GMDP academy
ISSUE 63 • MAY 9, 2025

GMDP ACADEMY ANNOUNCES NEW BOARD LEADERSHIP: DR. XAVIER LURIA AND DR. ROSLYN SCHNEIDER

GMDP Academy is honored to announce that Dr. Xavier Luria has been appointed Chair of the GMDP Academy Board of Officers, joined by Dr. Roslyn (Roz) Schneider as Co-Chair. Each brings decades of strategic, regulatory, clinical, and patient-centered expertise that will guide the Academy into its next chapter of growth and impact. Continue to page 2 to learn more about these visionary leaders, and stay tuned for exclusive interviews!

TABLE OF CONTENTS

MEET DR. LURIA

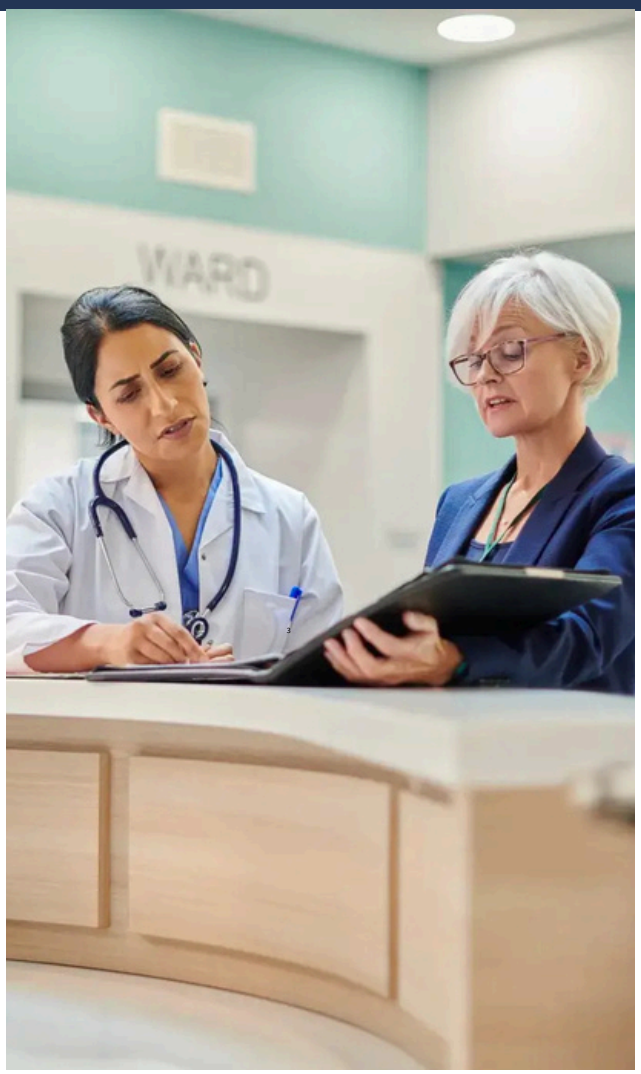
Dr. Xavier Luria is a global leader in regulatory science with over 18 years of industry experience spanning clinical development, pharmacovigilance, and medical affairs. Formerly Head of Safety and Efficacy of Medicines at the European Medicines Agency (2005–2012), he is widely recognized for his expertise in benefit-risk assessment and regulatory innovation. He founded Drug Development and Regulation (DDR), later acquired by Veristat, and co-founded EMA Solutions. Dr. Luria also consults internationally through NDA Partners and serves on multiple advisory boards. A Senior Visiting Lecturer at King's College London, he teaches at institutions across Europe and the U.S. Continue reading here.

MEET DR. SCHNEIDER

Dr. Roslyn "Roz" Schneider brings a unique perspective grounded in clinical medicine and the pioneering application of human-centered design in life sciences. A board-certified physician in Internal Medicine, Pulmonary, and Critical Care, she spent the first half of her career in hospital leadership and academia before spearheading industry transformation. At Pfizer, she founded the office of Global Patient Affairs, embedding patient partnership principles into R&D processes, which she carried through leadership roles at Theravance, BioMarin, and consulting.

Roz currently serves on multiple advisory boards and was awarded a Global Fellowship in Medicines Development by the GMDP Academy in 2023, among numerous other accolades.

A NEW FRONTIER IN ANTIBIOTICS: LASSO PEPTIDES AND THE FUTURE OF PHARMACEUTICAL MEDICINE



A groundbreaking discovery from a simple patch of soil has captured global attention: lariocidin, a lasso-shaped antibiotic that bypasses common resistance mechanisms and shows no harm to human cells. But scientific breakthroughs alone don't save lives—translating them into treatments requires deep expertise in regulation, ethics, trial design, and more [1,2,3].

Explore what lariocidin means for the future of medicine—and how GMDP Academy is preparing professionals to lead that journey.

👉 Read the full article on the GMDP Academy website.

WHAT EMANS 2028 MEANS FOR THE FUTURE OF PHARMACEUTICAL LEADERSHIP

The newly adopted EMANS 2028 strategy lays out how the European Medicines regulatory network will respond to an era defined by digital innovation, global health threats, and evolving access challenges. For professionals in medicines development, it's more than a policy—it's a call to action [4].

This article explores how EMANS 2028 aligns with the mission of GMDP Academy, and why the Academy's competency-based training is uniquely positioned to prepare leaders who will help implement this vision across the pharmaceutical landscape.

👉 Read more here.

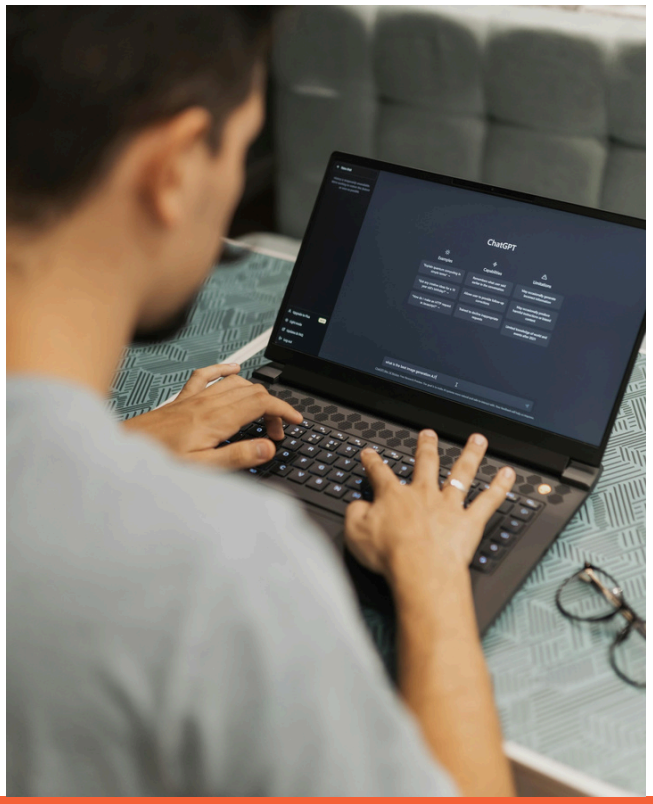
REVOLUTIONIZING DRUG DEVELOPMENT: FDA'S SHIFT FROM ANIMAL TESTING SETS THE STAGE FOR INNOVATION IN MEDICINES DEVELOPMENT

On April 10, 2025, the FDA announced a historic shift—ending the requirement for animal testing in the development of monoclonal antibodies and select drugs. This move embraces AI models, organoids, and global real-world data to create faster, more ethical evaluation pathways.

For professionals in medicines development, this is a game-changer. GMDP Academy is already preparing learners with the skills to lead in this new era—through modules focused on regulatory science, translational research, and digital health [2, 5].

👉Read more here.

THE GLOBAL EVOLUTION OF RESPONSIBLE AI IN MEDICINES DEVELOPMENT



Artificial intelligence is reshaping every stage of drug development—from discovery to delivery—but with that power comes a need for responsibility, transparency, and equity. Stanford's RAISE Health initiative is setting new standards for ethical AI in biomedical innovation, aligning closely with GMDP Academy's Module 8: Digital Technology in Medicines Development [6, 7, 8, 9, 10, 11, 12].

AI is transforming drug development—but ethical use is key. Stanford's RAISE Health and Module 8 spotlight how responsibility, equity, and innovation must go hand in hand.

👉 Read more here.

REFLECTING ON MODULE 3: THE FOUNDATION OF DRUG DISCOVERY AND EARLY DEVELOPMENT

Students at the GMDP Academy conclude Module 3: Drug Discovery, Exploratory, and Confirmatory Development this week. We are proud to celebrate their dedication and hard work.

Learners have explored the key elements of early drug development, from rational drug design and safety evaluations to trial ethics and statistical analysis. In an ever-evolving pharmaceutical landscape, understanding the early stages of drug development is critical. The innovations covered in Module 3 are shaping the future of therapeutics, and the ability to collaborate, analyze data, and navigate regulatory frameworks will define tomorrow's leaders.

Congratulations to our learners on completing this important milestone. We look forward to seeing how you'll apply your knowledge to real-world challenges.

UP NEXT: MODULE 4 FROM CONCEPT TO CLINICAL STUDY REPORT

With Module 3 wrapped, learners move into Module 4: Clinical Trials—From Concept to Clinical Study Report, gaining the skills to manage trials from design and ethics approvals to reporting and regulatory submission.

Key competencies include:

- Ethical oversight and subject protection
- Trial site and investigator management
- Data quality, safety monitoring, and governance
- Budgeting and interpreting trial results

Led by experts and rooted in real-world application, Module 4 equips professionals to lead ethical, efficient trials worldwide.

Ready to level up? Apply now and take the next step in your clinical development journey.

REFERENCES

1. Jangra, M., Travin, D. Y., Aleksandrova, E. V., Kaur, M., Darwish, L., Koteva, K., … & Wright, G. D. (2025). A broad-spectrum lasso peptide antibiotic targeting the bacterial ribosome. Nature. https://www.nature.com/articles/s41586-025-08723-7
2. Silva, H., Stonier, P., Chopra, P., Coots, J., Criscuolo, D., Guptha, S., … & Vandenbroucke, P. (2024). Blended e-learning and certification for medicines development professionals: Results of a 7-year collaboration between King's College, London and the GMDP Academy, New York. Frontiers in Pharmacology, 15, 1417036. https://doi.org/10.3389/fphar.2024.1417036
3. Silva, H., Stonier, P. D., Kerpel-Fronius, S., & Dubois, D. J. (2021). Editorial: Grand Challenges in Pharmaceutical Medicine: Competencies and Ethics in Medicines Development. Frontiers in Pharmacology, 12, 666406. https://doi.org/10.3389/fphar.2021.666406
4. European Medicines Agency & Heads of Medicines Agencies. (2025). Seizing opportunities in a changing medicines landscape: The European medicines agencies network strategy to 2028. Luxembourg: Publications Office of the European Union. https://www.ema.europa.eu/en/about-us/how-we-work/european-medicines-regulatory-network/european-medicines-agencies-network-strategyEuropean Medicines Agency. (2025, March 18). European medicines agencies network strategy: Network strategy to 2028. https://www.ema.europa.eu/en/documents/other/seizing-opportunities-changing-medicines-landscape-european-medicines-agencies-network-strategy-2028-final_en.pdf
5. U.S. Food and Drug Administration. (2025, April 10). FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs. https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs
6. Armitage, H. (2025, March 18). RAISE Health inaugural seed grant recipients announced. Stanford Medicine News Center. https://med.stanford.edu/news/all-news/2025/03/raise-health-grantees.html
7. Harrison, O. (2025, April 16). Bill Gates says AI is coming for 2 kinds of jobs that once seemed tech-proof. Business Insider. https://www.businessinsider.com/bill-gates-ai-job-shortages-doctors-teachers-work-free-time-2025-4
8. Pengelly, M. (2025, April 9). Dr Oz tells federal health workers AI could replace frontline doctors. The Guardian. https://www.theguardian.com/us-news/2025/apr/09/mehmet-oz-doctors-ai
9. RAISE Health. (2025). Seed grants: Advancing responsible AI in medicine. Stanford Medicine. https://med.stanford.edu/raisehealth/seedgrants.html
10. Simonite, T. (2023, February 15). AI is dreaming up drugs that no one has ever seen. Now we've got to see if they work. MIT Technology Review. https://www.technologyreview.com/2023/02/15/1067904/ai-automation-drug-development/
11. Stanford Institute for Human-Centered Artificial Intelligence. (2025). Artificial Intelligence Index Report 2025: Chapter 1 – Research and Development. https://hai-production.s3.amazonaws.com/files/hai_ai-index-report-2025_chapter1_final.pdf
12. Topol, E. J. (2019). Deep medicine: How artificial intelligence can make healthcare human again. Basic Books.

Thanks for reading!

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

Media Manager: Whitney English

Editorial Board: Pravin Chopra, Jacob Coots

Operations Office: Amanda Schmitt, Gustavo Silva, Kit Vale

CONTACT US:

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

(332) 333-2438