



CELEBRATING A 7-YEAR COLLABORATION WITH KING'S COLLEGE LONDON

We are excited to share the outcomes of our 7-year partnership with [King's College London](#), recently published in *Frontiers in Pharmacology*. This collaboration has focused on elevating the standards of Medicines Development education through our innovative blended e-learning and certification program.

Our [Certification in Medicines Development \(CMD\) Program](#) has made significant strides in fostering a global community of Medicines Development professionals. Though long-term impacts are still being established, preliminary evidence suggests enhanced knowledge transfer and career progression.¹

Continue to page 2 for key findings from this study!

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BLEND E-LEARNING & CERTIFICATION FOR MEDICINES DEVELOPMENT PROFESSIONALS: KEY FINDINGS¹



A Global Impact:

- Engaging 682 participants from 86 countries, we have successfully created a diverse and collaborative learning environment that transcends geographical boundaries.



Innovative Curriculum & High Satisfaction:

- The comprehensive curriculum, based on the PharmaTrain syllabus, combines asynchronous lectures and synchronous webinars. It has consistently received high satisfaction ratings, averaging over 4.0 on a five-point scale.
- The program's structure, featuring 64 online lectures, 24 webinars, 25 discussion forums, and regular evaluations, ensures a rigorous and interactive educational experience with experts from academia, the pharmaceutical industry, CROs and regulatory institutions.
- The program's success rate averages 83%, reflecting substantial cognitive gains.



Career Growth and Professional Competence:

- 70% of responding alumni have reported significant improvements in their job functions, supported by 30% of their supervisors.
- The program has facilitated notable career progression and professional development for many participants.

Advancing the Profession through Partnership:



- Our partnership with King's College London has been instrumental in ensuring the program's academic rigor and relevance. The Center for Pharmaceutical Medicine Research at King's College has provided invaluable expertise and support, facilitating continuous improvement and alignment with industry advancements.

Explore our findings: We invite you to delve into the detailed results of our study published in *Frontiers in Pharmacology* and join us in our mission to advance Medicines Development education. Click [here](#) to read the complete article.

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT

Academy Alumni Perspectives: Arlen Dewayne Brumlow



**ARLEN DEWAYNE
BRUMLOW**

“One need not look too far to see that public confidence in science is approaching all-time lows. Sadly, confidence in scientific discoveries relative to public health is polarizing at best and suspect at worst. The irony is stunning in that novel advancements in vaccines, oncology, maternal health, and other diseases are remarkably faster now and have never been more compelling or demographically diverse in their construct (Corey).² These turbulent, environmental factors are why having a well-aligned identity and purpose is of paramount importance for Medical Affairs Professionals. These challenges also mark our greatest opportunity to shine.

How can we as Medical Affairs Professionals collectively ensure that we succeed? The good news is that there is a somewhat simple and reliable pathway forward.

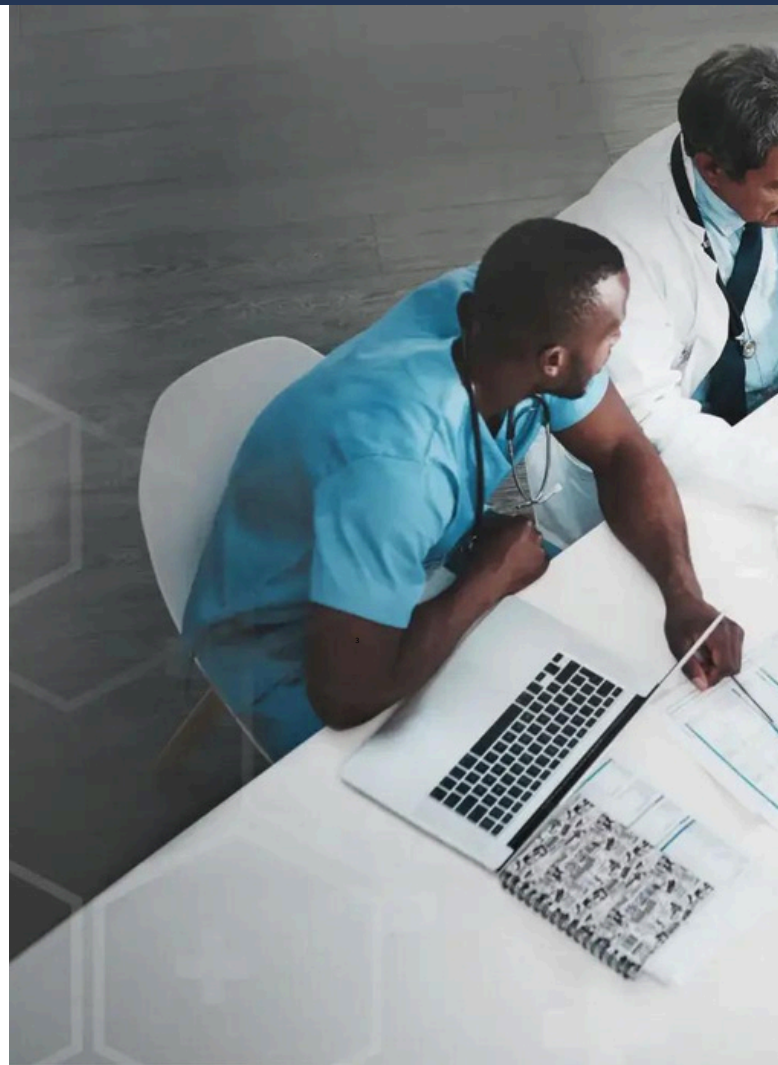
The way Medical Affairs Professionals can continue to blaze a progressive and maximally impactful trail is to always focus on doing what is right for the patient...always. This simple mantra begins and ends with us. This is our identity (patient-centricity) and our purpose (building trust). Building trust and making a positive impact on patient’s lives and in society as a whole is the foundational core of all that we do as Medical Professionals. Simply stated, it is our reason for being...our purpose.” **Read his complete essay [here](#).**

Arlen Dewayne Brumlow is a seasoned professional with over 30-years experience at Pfizer in roles of increasing responsibility in both commercial sales, marketing and global medical affairs. He recently began an exciting new chapter as the Senior Director, EveryGrant External Accounts with Conquer Cancer; The ASCO Foundation. He will work with the brightest minds in cancer research to accelerate breakthroughs in lifesaving research and empower people everywhere to conquer cancer.

EMA NEWS: NEW GUIDELINE ON DIABETES MELLITUS

We are pleased to share information about a new EMA guideline on the clinical investigation of medicinal products for the treatment and prevention of diabetes mellitus. This revised guideline, effective from 1 January 2024, replaces the previous 2012 guideline and reflects the current European Union regulatory stance on key issues in developing new treatments for type 1 and type 2 diabetes.

The primary motivation for the update was to enhance the section on cardiovascular safety, incorporating insights from the 2016 reflection paper on assessing the cardiovascular safety profile of medicinal products. Additionally, the revision aimed to address other evolving topics in the diabetes field that required clarification according to the EMA and other stakeholders.



Access the guideline [here](#).

FDA NEWS: NEW MEDICINE CENTER OF EXCELLENCE



The U.S. FDA's Center for Drug Evaluation and Research (CDER) has announced the establishment of the CDER Quantitative Medicine (QM) Center of Excellence (CoE). This center focuses on the development and application of exposure-based, biological, and quantitative modeling and simulation approaches using data from nonclinical, clinical, and real-world sources. These methods aim to inform drug development, regulatory decisions, and patient care.

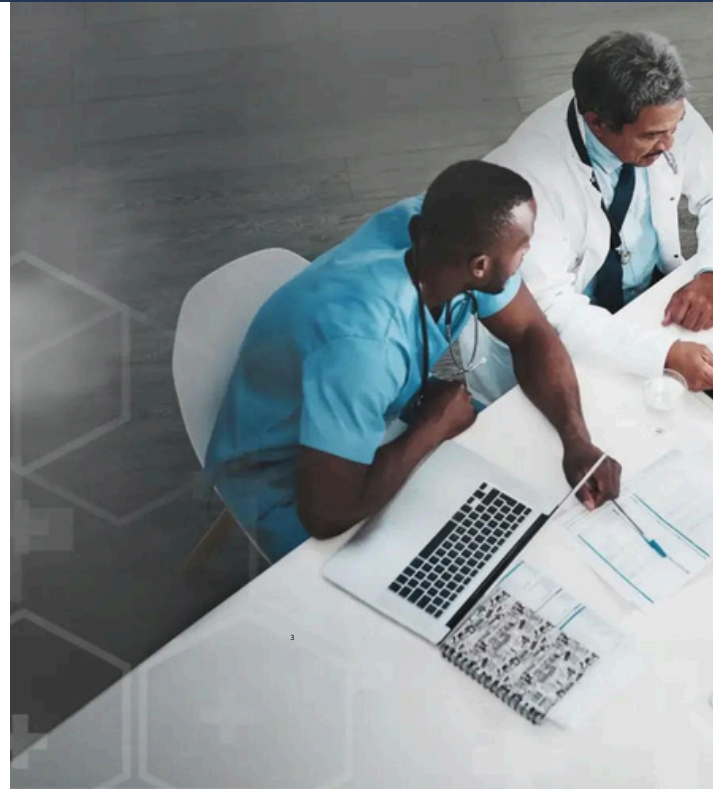
The QM CoE will unify efforts from various CDER offices, including the Office of Generic Drugs, Office of New Drugs, Office of Pharmaceutical Quality, and Office of Translational Sciences.⁴ Continue reading [here](#).

EMA NEWS: REVISED GUIDELINES FOR DEMONSTRATING THERAPEUTIC EQUIVALENCE AND PHARMACEUTICAL QUALITY IN INHALATION AND NASAL MEDICINAL PRODUCTS

The EMA has released two guidelines for public consultation:

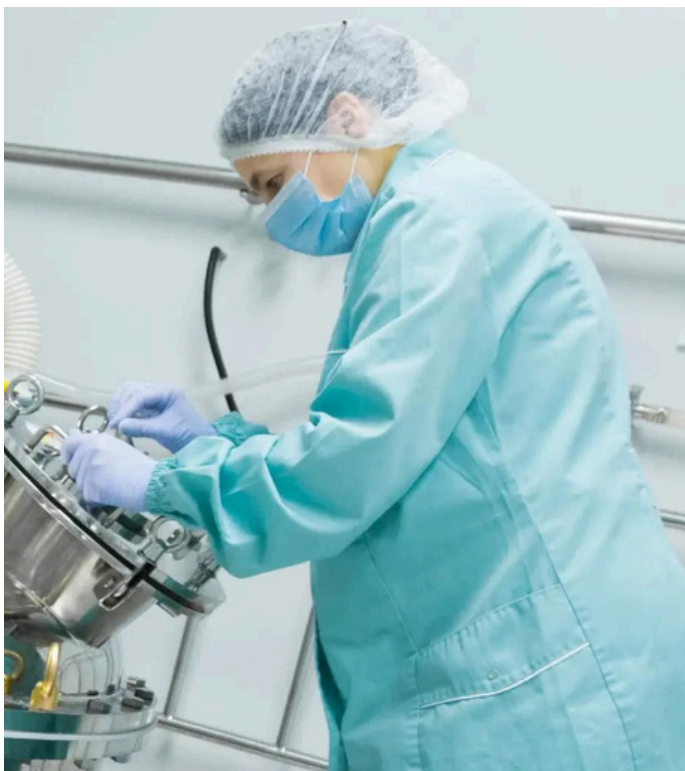
1. Guideline on the Requirements for Demonstrating Therapeutic Equivalence Between Orally Inhaled Products (OIP) for Asthma and Chronic Obstructive Pulmonary Disease (COPD)
2. Guideline on the Pharmaceutical Quality of Inhalation and Nasal Medicinal Products

These guidelines are critical for ensuring the safety, efficacy, and quality of inhalation and nasal medicinal products.



Public feedback is essential for refining these guidelines to reflect the latest scientific and regulatory standards. For more information on the purpose, deadlines, and to access the full revisions, click [here](#).

HIGHLY PATHOGENIC AVIAN INFLUENZA



The USDA, FDA, and CDC, along with state partners, are investigating an outbreak of highly pathogenic avian influenza (HPAI) affecting dairy cows in multiple states, leading to decreased lactation and low appetite among other symptoms. Despite this, the FDA and USDA assure that the commercial milk supply remains safe due to two main factors:

1. The pasteurization process, which heats milk to a specific temperature to kill harmful bacteria and viruses, has ensured milk safety for over 100 years.
2. The diversion or destruction of milk from sick cows, preventing it from entering the supply chain.

Almost all commercial milk in the U.S. comes from farms in the Grade “A” milk program. Continue reading [here](#). ⁶

ASSISTED DEATH: SOME THOUGHTS

Emmanuel Macron described France's new Aid in Dying bill as "simple and humane," aiming to legalize the prescription of lethal medication for adults with terminal illnesses. While the intention to honor patient choice and alleviate suffering is understandable, the notion that assisted dying is simple is misleading. The topic is far more nuanced, complex, and variable across jurisdictions. Over the past 20 years, physician-assisted dying practices have expanded globally, now legal in at least 29 jurisdictions. In Belgium and the Netherlands, it is allowed based on intolerable suffering, whereas in the USA and Australia, it requires a terminal diagnosis. In Canada, extending medical assistance in dying to people with mental illness remains highly controversial. Despite the central role of health-care professionals in the process, the impact of such legislation on clinicians has received relatively little attention. How might the public perception of doctors change with such legislation such as Macron's Aid in Dying bill?



Pieces of legislation such as this underscore the need for clinicians to remain informed and for debates to continue as the implications and expectations for the medical profession are also ever-changing.⁷

Continue reading [here](#).

A NEW VACCINE AGAINST CHOLERA



Cholera, caused by *Vibrio cholerae*, is closely linked to poverty and poor access to clean water and sanitation. Though often asymptomatic, severe cases can lead to rapid death from dehydration if untreated. Core interventions for mitigating cholera risk include water, sanitation, and hygiene (WASH) efforts. However, cholera cases are rising due to conflict, climate change, and inadequate sanitation infrastructure.

In 2022, WHO reported 472,697 cholera cases and 2,349 deaths from 44 countries, with the actual burden likely higher due to underreporting.⁸

Continue reading [here](#).

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Thanks for reading!

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