternatives in medical devices.

Commissioner's Award of Excellence 2012; US Food and Drug Administration. For outstanding media relations and external communications work surrounding the approval of Kalydeco, a novel therapy for the treatment of patients with a type of cystic fibrosis.

Commissioner's Award of Excellence in Review Science 2013; US Food and Drug Administration. For developing a scientific approach to the evaluation of safety data accounting for the multiple trial designs and comparisons in the tofacitinib clinical development program.

Center for Drug Evaluation and Research (CDER) Team Excellence Award 2015; for idiopathic pulmonary fibrosis review.

Center for Drug Evaluation and Research (CDER) Group Recognition Award 2017; for evaluation and presenting complex issues on quinacrine Pharmacy Compounding Advisory Committee Meeting.

Center for Drug Evaluation and Research (CDER) Group Recognition Award 2017; for utilizing an emerging technology for approval of first generic mometasone furoate nasal spray and advancing regulatory science for locally acting nasal products.

Center for Drug Evaluation and Research (CDER) Group Recognition Award 2017; for meritorious service to the Agency and American public through mutual collaboration in reviewing pharmacology-toxicology backlog consults to ANDA applications.

Center for Drug Evaluation and Research (CDER) Regulatory Science Excellence Award 2017; for scientific and regulatory work to develop and publish epinephrine auto-injector bioequivalence recommendations.

COMMITTEE MEMBERSHIPS:

Member, Human Studies Subcommittee, Department of Veterans Affairs Medical Center, Memphis, Tennessee, 1996 to 1997.

Member, US Food and Drug Administration's Working Group on the Phaseout of Chlorofluorocarbons (CFCs) from Metered Dose Inhalers (MDIs), 1997 to 2018.

Member, US Food and Drug Administration's Working Group on Comparative Clinical Trials of The Technical Committee on Oral Inhalation and Nasal Drug Products, 1998 to 2012.

Member and Chair, Division of Pulmonary Drug Products, CDER, US FDA's Working Group on Overwrap of Inhalation Drug Products in LDPE unit dose vials, 1998 to 2012.

Member, Division of Pulmonary Drug Products, CDER, US FDA's Working Group implementing the Pediatric Exclusivity Component of FDAMA, 1998.

Member, Pharmacotherapeutics Committee, American Academy of Allergy, Asthma, and Immunology, 1998 to 2012.

Member, Pediatric Exclusivity Board, Center for Drug Evaluation and Research, US Food and Drug Administration, July 2003 to July 2005.

Member, Protocol Review Committee, Asthma Clinical Research Network II, National Heart Lung and Blood Institute, National Institutes of Health, Bethesda, Maryland, April 2004.

Member, Joint FDA and IPAC-RS Working Group for Dose Content Uniformity of Orally Inhaled and Nasal Drug Products, May 2004.

Member of the US Delegation, Vienna Convention for the Protection of the Ozone Layer and the Parties to the Montreal Protocol on Substances that Deplete the Ozone Layer, United National Environment Program (UNEP).

- Twenty-sixth Meeting, Open-ended Working Group of the Parties to the Montreal Protocol, July 2006, Montreal, Canada
- Eighteenth Meeting, Parties of the Montreal Protocol, October-November 2006, New Delhi, India
- Nineteenth Meeting, Parties of the Montreal Protocol, September 2007, Montreal, Canada
- Twenty-eighth Meeting, Open-ended Working Group of the Parties to the Montreal Protocol, July 2008, Bangkok, Thailand
- Twentieth Meeting, Parties of the Montreal Protocol, November 2008, Doha, Qatar
- Twenty-ninth Meeting, Open-ended Working Group of the Parties to the Montreal Protocol, July 2009, Geneva, Switzerland
- Twenty-first Meeting, Parties of the Montreal Protocol, November 2009, Port Ghalib at Marsa Alam, Egypt.
- Thirtieth Meeting, Open-ended Working Group of the Parties to the Montreal Protocol, June, 2010, Geneva, Switzerland
- Twenty-second Meeting, Parties of the Montreal Protocol, November 2010, Bangkok, Thailand.
- Twenty-third Meeting, Parties of the Montreal Protocol, November 2011, Nusa Dua, Bali, Indonesia.

Member, National Asthma Education and Prevention Program Coordinating Committee, National Health Lung and Blood Institute, National Institutes of Health, 2007.

Member, Food Allergy Clinical Guideline Development Coordinating Committee, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 2008.

Member, World Health Organization (WHO) Expert Group, WHO Meeting on Severe Asthma, WHO Headquarters, Geneva, Switzerland, April 2009.

Member, US Technical Exchange Delegation on MDI to Russia, under the Environmental Working Group of the US-Russia Bilateral Presidential Commission, Moscow, Russia, September 28-30, 2010.

Member, External Scientific Board, Sub-populations and intermediate outcome measures in COPD study (SPIROMICS), National Heart Lung and Blood Institute, National Institutes of Health, 2011 to 2018.

Member, Biosimilar Review Committee, Center for Drug Evaluation and Research, US Food and Drug Administration, 2012 to 2018.

SOCIETY MEMBERSHIPS:

Member, American Medical Association, 1989
Member, American College of Physicians, 1991
Member, American Academy of Allergy, Asthma, and Immunology, 1992
Member, American Association of Immunologist, 1996
Fellow, American Academy of Allergy, Asthma, and Immunology, 2003

INVITED LECTURES AND OTHER PUBLIC PRESENTATIONS:

Jean A. Chapman Allergy and Asthma Symposium, Cape Girardeau, Missouri, April 1996. Sponsored by the Saint Francis Medical Center and the Cape Girardeau County Area Medical Society. Topic of presentation: Asthma Management in Special Situations.

Faculty member of a national educational program for the Diagnosis and Treatment of Allergic Rhinitis. 1996. The program was supported by Glaxo Wellcome Inc.

Invited Speaker, 26th International Congress of Allergology and Clinical Immunology, Cancun, Mexico, October 1997. Topic of presentation: The Histamine H1 Receptor.

Invited Speaker, Annual Meeting of the American College of Allergy, Asthma, and Immunology, San Diego, California, November 1997. Topic of presentation: The H1-Histamine Receptor – Where the Action is.

Faculty member of the Respiratory Clinical Development course organized by the Pharmaceutical Education and Research Institute, Arlington, Virginia, June 1999. Topic of Lecture: Regulatory Perspectives on Clinical Trial Endpoints.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, San Diego, California, March 2000. Topic of presentation: The Development of Products for Treatment of Seasonal and Perennial Allergic Rhinitis.

Faculty member of the Respiratory Clinical Development course organized by the Pharmaceutical Education and Research Institute, Baltimore, Maryland, June 2000. Topic of Lecture: Regulatory Perspectives on Clinical Trial Endpoints.

Presentation to the US FDA's Psychopharmacologic Drugs Advisory Committee, Bethesda, Maryland, July 19, 2000. Topic of presentation: Assessing Cardiac Safety of Second Generation Antihistamines with a View to Assessing Cardiac Safety of Ziprasodine (Geodon).

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, New Orleans, Louisiana, March 2001. Topic of presentation: Safety Issues with Newer Generation H1 Antihistamines.

Faculty member of the Respiratory Clinical Development course organized by the Pharmaceutical Education and Research Institute, Washington, DC, June 2000. Topic of lecture: Regulatory Perspectives on Clinical Trial Endpoints.

Presentation to the US FDA's Orally Inhaled and Nasal Drug Products Subcommittee of the Advisory Committee for Pharmaceutical Sciences, Rockville, Maryland, July 17, 2001. Topic of presentation: Difficulties in Showing a Dose Response with Locally Acting Nasal Sprays and Aerosols for Allergic Rhinitis.

Presentation to the US FDA's Advisory Committee for Pharmaceutical Sciences, Rockville, Maryland, July 19, 2001. Topic of presentation: Difficulties in Showing a Dose Response with Locally Acting Nasal Sprays and Aerosols for Allergic Rhinitis.

Invited Speaker, 34th Annual Meeting of the Mexican Association of Pharmaceutical Sciences, Manzanillo, Colima, Mexico, October 2001. Topic of presentation: Respiratory Disease Treatment Update.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, New York, New York, March 2002. Topic of presentation: Objective Methods for Evaluation of Patients with Allergic Rhinitis.

Presentation to the US FDA's Nonprescription Drugs Advisory Committee, Bethesda, Maryland, April 22, 2002. Topic of presentation: Clinical Development Programs for Chronic Idiopathic Urticaria Indication for H1-antihistamines.

Invited Speaker, New Drugs for Respiratory Disease V Meeting, Coronado Island, San Diego, California, July 2002. Topic of presentation: Regulatory Issues Surrounding the Development of Novel Drugs for the Chronic Treatment of Respiratory Disease.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Denver, Colorado, March 2003. Topic of presentation: Clinical Endpoints for Allergic Rhinitis and Asthma Trials.

Invited Speaker, Consensus Conference on Rhinosinusitis: Establishing definitions for clinical research and patient care. Bethesda, Maryland, May 2003. Topic of presentation: Efficacy and Safety Outcome Measures.

Invited Speaker, Workshop on Bronchoscopy and Bronchoprovocatoin in Clinical Research. Bethesda, Maryland, July 2003. Topic of presentation: Regulatory Considerations Regarding Investigational use of Agents for Bronchoprovocatoin.

Invited Speaker, Conference VII, Nasal and Pulmonary Drug Delivery, Barcelona Spain, September 2003. Topic of presentation: Clinical Development Programs for Orally Inhaled and Nasal Drug Products.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, San Francisco, California, March 2004. Topic of presentation: Regulation of Drugs for the Treatment of Allergic Diseases - Omalizumab (Xolair) as an Example.

Invited Speaker, 40th Annual Meeting of the Drug Information Association, Washington, DC, June 2004. Topic of presentation: Assessment Criteria for Asthma – US Perspective.

Faculty member of the Clinical Development of Drugs for Asthma and COPD course organized by the Pharmaceutical Education and Research Institute, Baltimore, Maryland, July 2004. Topic of Lecture: Endpoints of Asthma and COPD Drug Development – A Regulatory Perspective.

Invited Speaker, The Seventh Lyold V. Crawford Symposium on Allergy and Clinical Immunology, University of Tennessee, Memphis, Tennessee, August 2004. Topic of presentation: Impact of the US FDA on the Practice of Allergy.

Medicine Grand Rounds, Walter Reed Army Medical Center and the Uniformed Services University of the Health Sciences, Washington, DC, March 2005. Topic of Lecture: Clinical Development Program of Drugs for the Treatment of Asthma – US Regulatory Perspective.

Invited Speaker, The 2005 Annual Workshop on Statistical Methodology in the Biopharmacuetical Sciences, Drug Information Association. Washington, DC, March 2005. Topic of Presentation: Considerations in the Development and Review of Asthma Drug Products.

Invited Speaker, Annual Meeting of the American Thoracic Society, San Diego, California, May 2005. Topic of Presentation: Update on Current Pulmonary Issues at FDA.

Invited Speaker, Annual Meeting of the American Thoracic Society, San Diego, California, May 2005. Topic of Presentation: Overview of Drug and Device Approval Process.

Faculty member of the Clinical Development of Drugs for Asthma and COPD course organized by the Pharmaceutical Education and Research Institute, Baltimore, Maryland, June 2005. Topic of Lecture: Endpoints of Asthma and COPD Drug Development – A Regulatory Perspective.

Invited Speaker, FDA Member Service Program, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Miami Beach, Florida, March 2006. Topic of presentation: Regulatory Issues Affecting the Specialty of Allergy and Immunology.

Invited Speaker, Annual Meeting of the American Thoracic Society, San Diego, California, May 2006. Topic of Presentation: Safety of long-acting beta-agonists in asthma.

Invited State of the Art Speaker, 24th Annual Aspen Allergy Conference, Aspen, Colorado, July, 2006. Topic of Presentation: Overview of the Drug Approval Process and Safety Assessment of Drugs for Asthma and Allergic Diseases.

Invited Speaker, 2nd Annual Symposium on Current Biological Therapy in Immune Mediated Disease, University of California, Irvine, October 2006. Topic of Presentation: Anti-IgE therapy for asthma.

Invited Speaker, Annual Meeting of the American College of Allergy, Asthma, and Immunology, Philadelphia, Pennsylvania, November 2006. Topic of presentation: Black Box Warning and Beta Agonist Therapy.

Invited Speaker, FDA Member Service Program, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, San Diego, California, February 2007. Topic of presentation: Regulatory Issues Affecting the Specialty of Allergy and Immunology

Invited Speaker, Respiratory Drug Delivery Europe 2007, Paris, France, April 2007. Topic of presentation: The regulatory demands of clinical testing protocols for powder inhalers in the USA

Invited Speaker, FDA Member Service Program, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Philadelphia, Pennsylvania 2008. Topic of presentation: Regulatory Issues Affecting the Specialty of Allergy and Immunology

Invited Speaker, Respiratory Drug Delivery 2008, Scottsdale, Arizona, May 2008. Topic of presentation: Therapeutic equivalence of inhaled corticosteroids: US perspective.

Invited Speaker, Annual Meeting of the American Thoracic Society, Toronto, Canada, May 2008. Topic of Presentation: Omaluzimab and anaphylaxis.

Invited Speaker, Bio-International 2008: Towards Improved Harmonization in Regulating Multisource Products, Presented by the International Pharmaceutical Federation and the Royal Pharmaceutical Society of Great Britain, London, UK, October 2008. Topic of Presentation: Scientific and clinical considerations in evaluation of bioequivalence of respiratory drugs.

Invited Speaker, Product Quality Research Institute Workshop on Demonstrating Bioequvalence of Locally Acting Orally Inhaled Drug Products. Bethesda, Maryland, March 2009. Topic of Presentation: The FDA Critical Path Inititiative, Clinical Considerations for Demonstration of Dose-Response for Inhaled Corticosteroids – Exhaled Nitric Oxide Model.

Invited Speaker, FDA Member Service Program, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Washington, DC, March 2009. Topic of presentation: Regulatory Issues Affecting the Specialty of Allergy and Immunology – Update on Allergy and Immunology Drug Products.

Invited Speaker, FDA Roles Beyond the Drug Approval Process, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Washington, DC, March 2009. Topic of presentation: Endpoints, Surrogate Endpoints, Biomarkers, and Drug Approval Process.

Invited Speaker, Pro-Con Debate: Combination Therapy with Inhaled Corticosteroids and Inhaled Long-Acting Beta-Agonists is More Effective than Inhaled Corticosteroid Monotherapy in Step 3 Management of Persistent Asthma; Con Position. Pro Position by Paul O'Byrne of McMaster University; Session Moderated by Elliot Israel of Harvard Medical School. Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Washington, DC, March 2009.

Invited Speaker, Annual Meeting of the American Thoracic Society, San Diego, California, May 2009. Topic of Presentation: Update on Current Pulmonary Issues at the FDA.

Invited Speaker, 45th Annual Meeting of the Drug Information Association, San Diego, CA, June 2009. Topic of presentation: Quality by Design (QbD) – Linking Quality to Efficacy.

Invited Speaker, FDA Member Service Program, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, New Orleans, Louisiana, March 2010. Topic of presentation: Regulatory Issues Affecting the Specialty of Allergy and Immunology – Update on Allergy and Immunology Drug Products.

Invited Speaker, Respiratory Drug Delivery 2010, Orlando, Florida, April 2010. Topic of presentation: Regulatory uncertainties in bioequivalence – Exhaled nitric oxide as a possible efficacy endpoint for inhaled corticosteroids.

Invited Speaker, Annual Meeting of the American Thoracic Society, New Orleans, Louisiana, May 2010. Topic of Presentation: Safe use of long-acting beta-agonists in the treatment of asthma.

Invited Speaker, Asthma Therapies and the FDA, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, San Francisco, CA, March 2011. Topic of presentation: Role of FDA in monitoring Safety of Asthma Drugs.

Invited Speaker, FDA Member Service Program, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, San Francisco, CA, March 2011. Topic of presentation: Regulatory Issues Affecting the Specialty of Allergy and Immunology – Update on Allergy and Immunology Drug Products.

Invited Speaker, Respiratory Drug Delivery Europe 2011, Berlin, Germany, May 2011. Topic of presentation: The FDA and the safe use of LABAs in the treatment of asthma: Implications for post-market trials.

Invited Speaker, Annual Meeting of the American Thoracic Society, Denver, Colorado, May 2011. Topic of Presentation: Understanding the study design of the FDA-required safety study for long-acting beta-agonists (LABAs) in the treatment of asthma.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Orlando, FL, March 2012. Topic of presentation: Update from the US FDA – Year in review at the FDA.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Orlando, FL, March 2012. Topic of presentation: Safety of dynamic dosing of LABA/ICS therapy in the treatment of asthma.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, San Antonio, TX, March 2013. Topic of presentation: Update from the US FDA – Year in review at the FDA.

Invited Speaker, Respiratory Drug Delivery Europe 2013, Berlin, Germany, May 2013. Topic of presentation: Clinical requirement for new ICS/LABA combination in the USA.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, San Diego, CA, March 2014. Topic of presentation: Update from the US FDA – Year in review at the FDA.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Houston, TX, February 2015. Topic of presentation: Update from the US FDA – Year in review at the FDA.

Invited Speaker, Respiratory Drug Delivery Europe 2015, Antibes, France, May 2015. Topic of presentation: FDA's position on OTC use of drugs for asthma and allergies – Serving the patient and public health.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Los Angeles, CA, March 2016. Topic of presentation: Update from the US FDA – Year in review at the FDA.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Atlanta, GA, March 2017. Topic of presentation: Update from the US FDA – Year in review at the FDA.

Invited Speaker, Annual Meeting of the American Academy of Allergy, Asthma, and Immunology, Atlanta, GA, March 2017. Topic of presentation: Current treatment of non-allergic rhinitis and future directives for drug development in the United States.

Invited Speaker, Annual European Congress of Rheumatology, Madrid, Spain, June 2017. Topic of presentation: The FDA's view – Update from the US FDA.

Invited Speaker, Annual Meeting of the American College of Asthma, Allergy, and Immunology, Boston, MA, October 2017. Topic of presentation: The FDA's view – Update from the Center for Drugs at the FDA – Precision Medicine and Targeted Therapy.

Invited Speaker, Joint Congress of the American Academy of Allergy, Asthma, and Immunology, and the World Allergy Organization, Orlando, FL, March 2018. Topic of presentation: The Year in Review; An Update from the US Food and Drug Administration.

Plenary Session Speaker, Antibody Engineering & Therapeutics Annual Conference, San Diego, CA, December 2018. Topic of presentation: Benralizumab, A Monoclonal Antibody Engineered for Enhanced NK-cell Mediated Eosinophil Depletion.

Invited Speaker, Global Respiratory Leadership Forum, AstraZeneca, Gothenburg, Sweden, April 2019. The regulatory perspective and challenges on future disease classification and drug development.

FDA SPONSORED COURSES AND TRAINING:

FDA Staff College courses: Good Review Practices New Reviewer Workshop, September, 1997; Basic Statistical Methods, Fall, 1997; Basic Topics in Statistics: ANOVA and Regression, Fall, 1998; Topics in Applied Statistics: Multiple Endpoints and Multiple Comparison in Clinical Trials, June 1998; Topics in Clinical Trials, Spring, 1999; Biomarkers and Surrogate Endpoints: Advancing Clinical Research and Applications, May, 1999; Pediatric Rule Implementation, March, 1999; Technical Writing Skills, April, 1999; Managing Written Communication Skills for Team Leaders, September, 1999; Basic Drug Law, November, 2000; QT prolongation, Spring, 2001; Communication Skills for Leaders, Spring, 2002;

Leadership Fellow, Council for Excellence in Government, Washington, DC, 1999-2000.

Formula of Achieving Managerial Excellence I (FDA FAME Leadership Skills I Course), Reston, Virginia, November 15-19, 1999.

Formula of Achieving Managerial Excellence II (FDA, FAME Leadership Skills II Course), Reston, Virginia, September 11-15, 2000.

Personnel Practices for Supervisors (FDA FAME Leadership Skills III Course), Gaithersburg, Maryland, September 11-13, 2001.

FDA Personnel Practices for Supervisors FDA FAME Leadership Skills III Course), Gaithersburg, Maryland, August 20-22, 2002.

FDA Course: Managing the Employee Discipline and Performance Process, September 17-18, 2002.

EDITORIAL EXPERIENCE:

Assistant Editor, Nutrition Research, 1988. Pergamon Journals Inc., New York publish nutrition Research.

Reviewer, New England Journal of Medicine, 2002 to 2013.

Reviewer, Journal of Allergy and Clinical Immunology, 2008, 2009, 2010.

PREVIOUS RESEACRH GRANTS:

Project: Characterization of the human H1 histamine receptor gene.

Funded for 1994-95 by the University of Tennessee Medical Group. Awarded $12,500 for the period.

Project: Characterization of the promoter region of human H1 histamine receptor gene.
Funded for 1995-96 by the Memphis Veterans Affairs Medical Center Research Inc. Awarded $20,000 for the period.

Project: Promoter analysis of the eosinophil specific chemotactic receptor CCR-3 gene.
Awarded $45,000 as the recipient of the 1997 Glaxo Wellcome Allergy Research Award.

PUBLICATIONS:

1. Chowdhury BA, Chandra RK. Trace element regulation of immunity and infection. In: Branski D, Dinari G, Rozen P, Walker-Smith JA, eds. Pediatric Gastroenterology, Aspects of Immunology and Infections. Front Gastrointest Res. Vol 13, pp. 134-147, Karger Publication, Basel, Switzerland, 1986.

2. Chowdhury BA, Chandra RK. Nutrition, immunity, and resistance to infection. In: Jeffrey Bland, ed. 1986 A Year in Nutritional Medicine. 2nd edn. pp. 59-84, Keats Publishing, New Cannan, Connecticut, USA, 1986.

3. Chowdhury BA, Chandra RK. Biological and health implications of toxic heavy metal and essential trace element interactions. Prog Food Nutr Sci 1987; 11:57-113.

4. Chowdhury BA, Friel JK, Chandra RK. Cadmium-induced immunopathology is prevented by zinc administration in mice. J Nutr 1987; 117:1788-1794.

5. Chowdhury BA. Prevention of cadmium induced immunopathology by zinc in mice. Ph.D. Thesis, Memorial University of Newfoundland, St. John's, Canada, 1988.

6. Chowdhury BA, Chandra RK. Effect of zinc administration on cadmium-induced suppression of natural-killer cell activity in mice. Immunol Lett 1989; 22:287-292.

7. Chowdhury BA, Chandra RK. Prediction of the development of IgE-mediated atopic disorders and environmental engineering for their control. In: Nakagawa T. ed. Immunobiology of IgE. Clinical Reviews in Allergy. Vol. 7, pp. 3-22, Humana Press, New Jersey, USA, 1989.

8. Chowdhury BA, Chandra RK. Immunological effects of malnutrition. In: Cohen RD, Alberti KGMM, Lewis B, Denman AM, eds. The Metabolic and Molecular Basis of Acquired Diseases. pp. 571-582, Bailliere Tindall, East Sussex, UK, 1990.

9. Chowdhury BA, Chandra RK. Metal compounds and immunotoxicology. In: Ernest Merian, ed. Metal and Their Compounds in the Environment. pp. 607-615, VCH Verlagsgesellschaft, Germany, 1991.

10. Chowdhury BA, Chandra RK. Infections and the immune system. In: Stanfield JP, ed. Diseases of Children in the Sub Tropics and Tropics. 4th edn. pp. 449-454, Edward Arnold Publishers, London, UK, 1991.

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Graduate Student, Faculty of Medicine, Memorial University of Newfoundland, St. John's, Canada.

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Resident, Department of Internal Medicine, Wayne State University School of Medicine and the Detroit Medical Center, Detroit, Michigan.

July 1991 to June 1995
Medical Staff Fellow, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland.

July 1995 to July 1997
Assistant Professor, Department of Medicine, Division of Allergy and Immunology, University of Tennessee College of Medicine, Memphis, Tennessee; & Staff Physician, Department of Veterans Affairs Medical Center and The University of Tennessee Affiliated Hospitals, Memphis, Tennessee.

August 1997 to April 2018
Medical Officer, Medical Team Leader, Director, Division of Pulmonary, Allergy, and Rheumatology Products (was Division of Pulmonary and Allergy Products until March 2010), Center for Drug Evaluation and Research, US Food and Drug Administration, Silver Spring (was Rockville until September 2005), Maryland.

April 2018 to November 2019
Senior Vice President, R&D, AstraZeneca Pharmaceuticals, Respiratory Inflammation and Autoimmunity (RIA), Gaithersburg, Maryland, USA, April 2018 to November 2019.

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Independent Director, Proteostasis Incorporated, Boston, Massachusetts, USA, May 2019 to December 2020.

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Chief Medical Officer, Savara Pharmaceuticals, Austin, Texas, and, Langhorne, Pennsylvania, [Previously at: Horsholm, Denmark].

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