

Henrietta Ukwu, MD, FACP, FRAPS
Executive Vice President, Chief Regulatory Officer



Dr. Henrietta Ukwu is a Physician, Infectious Diseases Expert, Professor, Pharmaceutical Industry Executive, Thought leader, and Author of the landmark textbook, Global Regulatory Systems – A Strategic Primer for Biopharmaceutical Product Development and Registration and Self-Development Leadership Book – ‘ABCs of Leadership - Leadership Guiding Principles’

Numerous Award- Winning Inspirational leader including prestigious PharmaVoice and TOPRA awards for Inspirational Leadership and legacy Leader; known to create high performing global teams and transform existing teams to drive topline results and tangible bottom line outcomes with engagement.

One of the Pioneer Professors at Temple University Quality Assurance & Regulatory Affairs (QA/RA) Graduate Program.

Named One of Top Blacks in HealthCare in 2019

Named to Marquis Who's Who in America 2026

PROFESSIONAL HISTORY & EXPERIENCE

Novavax | Executive Vice President, Chief Regulatory Officer August 2022 – April 2026

Senior Vice President, Chief Regulatory Officer August 2021 – August 2022

Senior Vice President, Chief Regulatory and Quality Officer, Novavax Inc. January 2021 – August 2021

Otsuka| Jan 2013 – Dec 2020

Senior Vice President, Chief Regulatory Officer & Global Quality April -Dec 2020

Sr. Vice President & Global Head, Global Quality and Global Regulatory Affairs July 2016 – March 2020

Sr. Vice President, Head, Global Regulatory Affairs Jan 2013 – Jun 2016

PPD | Sr. Vice President, Head, Global Regulatory Affairs, May 2010 – Dec 2012

Pfizer Pharmaceuticals | Vice President, Global Regulatory Affairs, Oct 2009 – Apr 2010

Wyeth Pharmaceuticals | Vice President, Global Regulatory Affairs, Sep 2004 – Oct 2009

International Aids Vaccine Initiative-IAVI | Vice President, Global Reg. Affairs July 2004 – Sep 2004

Merck & Company, Inc. | Sep 1992 – Apr 2004

Vice President, Global Regulatory Policy, Aug 2002 – Apr 2004

Vice President, Worldwide Reg. Affairs – Biologics/Vaccines, Nov 1998 – Jul 2002

Senior Director, Worldwide Reg. Affairs – Biologics/Vaccines, Jul 1996 – Nov 1998

Director, Reg. Affairs – Pharmaceuticals and Vaccines, Sep 1992 – Jul 1996

Dr. Ukwu until recently (April 2026) served as Executive Vice President (EVP), Chief Regulatory Officer, Novavax, Inc. which she joined in January 2021, as SVP, Chief Regulatory and Global Quality Officer, a position she also held at Otsuka Pharmaceutical Company. In the Chief Regulatory Officer executive role, Dr. Ukwu has overseen the phenomenal race to global regulatory approvals of Novavax COVID vaccine for the pandemic and achieved the numerous Emergency use authorizations and full approvals for the Novavax COVID 19 vaccine including FDA Biologics License Approval (BLA) and the seasonal strain change formula across the globe for the Fall campaigns.

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Leadership Highlights: Dr. Ukwu has over two decades of executive Pharma Industry leadership including at Merck, Pfizer, PPD, Otsuka, Novavax where she held Vice President/Senior Vice President and Executive Vice President positions leading Global Regulatory and Global Quality teams. She has led numerous successful global regulatory product development and registration activities across all regions and with her teams is integral to the approval for over 30 original and key product approvals across multiple therapy areas and platforms (see list of approved products below). Dr Ukwu is skilled at globalizing and transforming teams requiring cross regional, cross functional alignment, by galvanizing around joint ownership of the vision, focusing team efforts strategically to drive excellence. This is fueled by robust regulatory intelligence, active engagement with regulatory agencies and internal stakeholders to attain optimal performance motivated by visible, tangible results and pride in outcomes. Dr. Ukwu has notably led globalization and optimization of her teams in all the companies she has worked for.

Strategic and agile Leader: recognized for her inspirational, solutions and results-driven leadership, Dr. Ukwu has effectively and successfully led Global Regulatory organizations of over 300 employees with significant annual operating budget, driving operational and organizational excellence, building and transforming teams, delivering solid, impactful results with top and outstanding team performance. Success is driven by the ability to build and deliver clinical, CMC and commercial regulatory strategies, introduce global systems, policies, and procedures, to govern global operations and establish threshold of performance excellence across the globe of team members.

Innovative solutions: Dr. Ukwu is an avid adopter of innovative technology, leading teams on the cutting edge of technology and driving towards automated end to end processes, digitization and innovative solutions for high yield outputs and added value of quality and efficiency. Establishing e-solutions to processes, driving digitization of the workspace. Dr. Ukwu led the Regulatory Team at Otsuka to achieve the First ever Digital Medicine i.e., Device-Drug Combination Product – MYCITE approved by the FDA in November 2017 and the ongoing validation efforts for the dynamic device software. (See below list of approvals and external presentations).

Communication acumen: Dr. Ukwu is an engaging executive, with effective communication skills and has actively contributed to defining the regulatory profession as a strategic resourceful value- adding business partner within industry. This is accomplished through her leadership model, publications, presentations, teaching of the profession and writing the landmark textbook on Global Regulatory Systems as well as the Leadership self-help book: ABCs of leadership.

Value proposition: Dr Ukwu embodies a unique blend of visionary, strategic, analytical and operations expertise, consistently exceeding performance goals by aligning team talents and efforts with organizational top and bottom-line objectives. Dr. Ukwu is an influential leader who creates immediate noticeable impact, motivates teams, instills enjoyment of the projects with positive ‘can-do’ attitude and produces results.

Dr. Ukwu therefore, has made significant contributions to the pharmaceutical industry through developing and enriching the regulatory profession by producing many protégés in senior leadership positions in industry. She has received numerous awards and recognition for these contributions (see below list of recognitions) including Fellow of the Regulatory Affairs Professional Society (FRAPS) and Fellow of the American College of Physicians (FACP), and other prestigious awards.

Dr. Ukwu is a pioneer professor at Temple University’s Quality Assurance / Regulatory Affairs graduate program. Below is the list of original product registrations Dr. Ukwu and her teams have led and achieved:

List of Products directly involved in development and Global Regulatory Approval/Registration:

- Novavax COID 19 vaccine US-FDA Biologics License Approval (BLA) Approval May 19, 2025 and BLA Supplement (sBLA) for 2025-2026 Strain Change Formula Approval September 5, 2025
- Novavax COVID 19 Vaccine (2024-2025 Formula) Regulatory Agency Authorizations in 2024 including FDA Emergency Use Authorization (EUA)

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- Novavax COVID 19 Vaccine (2023-2024 Formula) Regulatory Agency Authorizations in 2023 including FDA Emergency Use Authorization (EUA)
- Novavax COVID 19 Vaccine (Nuvaxovid) Regulatory Agency Authorizations in 2022 including FDA Emergency Use Authorization (EUA), UK, Singapore, Taiwan, Canada, Australia.
- Novavax COVID 19 Vaccine (Nuvaxovid) EMA Approval and WHO Emergency Use Listing December 2021
- Jynarque- First Treatment for Autosomal Dominant Polycystic Kidney Disease (May 2018)
- Abilify MYCITE—First Digital Medicine ever!!! (Nov 2017)
- Abilify Maintena Bipolar Indication (2017)
- Brexpiprazole for Schizophrenia (2015)
- Brexpiprazole for Adjunctive treatment for Major Depressive Disorder (MDD) 2015
- Abilify Maintena Dual Chamber for CNS Indication 2014
- Abilify for Acute Schizophrenia 2014
- Abilify for Tourette's Syndrome 2014
- Abilify Maintena IM for CNS indications 2013
- Protonix® Granules (pantoprazole), geriatric erosive esophagitis, 2009
- Prevnar 13®, pneumococcal conjugate vaccine, 2009
- Pristiq® (desvenlafaxine), SNRI, depression, 2008
- Relistor® opioid antagonist, opioid induced constipation, 2008
- Xantha®, recombinant plasma/albumin-free, Hemophilia A, 2008
- BeneFix® Coagulation Factor IX (Recombinant), hemophilia B, 2008
- Lybrel®, extended cycle oral contraceptive, 2007
- Torisel® (temsirolimus), advanced renal cell carcinoma, 2007
- Viviant (bazodoxifene) postmenopausal osteoporosis, 2007
- Tygacil® (tigecycline), cIAI & SSTI, 2005
- Hexavac®, six valent pediatric combo vaccine, 1999
- Crixivan®, (indinavir), HIV protease inhibitor, 1996—**Industry record for most rapid FDA - NDA review in total of 45 Days!!!**
- Comvax®, hepatitis A and B vaccine, 1996
- Varivax®, chickenpox varicella vaccine, 1995

Dr Ukwu is well recognized as an Inspirational Leader and Top performer with gravitas and outstanding results in Pharmaceutical Industry. Below is the list of awards and recognitions received:

PROFESSIONAL AWARDS & RECOGNITION

- Author ABCs of Leadership -republished by Amazon April 2026
- Marquis Who's Who in America 2026
- PharmaVOICE 100 Most Inspiring People- Two Time Award winner - Legacy Leader 2022: Featured in the PharmaVoice Forum for Industry Executives, July/August 2022
- Author, ABCs of leadership: Leadership Guiding Principles, published by Authorhouse, November 2020;
- Top Black in Health Care -USA (April 2019)
- Otsuka Magnet Leadership Award (2014, 2015, 2016, 2017, 2018)
- Otsuka Outstanding Performance Award (2016)
- Otsuka President's Achieving Excellence Award (2014, 2015)
- Otsuka President's Distinguished Performance - December 2014
- TOPRA award for Most Inspiring Leaders; London - November 2012
- PharmaVOICE 100 Most Inspiring People: Featured in the PharmaVoice Forum for Industry Executives, July/August 2011
- Author, *Global Regulatory Systems: A Strategic Primer for Biopharmaceutical Product Development and Registration* (book published by CenterWatch), June 2011
- Member, United Nations Economic Commission for Africa (UNECA) Scientific and Technical Advisory Committee (STAC) of the African Network for Drugs and Diagnostics Innovation (ANDI,) 2011

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- BEYA Stem Minorities in Research Science - Scientist of the Year- 2010
- Queens School Enugu USA National Patron & Torch Bearer (2009)
- Queens School Enugu-Alumni Association Most Distinguished Women Award - Atlanta chapter, September 2008
- Research Award 2006 - named one of the 100 Most Important Blacks in Technology in USA July 2006
- USA-Africa Class Award for Ambassador of Scientific Excellence, 2006
- Role Model Award 2004 – Alumni recognition at the 50th Jubilee Anniversary of Queen’s School Enugu, Nigeria, 2004
- Featured in book “Tall Drums” – Nigerians Making an Impact in America, launched April 2003
- Women of Color Emerald Award for Research Leadership, 2003
- Merck Special Achievement Award for Contribution to Diversity Worldwide Business Strategy Team, 2003
- Award of Excellence – 2002 Merck Employee Giving Campaign
- Award of Excellence for Successful Re-design of BPC Technology Transfer 2002
- African Women’s AIDS Project (AWAP), 2002
- Award of Excellence 2001 Merck Employee Giving Campaign
- University of Jos Medical school alumni association Alumni Excellence Award, October 2001
- Merck Special Achievement Award for Contribution to Merck Diversity Initiatives, 2001
- Nigerian People’s Forum Health Science Achievement Award, November 2001
- Merck’s Most Amazing Woman Award, 2001
- Nigerian Excellence in Science and Technology (NEST) Award – London, April 2001
- Outstanding Woman in Technology of the National Society of Black Engineers’ Golden Torch Awards, March 1999
- Represented Pharmaceutical Industry (PhRMA) in Media commercial for HIV/AIDS, 1999-2000
- Merck (MRL) Distinguished Div. Scientific Award (Regulatory Affairs) for CRIXIVAN, 1998
- Nigerian Eagles Award for Outstanding Contributions to Science, October 1997
- Harlem YMCA Black Achievers in Industry, March 1997
- Merck Award for Accomplishments in Medicine, February 1997
- Merck Award of Excellence, Crixivan Approval, March 1996
- Merck Award of Excellence, NDA Submission of Crixivan, January 1996
- Merck Award of Excellence, Crixivan closed advisory, November 1995
- Merck Award of Excellence, Varivax Approval, April 1995
- International Fellow for AIDS Pathogenesis and Vaccine Development, National Institute of Health, 1990
- Intern of the Year, Meharry VA Hospital, 1987

PUBLICATIONS, BOOKS & BOOK CHAPTERS

BOOKS AND BOOK CHAPTERS:

ABCs of leadership: Leadership Guiding Principles, authored by Henrietta N. Ukwu MD and published by AuthorHouse, November 2020 and republished by Amazon April 2026

Global Regulatory Systems: A Strategic Primer for Biopharmaceutical Product Development and Registration, book, authored by Dr. Henrietta Ukwu and published by CenterWatch, June 2011

“Clinical Trials in Latin America,” book chapter (Chapter 14) in *Global Clinical Trials: Effective Implementation and Management, 2011*. Henrietta Ukwu, MD, Anna Paula Más, Bess Villeponteaux, et al.

Publications:

The East African Community’s Medicines Regulatory Harmonization Initiative in context: An independent perspective on the initiative’s role in the journey to improve access to quality medicines.

- PLOS Medicine Journal August 2020

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Six Guiding Principles for Pharmaceutical Companies to Achieve Global Quality, Henrietta Ukwu; DIA Global Forum, July 2020

The Quality and Compliance Benefits to eConsent, Henrietta Ukwu, M.D., FACP, FRAPS, Debbie Profit, Ph.D., Kristen Bequeath, Ph.D., Ken Getz, M.B.A. Abhinav Dulur, M.E., Hannah Glenn: Poster at DIA Convention June 2020

Facing the Challenges of Global Product Registration—PharmaVoice—September 2012

Navigating the Initiatives: PDUFA V in International Clinical trials, Henrietta Ukwu et al; July 2012

Clinical Trial Registration and Data Disclosure. Drug Discovery & Development. An, J., Farrow, T., Henry, J., & Ukwu, H. (2012, Dec 3). Navigating the Initiatives. International Clinical Trials. Baluja, N., Hemsworth, G., Hezari-Adam, M., Mann, P., & Ukwu, H. (2012, Summer).

Exclusivity Protections for Biopharmaceuticals,” article in *European Pharmaceutical Contractor* (June 2011), Onesmo Mpanju, PhD, Stephen Dodds, Henrietta Ukwu, MD.

Blueprint – Driving Regulatory Excellence. Henrietta Ukwu, M.D., FACP and Hilary Malone, Ph.D. RAPS *Regulatory Focus*, March 2009

Perspective: *Role of Regulatory Scientist in Pharmaceutical Industry.* Henrietta Ukwu, M.D., FACP. RAPS *Regulatory Focus*, March 2003.

Acute Pubic Osteomyelitis in Athletes, Henrietta Ukwu, M.D., FACP, Barney S. Graham, M.D. and Robert H. Latham, M.D. Clinical Infectious Diseases: Vol. 15: 636-8, October, 1992.

Perinatal Transmission of HIV-1 Infection and Maternal Immunization Strategies for Prevention, Henrietta Ukwu, M.D., FACP, Barney S. Graham, Peter Wright. *American Journal of Obstetrics and Gynecology*: Vol. 80, No. 3: 458-468, September 1992.

Clostridium Septicum Sepsis and Myonecrosis in the Absence of Trauma, Henrietta Ukwu, M.D., FACP and David Gregory, M.D. *Southern Medical Journal*: Vol. 84, No. 9: 1128-30, September 1991.

EXTERNAL PRESENTATIONS:

- Panelist: DIA Convention - Advancing Regulatory Excellence in Digital Age, February 2-5th 2026 Bethesda, MD.
- Moderator; American Biomanufacturing Summit – Women in Leadership, April 12-13, 2023, San Francisco
- Panelist: BIO International Convention – Friend or Foe: How COVID -19 Changed Dynamics with Global Regulatory Agencies, June 5-8, 2023, Boston, MA.
- Speaker: WTO Technical Workshop on COVID-19 Vaccine R&D, Manufacturing and Distribution: How does it work in Practice? February 11, 2022
- Keynote Speaker: BIT’s 17th Annual International Congress of Drug Discovery Science & Technology 2019 Topic: Advancing Digital Innovation in Pharmaceutical Quality November 15-17, 2019, Nanjing, China
- Speaker at WOCIP Annual Conference: *The Expanded Role of Regulatory and Need to Thrive in the Grey* November 2, 2019, Atlantic City, NJ
- Nigerian Association of Pharmacists and Pharmaceutical Scientists (NAPPSA)– Speaker & Moderator September 2019

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- Speaker, ICCD Austin TX --The Road to Regulatory Approval: ABILIFY MYCITE® (aripiprazole tablets with sensor) First Digital Medicine; Feb 2018
- Speaker panel session on Global Regulatory Options for Accelerated Drug Development at the Innovative Regulatory Pathway summit January 2018.
- Keynote speaker, Queen's School Alumni Association Inauguration New Jersey Chapter 2019
- Nigerian Association of Pharmacists and Pharmaceutical Scientists (NAPPSA) – Speaker & Moderator 2018
- Panel Session Moderator, Otsuka Town Hall Bipolar Disorder, August 15, 2017
- Speaker & Moderator: Female “Scientific Force” in Pharma—Otsuka Fireside Chat, March 2017
- The African American Chamber of Commerce of New Jersey, AACCNJ, *Women Who Empower Panel Speaker*- August 2016
- Keynote Speaker and Sessions Moderator, 3rd Clinical Trial Summit, Lagos Nigeria, June 3-5, 2015
- Keynote Speaker, Queen's School Alumni Association, “Knowledge, Vehicle to Success” May 2014
- Nigerian Association of Pharmacists and Pharmaceutical Scientists (NAPPSA) – Speaker & Moderator 2013
- Otsuka Town Hall Speaker: Project 7 Regulatory Submissions End to End process, Dec 2013
- Keynote Speaker, African Training and Policy Studies (ATPS) USA Chapter Inauguration “Pharmaceutical Innovation – Challenges and Opportunities for Africa,” June 8, 2012
- Speaker, North Carolina Regulatory Affairs Forum (NCRAF) on “Global Regulatory Affairs Landscape,” November 2011
- Speaker and panelist, Institute of Medicine workshop on “Strengthening Workforce for Innovative Regulatory Science in Therapeutics Development,” September 20-21, 2011
- Guest Speaker, Medical Grand Rounds, Baptist Hospital, Nashville, TN. “Bench to Bedside and Beyond—Journal of Pharmaceutical Product from Discovery to Patient,” September 7, 2011
- Speaker, “Strategic Transformation of the Vaccine Industry,” World Vaccine Congress, April 11, 2011
- Speaker, the Moving Target of Global Clinical Data Disclosure, - Fierce Biotech webinar, June 2010
- Guest Speaker, Clinical Trial Registration and Data Disclosure- An Evolving Landscape, PPD-NCRAF Educational Dinner, Raleigh, N.C., October 14, 2010
- Speaker, Drug Development Training for Nigeria NAFDAC – National Agency for Food and Drug Administration and Control, Abuja Nigeria, May 2010
- Executive Board Member and Speaker, Africa Cancer Care Inc. – Raising Awareness of Cancer in Nigeria. Contributed to the preparation and attended the launch of groundbreaking for the International Cancer Center Abuja, July 2009
- Guest Speaker, Value of Vaccines for Developing World Countries, NAPPSA Washington, 2009
- Speaker, Childhood Immunization Challenges and Opportunities, ANPA Abuja, Nigeria, July 2009
- Wyeth spokesperson, Moxidectin, at World Congress of Science Journalists, London June 2009
- Loyola University Chicago and African Women in America Inaugural Conference – October 2008
- Lead PhRMA SGD for Tripartite Regulatory Meeting with Japan, Korea, and China, October 2008
- Guest Speaker, POWER – Opening Doors to Women, Philadelphia inaugural event, September 2008
- Led and designed Blueprint – Regulatory Strategic Excellence, Wyeth breakthrough initiative, 2007
- Moderator, Clinical Trials and Regulatory Platform, NAPPSA, Houston, Texas, September 2007
- Guest speaker, Cancer Awareness, Houston, Texas, August 2007
- Speaker and member, AGCPN, Association for Good Clinical Practice in Nigeria, Abuja, July 2007
- Keynote speaker, Queen's School Alumni Association Inauguration, Atlanta Chapter, September 2007; Houston Chapter, November 2006
- Speaker/ moderator, Association of Nigerian Physicians in America (ANPA), 1999, 2001, 2005, 2007
- Speaker on Successful Women, Wyeth Network/Mentoring, April 2006
- Wyeth lead regulatory representative at EMEA/Wyeth meeting on EU Roadmap 2010, February 2006
- Key regulatory expert on MMV-ESAC Geneva, November 2004-January 2007
- IAVI senior representative and Speaker to Zambia Ministry of Health, HIV Clinical Trials August 2004
- WHO-sponsored Merck representative, Discussion: HIV Clinical Trials, Tanzania, December 2003
- Moderator, BIO 2003 Annual Meeting session on FDA reorganization, June 2003

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- Lead panelist on BIO CEO Investors Meeting on FDA recent developments, February 2003
- Merck senior representative at Harvard Black Men's Forum, March 2003
- Guest speaker, UNCF/Merck Science Initiative Fellows' Day, June 2002
Mentor, Regulatory Careers and Competencies Team, 2002
- Merck senior representative at public events:
 - Nathan Davis Award Ceremony for American Medical Association, 2001
 - Africare, 2000, 2001
- Invited speaker, Bioequivalence and Bioavailability of Biotechnology/Biologic Products
- International Symposium on the Harmonization of Registration/Licensing Procedures, Turkey, October 2001
- PhRMA Researcher's "Fly-In" to Capitol Hill, 1999, 2000, 2001
- Merck Executive Leadership Harvard, 2001
- Invited speaker, biotechnology lecture, Yale University Medical School, April 2000
- Merck Executive Business Leadership Harvard, 2000
- PhRMA Commercial for Aging – Medicare, 2000 (all major USA TV networks)
- PhRMA Commercial for HIV/AIDS, 1999 (all major USA TV networks)
- Merck MIT Fall Symposium, Massachusetts Institute of Technology, Boston, November 1998
- Guest speaker, Health Care Opportunities in Industry, Rutgers University College Seminar on "Special Topics on Medical and Health Issues," October 1998
- Chairperson, session on HIV Infections in Africa, Fourth Annual Convention of Association of Nigerian Physicians in America (ANPA), June 1998
- Update on International Conference on Harmonization ICH, May 1998
- University of Pennsylvania Infectious Diseases Research Conference: Transmissible Spongiform Encephalopathy Current Research and Regulatory Environment, March 6, 1998
- Henry Ford Hospital, Michigan - Grand Round Drug/Vaccine Development, May 1997
- Invited speaker, "International Conference on Harmonization (ICH) Standards as Global Regulatory Standards," Institute of International Research, April 29, 1997
- University of Pennsylvania, Student Conference, November 1996
- Keynote speaker, Merck Comvax Approval Celebration, October 1996
- Infectious Disease Attending, VAMC, Philadelphia, Pennsylvania, March 1994
- Co-moderator, ICAAC session, Acellular Pertussis and other Vaccines, September 1994
- Invited speaker, HIV/AIDS Drugs and Regulatory Issues, National Organization for the Professional Advancement of Black Chemists and Chemical Engineers, April 1994

LICENSES & CERTIFICATIONS

- Fellow, American College of Physician (FACP)
- Fellow, Regulatory Affairs Professional Society (FRAPS) September 2009
- Diplomate, American Board of Internal Medicine (ABIM) 2009
- Diplomate, American Board of Internal Medicine - Infectious Diseases Subspecialty 2009
- Medical License Tennessee
- Medical License Pennsylvania
- Medical License New Jersey
- ECFMG Certification

EDUCATION

Vanderbilt University Medical Center – Nashville, Tennessee

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Henrietta Ukwu, MD, FACP, FRAPS
Executive Vice President, Chief Regulatory Officer
Fellow in Infectious Diseases, July 1989- June 1991

University of Tennessee, Baptist Hospital – Nashville, Tennessee
Resident in Internal Medicine, July 1987- June 1989

Meharry Hubbard Hospital – Nashville, Tennessee
Intern in Internal Medicine, July 1986- June 1987

Emory University Medical School – Atlanta, Georgia
Electives, July-August 1985

ECFMG (Examination for Foreign Medical Graduates), September 1985

University of Nigeria Teaching Hospital – Nigeria
Rotational Internship, July 1982- June 1983

University of Jos School of Medicine – Nigeria
Medical and Surgical Degrees BM, BCH, July 1976- June 1982

