



GMDP ACADEMY UNVEILS NEW GOVERNANCE FRAMEWORK WITH ESTEEMED BOARD MEMBERS

GMDP Academy is excited to start the New Year with a newly restructured governance framework to enhance our mission of advancing education in medicines development and pharmaceutical sciences. At the heart of this update is the appointment of a distinguished Board of Directors, whose expertise in biopharmaceuticals, patient care, and regulatory science will guide the Academy's strategic vision.

Click [here](#) to meet the new Board members.

TABLE OF CONTENTS

Professional Identity and Medicines
Development: Insights from
Verónica Del Carmen Nateras • P. 2

EMA Seeks Feedback on New
Concept Paper • P. 3

Breakthrough Insights on
Endometriosis • P. 3

EMA Reaffirms Translarna Ruling
• P. 4

GMDP Academy 2024 Student
Graduation Ceremony • P. 4

PROFESSIONAL IDENTITY & MEDICINES DEVELOPMENT



Academy Alumni Perspectives: Verónica Del Carmen Nateras

Identity is the alignment of roles, responsibilities, values, and ethical standards within a specific field. In business, professional identity reflects an individual's self-concept, shaped by attributes, values, and experiences. A strong professional identity often emerges from an organizational philosophy that manifests in a distinct corporate culture or "corporate personality."¹

Purpose is the belief that your life matters and that your actions make a difference. It provides a sense of being guided by meaningful values and goals. Purpose can manifest in various aspects of life, including family, parenting, career, religion, activism, artistic pursuits, etc.

The Japanese concept of Ikigai embodies this idea, meaning "a reason for being" or "a reason to wake up in the morning." Ikigai encourages individuals to align four elements: doing what you love, doing what you're good at, meeting the world's needs, and receiving rewards for your efforts.

We are most engaged in our work when the organization's mission and goals resonate with our own values and when we feel we can contribute to the bigger picture. To achieve this, it's essential to keep the bigger picture in mind and ensure that our actions align with what matters most—whether as a leader within a company or as an individual contributor.

As the saying goes, "We are the choices we make." Or as Aristotle suggested, "We are what we repeatedly do." Purpose should inform and drive all these choices and actions. We will find the greatest happiness and fulfillment when our decisions and actions align with a clear and meaningful sense of purpose.²

Verónica Nateras Durante, MD is a medical doctor with a post-degree in Clinical Pharmacology and a seasoned professional with over 15 years of experience leading diverse groups, with a deep understanding of the pharmaceutical industry and the value it brings to society and people's lives. A passionate people leader who has a record of accomplishments in building strong teams and a strong background in R&D and Medical Affairs. During the last 15 years, she has held various positions at local, regional, and global level. She has worked in Mexico and other Latin American countries such as Chile & Brazil big pharma companies like J&J, Novartis and currently Pfizer. She has always been characterized by a passion for promoting young talents in medicine and other health-related sciences. She has a fervent commitment to society and a keen interest in digital transformation, coaching and leadership development which she pursues through continuous education and certification. Click [here](#) to read her essay in its entirety.

EUROPEAN MEDICINES AGENCY SEEKS FEEDBACK ON NEW CONCEPT PAPER

The European Medicines Agency has released a concept paper for public consultation, focusing on the clinical evaluation of therapeutic radiopharmaceuticals (tRPs) in oncology. This paper aims to identify unique considerations for tRPs to support the future development of a guideline that will complement existing guidance on anticancer drugs. The guideline will address key legislative concepts and adapt to recent advancements and changing practices in radiopharmaceuticals. Stakeholders are invited to submit feedback by January 31, 2025. Personal data of respondents may be processed in accordance with the EMA's privacy policies.

Continue reading [here](#).³



BREAKTHROUGH INSIGHTS ON ENDOMETRIOSIS



A new study in Nature Genetics presents a detailed map of the endometrium throughout the menstrual cycle, offering insights into the mechanisms behind endometriosis.

Endometriosis, where endometrial-like tissue grows outside the uterus, affects 10% of reproductive-age women worldwide, causing severe pain, heavy bleeding, fertility issues, and fatigue.

Despite its significant impact on quality of life, the condition is often misdiagnosed, with global diagnostic delays averaging 7–9 years. Read more [here](#).⁴

EMA REAFFIRMS TRANSLARNA RULING

The European Medicines Agency’s human medicines committee (CHMP) has upheld its decision not to renew the conditional marketing authorization for Translarna (ataluren), a treatment for certain patients with Duchenne muscular dystrophy (DMD) caused by a “nonsense mutation” in the dystrophin gene. Despite multiple re-evaluations requested by the manufacturer, including reviews of additional real-world data and new analyses, the CHMP concluded that Translarna’s effectiveness remains unproven.

The initial negative opinion was issued in September 2023, reaffirmed in January 2024, and again in June 2024 after further review by the EMA.⁵



Continue reading [here](#).

CELEBRATING OUR GRADUATES: A VIRTUAL GMDP ACADEMY EVENT

Celebrate with us as our graduates embark on their journey as leaders in medicines development! This virtual event will recognize the dedication and perseverance of students who have successfully completed the Certification in Medicines Development program, in partnership with King’s College London.



Jan 28, 2025 at 10:00 AM EST
Click [here](#) to register!

REFERENCES

1. Olson, Eric T. (2019). "Personal Identity". In Zalta, Edward N. (ed.). The Stanford Encyclopedia of Philosophy (Fall 2019 ed.). Metaphysics Research Lab, Stanford University. Retrieved 2020-12-12.
2. The Power Of Purpose And Why It Matters Now, Tracy Brower, PhD
3. Clinical evaluation of therapeutic radiopharmaceuticals in oncology – Scientific guideline | European Medicines Agency (EMA). (2024, November 10). European Medicines Agency (EMA). <https://www.ema.europa.eu/en/clinical-evaluation-therapeutic-radiopharmaceuticals-oncology-scientific-guideline>
4. Lancet, N. (2024). Endometriosis: addressing the roots of slow progress. The Lancet, 404(10460), 1279. [https://doi.org/10.1016/s0140-6736\(24\)02179-2](https://doi.org/10.1016/s0140-6736(24)02179-2)
5. EMA recommends non-renewal of authorisation of Duchenne muscular dystrophy medicine Translarna | European Medicines Agency (EMA). (2023, September 15). European Medicines Agency (EMA). <https://www.ema.europa.eu/en/news/ema-recommends-non-renewal-authorisation-duchenne-muscular-dystrophy-medicine-translarna>
6. Office of the Commissioner. (2024, September 17). Prostate cancer. U.S. Food And Drug Administration. <https://www.fda.gov/consumers/minority-health-and-health-equity-resources/prostate-cancer>

Thanks for reading!

The GMDP Academy Newsletter is published twice monthly and is compiled by the following:

Medical Editor: Domenico Criscuolo

Media Manager: Whitney English

Editorial Board: Pravin Chopra, Jacob Coats, Honorio Silva, Peter Stonier

Operations Office: Amanda Schmitt, Gustavo Silva, Kit Vale

CONTACT US:



420 Lexington Ave. Ste. 300
New York, NY 10170

(332) 333-2438