



## PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT

Continuing our series on Professional Identity and Medicines Development, we are excited to present an insightful essay by Khushbu Jethwa, a member of our 2023 cohort. By highlighting the significance of ethical decision-making, collaboration, and lifelong learning, she illustrates how professionals contribute to global health advancements.

The Academy is grateful to Khushbu for her thought-provoking contribution to our ongoing discussion on this topic.

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## ACADEMY ALUMNI PERSPECTIVES: KHUSHBU JETHWA, MSC PHARMACOLOGY, MBA

The significance of a professional identity in the development of medicine goes beyond traditional occupational classifications; it encompasses the combination of skills, values, competencies, and ethical beliefs that determine a person's place in the larger healthcare system. Successful professionals in this field navigate a multidisciplinary environment, collaborating with scientists, clinicians, regulatory experts, and industry partners, integrating diverse perspectives while maintaining a distinct professional identity.

Professional identity in the pharmaceutical industry is multi-faceted, encompassing expertise, ethical considerations, collaboration, and a shared sense of purpose. This identity extends beyond job roles, requiring a commitment to continuous learning and adaptability in the face of evolving scientific and regulatory landscapes. Ethical decision-making is paramount given the industry's impact on patient well-being. Professionals contribute to a broader societal mission, uniting under the common goal of improving global health. The dynamic nature of pharmaceuticals necessitates a robust professional identity that aligns with industry values and objectives. Successful professionals in this field navigate complexities, collaborate effectively, and contribute to the advancement of pharmaceutical science and healthcare.

In the pharmaceutical sector, a profound sense of purpose is integral to the professional identity of individuals. This sense of purpose transcends job roles, motivating professionals to contribute meaningfully to the broader mission of advancing global health. Whether engaged in drug development, regulatory affairs, or patient advocacy, professionals share a common goal of improving patient outcomes and public well-being. This intrinsic motivation becomes a driving force during challenging phases, fostering resilience and perseverance.

-Khushbu Jethwa, MSc Pharmacology, MBA



Khushbu Jethwa is a Senior Manager with a rich 8.5-year trajectory in the pharmaceutical industry, skilled in medical content strategy, medical review, and clinical trials. Her career reflects a commitment to excellence in medical affairs and clinical trials, underscored by a passion for driving innovation in training and content development.

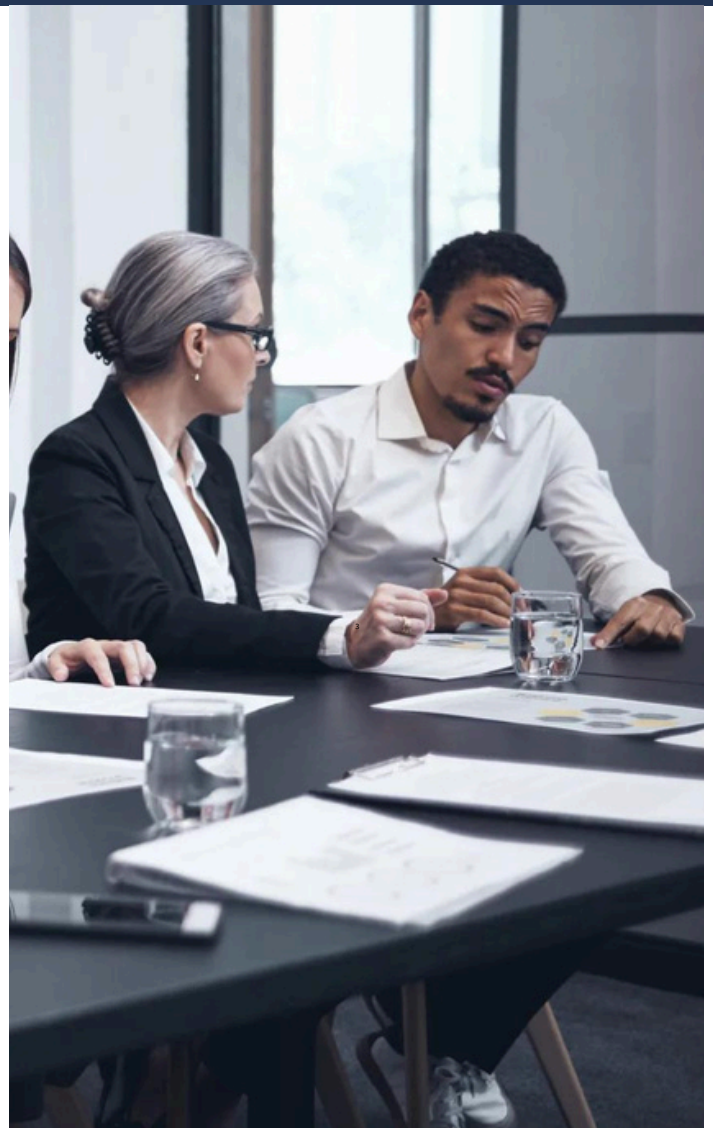
To read Khushbu's essay in its entirety, click [here](#).

# ADVANCING AI IN MEDICINE: HMA/EMA JOINT WORKSHOP

Mark your calendars for November 5, 2024, to explore the latest AI developments and their impact on healthcare at the HMA/EMA Joint Workshop on AI in Medicine. It is a hybrid, multi-stakeholder workshop which will aim to:

- Provide updates on AI developments through keynote speakers.
- Inform stakeholders about the policy and legislative environment, as well as HMA/EMA activities on AI.
- Discuss the progress and potential updates to the multi-annual AI workplan.
- Explore AI use cases in the medicine lifecycle.<sup>1</sup>

Read more [here](#).



## H5N1: A WORRY FOR THE FUTURE

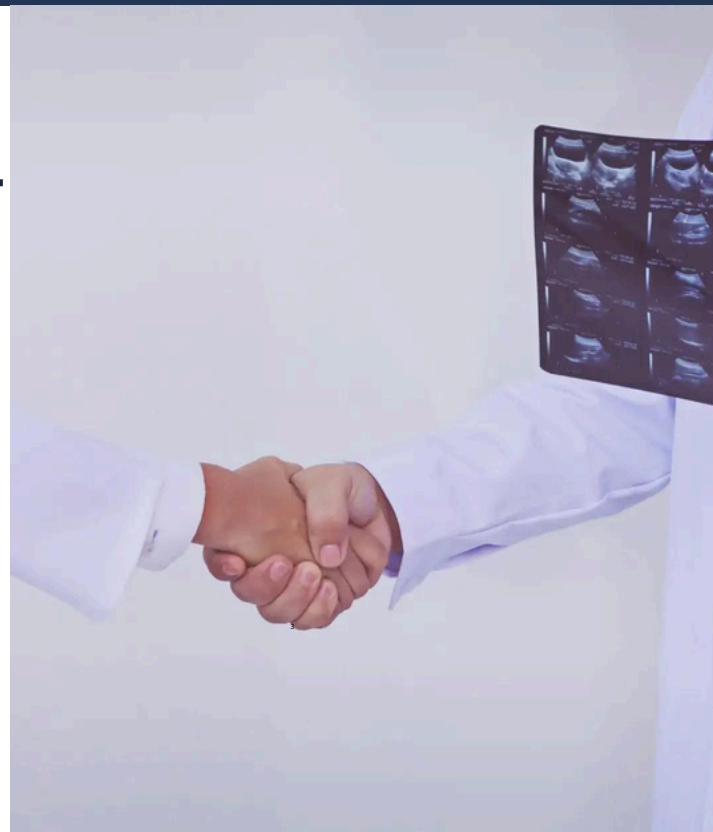


Any infectious diseases specialist would likely stress the importance of consistently monitoring influenza A H5N1, a significant global health threat. Since its identification in 1996, H5N1 has infected over 800 people with a mortality rate exceeding 50%. Since 2020, it has become endemic in bird populations and has triggered a large-scale animal pandemic, affecting at least 26 mammal species. While influenza strains often evolve and infect humans, human-to-human transmission of H5N1 remains rare. Recent developments, including the unprecedented outbreak of H5N1 in dairy cows reported on March 25, 2024, in Texas, Kansas, and New Mexico, have raised concerns about potential cow-to-human transmission.<sup>2</sup> Read more [here](#).

# FDA LAUNCHES RARE DISEASE INNOVATION HUB TO ACCELERATE TREATMENT DEVELOPMENT

Over 30 million people in the U.S. are affected by more than 10,000 rare diseases, with about half of these individuals being children. Many rare diseases are life-threatening and lack approved treatments. The FDA aims to engage patients and caregivers to incorporate their perspectives into the review of medical products for rare disease patients.

Recent advances in drug target identification and gene therapies are promising for rare disease treatment. In 2023, over half of the novel drugs and biologics approved by the FDA's CDER and CBER were for rare diseases. Despite these advances, many rare diseases still lack treatment options, requiring new approaches for the development and approval of safe and effective drugs.



To address these needs, the FDA plans to establish a Rare Disease Innovation Hub through single point of engagement, enhanced intercenter collaboration,<sup>3</sup> and advancement of regulatory science. Read more [here](#).

# EMA OPENS ICH M14 GUIDELINE CONSULTATION



The European Medicines Agency EMA has released the ICH M14 guideline for public consultation. This guideline covers the general principles on planning, designing, and analyzing pharmacoepidemiologic studies that use real-world data to assess the safety of medicines.

The use of these studies as evidence for regulatory decisions has grown globally, leading to the creation of multiple guidelines and best practice documents by health authorities and professional societies. Generating robust evidence for regulatory purposes depends on the quality of the data and the use of sound pharmacoepidemiologic methods.<sup>4</sup>

Comments on the guideline should be submitted by August 30, 2024. Access the draft guideline [here](#).

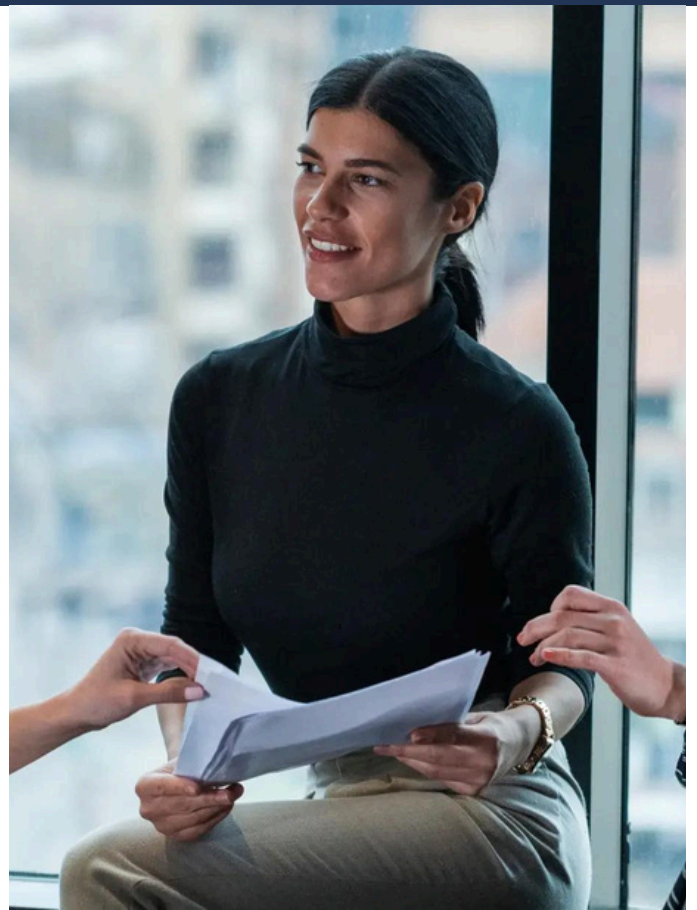
# CIOMS JUNE 2024 NEWSLETTER: CELEBRATING 75 YEARS WITH NEW PUBLICATIONS AND GLOBAL HEALTH UPDATES

The CIOMS June 2024 Newsletter is now available.

In the second quarter of our 75th Anniversary year, CIOMS issued three publications:

1. The Working Group XIII report on Real-world data and real-world evidence in regulatory decision making.
2. The draft report of the Working Group on Severe Cutaneous Adverse Reactions (SCAR) for public consultation.
3. The sixth edition of the CIOMS Glossary of ICH terms and definitions.

CIOMS held one in-person and two virtual Working Group meetings.



It convened the CIOMS General Assembly for its Twenty-Seventh Session. CIOMS continued to be represented at various international events.<sup>5</sup>

Access the newsletter [here](#).

## THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH EXPANDS THE TPLC ADVISORY PROGRAM



The Center for Devices and Radiological Health (CDRH) is expanding the Total Product Life Cycle (TPLC) Advisory Program (TAP). This expansion will include devices reviewed in the Office of Radiological Health (OHT8) and the Division of Ophthalmic Devices (DHT1A) in fall 2024, followed by the Office of Orthopedic Devices (OHT6) in 2025.

Launched in 2023 as part of the Medical Device User Fee Amendments (MDUFA) V reauthorization, TAP aims to expedite the development of high-quality, safe, effective, and innovative medical devices critical for public health. Read more [here](#).

# REFERENCES

1. HMA/EMA multi-stakeholder workshop on Artificial Intelligence | European Medicines Agency (EMA). (n.d.). European Medicines Agency (EMA). <https://www.ema.europa.eu/en/events/hma-ema-multi-stakeholder-workshop-artificial-intelligence>
2. H5N1: international failures and uncomfortable truths. (2024). In The Lancet (Vol. 403, p. 2455). <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2824%2901184-X>
3. Research, C. F. D. E. A. (2023, August 29). Rare Diseases Team. U.S. Food And Drug Administration. <https://www.fda.gov/about-fda/accelerating-rare-disease-cures-arc-program/rare-diseases-team>
4. European Medicines Agency, Committee for Human Medicinal Products, & International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. (2024). ICH M14 Guideline on general principles on plan, design and analysis of pharmacoepidemiological studies that utilize real-world data for safety assessment of medicines. [https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m14-guideline-general-principles-plan-design-analysis-pharmacoepidemiological-studies-utilize-real-world-data-safety-assessment-medicines-step-2b\\_en.pdf](https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m14-guideline-general-principles-plan-design-analysis-pharmacoepidemiological-studies-utilize-real-world-data-safety-assessment-medicines-step-2b_en.pdf)
5. CIOMS June 2024 Newsletter • COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES. (2024, July 1). COUNCIL FOR INTERNATIONAL ORGANIZATIONS OF MEDICAL SCIENCES. <https://cioms.ch/news/cioms-june-2024-newsletter/>
6. Center for Devices and Radiological Health. (2024, July 1). CDRH announces expansion of the Total Product Life Cycle Advisory Program. U.S. Food And Drug Administration. <https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-announces-expansion-total-product-life-cycle-advisory-program>

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## Thanks for reading!

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