

Henrietta UKWU, M.D.

A RENAISSANCE WOMAN

PASSIONATE. GIVING.

NAME: Henrietta Ngozi Ukwu, M.D.

CURRENT POSITION: Senior VP, Global Regulatory Affairs, PPD Inc.

DATE AND PLACE OF BIRTH: July 1959; Enugu, Nigeria

EDUCATION: Fellowship in Infectious Diseases, Vanderbilt University Medical Center; Residency in Internal Medicine, Baptist Hospital, University of Tennessee; Internship in Internal Medicine, Meharry Medical College; medical and surgical degrees, University of Jos Medical School, Nigeria

FIRST JOB: Chief, infectious diseases division, and attending physician, Veterans Administration Hospital

FIRST INDUSTRY-RELATED JOB: Director, regulatory affairs, Merck & Co. Inc.

ALTERNATIVE PROFESSION: University professor

PROFESSIONAL MENTORS: Dr. Edward Scolnick, past president, research and development, Merck & Co. Inc.; Dr. Robert Ruffolo, past president, research and development, Wyeth Pharmaceuticals; Bernard Pousot, past chairman and CEO Wyeth Pharmaceuticals; Dr. Christine Dingivan, chief medical officer and executive VP, PPD

PROFESSIONAL ASSOCIATIONS: American College of Physicians; American Board of Internal Medicine and Infectious Diseases; the American College of Physicians-American Society of Internal Medicine; American Medical Association; Infectious Diseases Society of America; American Academy of Pharmaceutical Physicians; Association of Nigerian Physicians in the Americas (ANPA); the United Nations Economic Commission for Africa (UNECA) Scientific and Technical Advisory Committee for Drug Development and Innovation.

GIVING BACK: Restoring the declining schools in Nigeria, specifically her high school

WORDS TO LIVE BY: Do all things for God and in all things give thanks to God

AWARDS: Scientist of the Year, BEYA Minorities in Research Science, 2010; Most Distinguished Women Award, Queen's School Alumni Association, 2008; One of 100 Most Important Blacks in Technology, NSBE Award, 2006; Ambassador of Scientific Excellence, USA-Africa Class Magazine Award, 2005; Role Model Award, Queen's School Enugu Alumni Jubilee, 2004; Emerald Honors for Research Excellence Women of Color Research Award, 2003; Nigerian Excellence in Science and Technology, ARCO Award, 2001; Health Science Achievement, Nigerian People's Forum Award, 2001; Alumni Excellence Award, University of Jos Medical School, 2001; Merck's Most Amazing Woman Award, Merck, 2001; and many others

Henrietta Ukwu, M.D., is a medical doctor, professor, book author, leader, and expert in her field. Not many people have the opportunity to be experts in medicine, academia, the pharmaceutical industry, and global regulatory affairs/policy as Dr. Ukwu.

Dr. Ukwu, senior VP for global regulatory affairs at PPD, is an inspiration to all who know her. She radiates passion, joy, and confidence.

Nothing pleases her more than sharing her talent, knowledge, and gifts with her colleagues; she enjoys bringing smiles to those she teaches and is happy to provide constructive development. She teaches global regulatory affairs at Temple University, and revels in the feedback that her passion and sharing of knowledge and experiences resonate with her students.

She is an infectious disease physician, pharmaceutical industry executive, and industry thought leader with extensive global regulatory experience across all biopharmaceutical therapeutic platforms and regions.

Throughout her career, Dr. Ukwu has played a strong leadership role in building strategic regulatory teams, leading major initiatives to drive regulatory excellence, and making significant contributions to the development and enrichment of the regulatory profession. She has been responsible for overseeing strategic product development and registration plans; regulatory interactions with boards of health, human subject protection for clinical/preclinical development; ensuring rigorous regulatory standards, and successfully registering new drugs and biologics.

Since joining PPD in June 2010, Dr. Ukwu has provided inspiring leadership in guiding global regulatory services across all PPD lines of business and providing clinical development expertise to advance the company's vaccines and biologics operations. Under Dr. Ukwu's leadership, PPD's global regulatory affairs organization, which encompasses global regulatory development, global chemistry regulatory development, global medical manufacturing and controls, global medical writing and global regulatory operations and publishing, is maximizing its focus on the provision of strategic regulatory intelligence and expertise to help the CRO's clients

During her career, Dr. Henrietta Ukwu has earned acclaim in several fields, including medicine, academia, the pharmaceutical industry, and global regulatory affairs/policy.

DID YOU KNOW?

Dr. Henrietta Ukwu starred in the PhRMA commercial for HIV/AIDS in 1999; the commercial ran for two years and many got to know her face and voice from television.



successfully navigate today's dynamic global regulatory landscape.

Dr. Ukwu has been involved in numerous product development activities and has directly overseen the successful original regulatory development, filings, and approvals of 14 new products (10 drugs; four biologics).

Dr. Ukwu's demonstrated vision, leadership, and passion for impacting humanity through the pharmaceutical and CRO industry make her a great leader and role model. Her colleagues are inspired by her and her mentorship has helped them grow and advance in their own careers.

Recently, she completed and has had published her text book, Global Regulatory Systems — A Strategic Primer for Biopharmaceutical Product Development and Registration. This is the first textbook that consolidates all global regulatory systems and provides the strategic application of regulatory knowledge and intelligence to enable and facilitate successful product development and registration.

This book created the vehicle for Dr. Ukwu to communicate the diverse global, strategic and extensive hands-on experience, comprehensive knowledge and critical success factors for product development, registration and commercial success that she has gained over 18 years in global regulatory affairs.

Dr. Ukwu earned her medical and surgical degrees from the University of Jos School of Medicine in Nigeria. She completed her internship at Meharry Medical College, residency in internal medicine at Baptist Hospital, and her fellowship in infectious diseases at Vanderbilt University. **PV**

Dr. Henrietta UKWU

A WEALTH OF EXPERIENCE

Henrietta Ukwu, M.D., a physician and infectious diseases expert, joined PPD in 2010 as senior VP and head of global regulatory affairs, bringing more than 18 years of pharma and global regulatory experience to the company. Under her leadership, PPD's global regulatory affairs organization is strengthening its focus on the provision of strategic intelligence and expertise to help its clients navigate today's dynamic regulatory landscape. Before joining PPD, Dr. Ukwu served as VP of global regulatory affairs at Wyeth Pharmaceuticals Inc., now Pfizer, where her responsibilities spanned all therapeutic areas. During her six-year tenure, she led regulatory efforts for vaccines, biologics, and pharmaceuticals in the United States, Canada, Asia Pacific, Latin America, Europe, Middle East, and Africa. Her responsibilities included strategic product development, registration of new drugs and biologics, and ensuring human subject protection for clinical and preclinical development and adherence to rigorous regulatory standards. Before joining Wyeth Pharmaceuticals, Dr. Ukwu spent almost 12 years with Merck & Co., where she was promoted to positions of increasing responsibility, including VP of global regulatory affairs and global regulatory policy.

She is a strong advocate of the medical, scientific, research, and regulatory profession. Dr. Ukwu enjoys sharing her leadership, management, and personal relationship skills; as a result, she has many formal and informal mentees. She is proud to have recruited many individuals into the regulatory profession, many of whom came directly from academic medicine and other scientific fields. Many of her protégés have gone on to assume senior and executive-level positions in the pharmaceutical industry.

Having worked for several of the healthcare industry's best companies, including Merck, Wyeth/Pfizer, and now PPD, Dr. Ukwu took her experiences and published a book that allows her the unique opportunity to share her knowledge. Furthermore, the book provides tools for students in regulatory affairs and new entrants into the industry to facilitate the study and effective application of regulatory affairs.

In addition to writing the book, another highlight of her career includes leading the effort to gain U.S. regulatory approval of

Crixivan, Merck's HIV protease inhibitor, which was approved in 1996. Crixivan is one of a class of compounds that significantly reduced the mortality of HIV/AIDS and introduced a new era for managing this disease.


Since that time, Dr. Ukwu is also proud to have led original regulatory approvals of 14 new drugs and biologics, which have provided significant contributions to humanity, medicine, and science.

Another highlight was transitioning from the pharmaceutical industry to the CRO industry. She joined PPD in 2010 at a critical time, as PPD is shifting the paradigm of transforming operational relationships to more strategic partnerships with industry leaders. This opportunity allowed her to leverage her breadth and depth of knowledge of the pharmaceutical industry and strategic global regulatory experience.

One of the most challenging assignments of her career was leading the entire human therapeutic portfolio of Wyeth Pharmaceuticals as VP, global regulatory affairs, from 2005 to 2008. During this three-year period, eight new products were filed for global regulatory review and approvals.

In the future, Dr. Ukwu would like to give back and undertake a healthcare public service platform in her native country Nigeria that will enable impactful and constructive changes to healthcare delivery and solutions in the country.

Enthusiastic about life, she embraces a spiritual relationship with God, that extends to her medical and research professions, professional teams, family, including her husband, children, parents, siblings, and extended family.

Dr. Ukwu draws inspiration from her husband, Dr. Isaac Ukwu, a chemical engineer and business entrepreneur; her late father, Sir James Ude, who was an accomplished economist, who retired as chairman of the African Continental Bank, and her mother, Lady Theresa, a nurse, homemaker, and "angel." Dr. Ukwu who is the second-oldest of nine children, loves being part of a large closely knit family. 



Getting Personal with **DR. HENRIETTA UKWU**



FAMILY: Husband, Isaac Ukwu, Ph.D.; three children, Victor, Yvonne, and Henry

HOBBIES: Traveling and writing

READING LIST: The Audacity of Hope by Barack Obama

FAVORITE BOOK: The Bible

FAVORITE MOVIE: The Lion King

BUCKET LIST: Write several biographies – her father's and her family's, and to serve in public office, specifically in the healthcare sector in Nigeria

INSPIRED BY: Her late father and her husband

MOST UNUSUAL PLACE VISITED: Thailand

LIFE LESSONS: Why fly as a barn hen when you can soar as an eagle

TIME TRAVEL: Back to the times of the African traditional empires; to the time when Jesus Christ walked the Earth; and forward to travel to the moon



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