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PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT: INSIGHTS FROM DR. DRAGANA KOLARSKI, ACADEMY ALUMNA

In our ongoing exploration of Professional Identity and Medicines Development, we are delighted to showcase yet another excellently crafted essay, this time authored by the talented student from our 2022 cohort, Dr. Dragana Kolarski. Dr. Kolarski was prompted to "**Discuss Professional Identity and the Sense of Purpose in Medicines Development and their relevance for professionals involved in the field**." Read more on page 2.

TABLE OF CONTENTS

PROFESSIONAL IDENTITY AND MEDICINES DEVELOPMENT

Reflections from Academy Alumna: Dr. Dragana Kolarski

DR. DRAGANA KOLARSKI

"We are not our jobs, but our jobs are a significant source of our individual wellbeing. Being professional in the field of Medicines Development is very challenging nowadays. The environment is constantly changing, and the role of Medicines Development keeps pace with the change. It is undergoing significant transformation and from mere support to marketing and commercial, Medicines Development and Medical Affairs are established as third strategic pillars in pharmaceutical companies. It is indeed the only department which connects all the dots of the medical process, from very early phases of Medicines Development to the latest stages of product life cycle. Because of that, Medicines Development professionals are essential partners to all internal and external stakeholders.

During this challenging journey that is our career in Medicines Development, our own responsibility is to touch base with ourselves and reflect of if we are on the right track. Our goal should be to keep high individual standards in performing our jobs, maintaining ethics and compliance along the way. We should always remember that we touch not just patients' lives, but also lives of their caregivers and families and the public in general. If we do our best in the process, we can be sure that this will be a rewarding journey with the best outcomes for all."
Read her complete essay here.

Dr. Kolarski is a medical doctor specialized in internal medicine. She is currently working as the Internal Medicine Medical Affairs Scientist Lead in Adriatic, Serbia and CBC for Pfizer. She is based in Belgrade, Serbia.

EXPLORING THE HISTORICAL ROOTS OF ARTIFICIAL INTELLIGENCE IN MEDICINE

Artificial intelligence (AI) has emerged as a transformative field of science and engineering, aiming to understand and replicate intelligent behavior in computational systems. This article, written in 2004 by The Royal College of Surgeons of England, explores the historical roots of AI, from Aristotle's syllogisms to Alan Turing's pioneering work, culminating in the Turing test. The application of AI in medicine has seen significant growth, with a particular focus on surgery.

This paper provides an overview of various AI techniques, including artificial neural networks (ANNs), fuzzy expert systems, evolutionary computation, and hybrid intelligent systems, along with their clinical applications. NNs, inspired by the biological nervous system, are widely used for their ability to analyze complex, non-linear data.[1]

Continue reading here.

APPLICATIONS NOW AVAILABLE FOR WORLD-CLASS EDUCATION IN MEDICINES DEVELOPMENT

The GMDP Academy, in collaboration with King's College London, is pleased to accept applications for the 2024 cohort of the highly acclaimed Certification in Medicines Development (CMD) program.

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FDA SUPPORTS GLOBAL DRUG DEVELOPMENT THROUGH ICH

Amidst the intricate and global landscape of pharmaceutical industry operations, the significance of international regulatory alignment for drug development has grown significantly. The pharmaceutical sector operates on a worldwide scale with diverse characteristics, making it imperative to streamline regulatory standards. Various regulatory bodies often impose distinct scientific and administrative criteria that drug manufacturers must adhere to for product approval. This divergence can result in redundant efforts, heightened expenses, extended timelines for product launches, and delayed patient accessibility. To confront this challenge, the FDA collaborates with regulatory bodies and industry stakeholders across the globe to unify regulatory requirements spanning different regions.

One pivotal aspect of the FDA's pursuit of regulatory harmony is its role as a Founding Regulatory Member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).[2]

Read more here.

EMA: REPLACEMENT, REDUCTION, AND REFINEMENT

The EMA maintains a longstanding dedication to upholding the principles of Replacement, Reduction, and Refinement (3Rs) in the regulatory testing of both human and veterinary medicinal products (HMPs and VMPs). This commitment arises from the directives outlined in Directive 2010/63/EU, as well as the pressing need for enhanced tools to accurately anticipate the quality, safety, and efficacy of novel medicinal products.

The recently established 3Rs Working Party (3RsWP) operates as a collaborative body comprising members from both the Committee for Medicinal Products for Human Use (CHMP) and the Committee for Veterinary Medicinal Products (CVMP). Continue reading here.[3]

AMBULATORY BLOOD PRESSURE AND MORTALITY: INSIGHTS FROM THE WEST

As our readers may be aware, despite the considerable attention given to oncology trials, the leading cause of death in Western countries remains cardiovascular events. High blood pressure, which affects approximately one in every two adults residing in Western nations, stands as a significant contributor to both morbidity and mortality. Ambulatory blood pressure monitoring offers a more comprehensive evaluation compared to clinic-based blood pressure readings. Studies have indicated its superior predictive value for health outcomes when compared to measurements taken in clinical or home settings.

In this study, the authors aimed to investigate the associations between clinic-based and 24-hour ambulatory blood pressure readings with regards to all-cause and cardiovascular mortality. [4] Continue reading here.

IQVIA REPORT: PROJECTIONS IN GLOBAL PHARMACEUTICAL MARKET TRENDS

The IQVIA 2023 report on the Global Use of Medicines continues to provide insights into global pharmaceutical market spending, past and future. The COVID-19 pandemic continues to impact pharmaceutical markets globally and is estimated to expand the net cumulative pharmaceutical market by $500 billion from 2020 through 2027.

Highest volume growth is expected in Latin America, Asia and Africa, driven by a mix of population growth and expanded access. North America and Europe will see very low growth.

Demand for innovative drugs will drive oncology spending to approximately $370 billion by 2027, almost double the current level.

Biotech will represent 35% of spending globally in 2027 and will include both breakthrough cell and gene therapies, as well as a maturing biosimilar segment.[5] Continue reading here.

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Thanks for reading!

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