IFAPP TODAY

The Global Pharmaceutical Medicine Journal

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS AND PHARMACEUTICAL MEDICINE

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In Memoriam: Dr Johanna Schenk – A Champion of Global Collaboration in Pharmaceutical Medicine

With deep sorrow we announce the passing of Dr Johanna Schenk who left us on 26 October. Her vision and leadership transformed the discipline of Pharmaceutical Medicine and strengthened the global community of IFAPP.

Johanna's presidency of IFAPP (2000-2002), under the guiding theme "The Future is Now", ushered in an era of strategic international outreach and educational innovation. She wrote:

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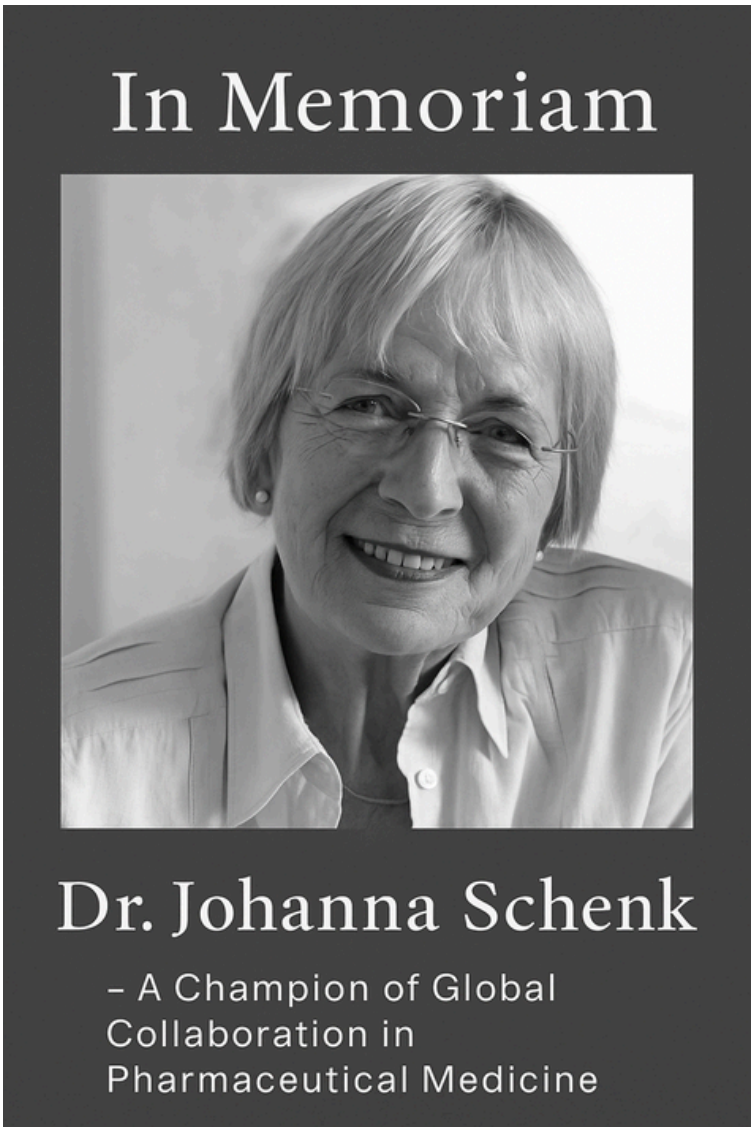

"The future is now, and I am confident that Pharmaceutical Medicine has a bright one, despite its complex challenges, provided we utilise our international network wisely." (Schenk, J. Message from Dr Johanna Schenk, retiring President of IFAPP. International Journal of Pharmaceutical Medicine 16, 43–44 (2002))

Her words underscore her enduring conviction that a worldwide network of professionals working together was key to progress in our field.

As Editor-in-Chief of IFAPP's journal IFAPP TODAY, Johanna elevated the platform into a cornerstone of scientific dialogue and thought leadership.

Johanna's legacy lies in the bridges she built between nations, between academia and industry, and between professionals sharing a common purpose. In her message she also remarked:

"Overall, it was indeed Pharmaceutical Medicine 'springtime' ... The increasing acknowledgement of our discipline and the impact of sharing best Pharmaceutical Medicine practices let us look optimistically ...". This optimism reflected her belief in progress through shared knowledge and joint enterprise.

She challenged us to look beyond borders, to embrace global research, to engage diverse stakeholders, and to make the discipline ever more inclusive and internationally impactful. As she aptly said: "The future is bright if we utilise our international network wisely."

To her many colleagues, mentees, and friends around the world, Johanna was a beacon of inspiration – not only for what she achieved, but for how she empowered others. Her legacy now becomes our invitation: to carry forward the spirit of collaboration, innovation and shared purpose that she championed.

Dear Johanna, thank you. We honour your life, your leadership, and your enduring vision. In your memory, we commit to fostering the international connections, research synergies and educational excellence that you believed in so wholeheartedly. You will always remain a Hero of Pharmaceutical Medicine.

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15th Anniversary of the Bulgarian Drug Information Association

Emer Cooke, Executive Director of the European Medicines Agency (EMA), and Bogdan Kirilov, Executive Director of the Bulgarian Drug Agency, both prominent leaders in European pharmaceutical regulation, attended the 15th anniversary of the Bulgarian Drug Information Association (BADI) on 9 October 2025, underscoring the event's significance for professional education and collaboration in the pharmaceutical sector.

Emer Cooke, Executive Director EMA giving the welcome address

Emer Cooke and Advisory Board and Board members of BADI

Emer Cooke's presence at this milestone event highlighted the growing importance of evidence-based drug information and regulatory compliance in Bulgaria and the wider European context. As Executive Director of the EMA, her participation reflects a strong endorsement of BADI's mission to facilitate high-quality training, professional development, and knowledge exchange among healthcare professionals and regulatory stakeholders.

This meeting also served as a platform for enhancing collaboration between national and European regulatory bodies, the pharmaceutical industry, and healthcare professionals. Emer Cooke's attendance signals support for BADI's ongoing efforts in fostering dialogue, promoting compliance with EU standards, and advancing the quality of drug information available to professionals and patients.

In summary, Emer Cooke's guest appearance at the 15th anniversary underscored BADI's role as a central hub for professional development in the pharmaceutical field, validating the association's longstanding impact on education, regulatory knowledge dissemination and cross-border collaboration within the European pharmaceutical landscape. She received a special award for her exceptional contribution.

Emer Cooke and audience

Author: Professor Tatyana Benicheva, President of BADI and Professor in Drug Regulatory and Clinical Trial Affairs at Medical University, Faculty of Public Health, Sofia, Bulgaria

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We All Have the Power to Make Medicines Safer

From 3 to 9 November 2025, the global **MedSafetyWeek** campaign celebrated its 10th anniversary. This annual initiative, led by the World Health Organization's (WHO) Uppsala Monitoring Centre (UMC) in collaboration with national regulatory authorities, regularly calls attention to the collective responsibility for medicine safety (1).

With this year's theme "**We all have the power to make medicines safe**r", the UMC reminded everybody that despite the global reach of pharmacovigilance systems, only 5–10% of adverse events are ever reported. On the other hand, regulatory authorities around the world rely on adverse event reports from patients and healthcare professionals to monitor the safety of medicines. Hence, this underreporting likely hinders the early detection of safety signals and delays interventions that could prevent harm from patients.

However, if all stakeholders, such as physicians and other medical personnel, patients, care givers, university researchers, pharma and biotech industry, as well as regulators contribute their piece of effort to this system, the chances for "making medicines safer" will significantly increase.

Pharmaceutical companies and their pharmacovigilance (PV) professionals represent one of the backbones of this global safety ecosystem. Their vigilance, expertise, and systems transform unstructured data from various sources into meaningful safety actions that protect patients across the world.

From Compliance to Culture - the Evolution of Pharmacovigilance

Traditionally, PV was viewed as a regulatory necessity. Over time, it has matured into a scientific discipline and ethical commitment integral to Pharmaceutical Medicine.

Modern PV departments are responsible for, e.g., signal management (using advanced analytics and epidemiologic evaluation), risk management planning and risk minimisation activities, aggregate reporting and benefit-risk evaluation as well as patient communication and post-authorisation surveillance integration.

This reflects a broader industry transformation - from reactive compliance to proactive safety culture - embedding PV into research, development, and commercialisation processes.

The Pharma Industry's Central Role in Medicine and Patient Safety

Pharmaceutical companies are uniquely positioned to integrate scientific data, clinical insights, and regulatory requirements into a coherent safety strategy. Their contributions include, e.g.:

- Signal Detection and Management: Company PV systems analyse vast global safety databases, using statistical and clinical expertise to identify emerging safety signals. These are then communicated to authorities and healthcare professionals, often prompting timely risk mitigation.

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- Collaboration with Regulatory Authorities: PV today is a partnership-based discipline. Regular data exchanges, joint signal evaluations, and transparent dialogue between industry and regulators enhance the timeliness and robustness of safety actions.

- Data Contribution to Global Safety Databases: Pharmaceutical companies are major contributors to the WHO's VigiBase, the European EudraVigilance, and the US FDA's Adverse Event Reporting System (FAERS), providing the foundational data for global signal detection. The quality and completeness of industry-submitted Individual Case Safety Reports (ICSRs) are crucial for reliable analyses.

- Technology and Innovation: Automation, artificial intelligence (AI), and natural language processing streamline case management, literature surveillance, and trend analysis. However, the final judgement on clinical relevance still rests with experienced PV scientists.

Furthermore, modern pharmacovigilance is increasingly networked and modular. Apart from permanent employees, contract research organisations (CROs) and external consultants provide specialised expertise and/or take over central PV roles. Particularly for small and mid-sized companies, they ensure flexibility and compliance.

Underreporting - the Persistent Challenge

Despite improved systems, underreporting of adverse events remains a critical weakness. Reasons include e.g., time constraints (e.g., physicians, care givers), unawareness of reporting pathways (e.g., patients, relatives) or underestimated importance of such information.

Each unreported case represents a missed opportunity to detect a signal early, potentially delaying the recognition of serious risks.

Industry can help close this gap by simplifying reporting mechanisms, integrating digital tools, and engaging healthcare professionals and patients through education and communication initiatives (e.g., aligned with campaigns such as the MedSafetyWeek).

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Empowering Every Voice in Medicine Safety

Each stakeholder adds a vital piece to the global puzzle of drug safety. Every report counts - and each voice strengthens collective drug surveillance. Therefore, empowerment is the heart of the UMC's MedSafetyWeek.

For the pharmaceutical industry, this means options such as supporting healthcare professionals with easy reporting tools and education, and encouraging patients to share experiences without hesitation.

Within the industry, the MedSafetyWeek message translates into shared efforts for safety. From research and development (R&D) to medical affairs and marketing, every employee contributes to pharmacovigilance by identifying and communicating potential safety information.

Internal initiatives - such as "Safety Days," cross-functional training, and internal reporting awareness campaigns - foster a sense of ownership. A company's safety culture becomes a critical determinant of its pharmacovigilance effectiveness and public trust.

Patient-Centred Pharmacovigilance - from Data to Dialogue

PV increasingly integrates the patient voice. Digital tools and mobile applications now allow patients to directly report adverse events, complementing traditional channels.

Patient-reported data can illuminate real-world experiences that may otherwise go unnoticed, such as quality-of-life impacts or delayed-onset effects. However, ensuring data reliability, confidentiality, and meaningful feedback loops is essential.

The industry's responsibility lies in closing the communication circle - showing patients that their reports matter, and how their contributions help make medicines safer.

The Power of Collective Pharmacovigilance

A decade of MedSafetyWeek has shown that medicine safety is a shared responsibility. Regulatory authorities, healthcare professionals, patients, and industry together ensure that benefits outweigh risks. PV professionals - both within and beyond the industry - form one of the scientific and ethical backbones of this mission. Their work transforms data into understanding and vigilance into risk prevention.

Hence, the message **"We all have the power to make medicines safer"** indeed holds true, and PV professionals turn this power into action for patient safety worldwide.

Author:
Monika Boos, M.D., Ph.D., LL.M.
on behalf of the IFAPP Pharmacovigilance Group

(1) Uppsala Monitoring Centre (UMC). #MedSafetyWeek 2025: 10 Years of Global Collaboration for Safer Medicines. UMC; 2025. Available at: https://www.who-umc.org/

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IFAPP and Frontiers Announce Strategic Partnership

Collaboration to Advance Pharmaceutical Medicine Research and Communication
IFAPP is proud to announce a new Community Partnership Agreement with the renowned publishing group Frontiers, marking a significant milestone in advancing scientific communication and research within the field of Pharmaceutical Medicine.

About the Partnership
The agreement between IFAPP and Frontiers establishes a collaborative framework aimed at enhancing the dissemination of high-quality scientific content and facilitating greater engagement within the global Pharmaceutical Medicine community. Through this partnership, IFAPP will work closely with Frontiers in Pharmacology, a leading open-access journal, to promote research, foster dialogue, and support innovation in the development and regulation of medicines.

Shared Vision and Benefits
Both organisations share a commitment to scientific excellence, transparency, and open access. The collaboration will provide IFAPP members and stakeholders with new opportunities to publish their work, participate in editorial activities, and contribute to original research topics for collections of articles that address pressing topics in Pharmaceutical Medicine. The joint efforts are expected to accelerate knowledge exchange and raise the visibility of research outputs from IFAPP-affiliated experts worldwide.

What This Means for the IFAPP Community
The partnership with Frontiers brings multiple benefits to IFAPP's membership. Authors will enjoy streamlined submission processes, reduced publication fees for select content, and expanded avenues for interdisciplinary collaboration.

Looking Forward
This collaboration underscores IFAPP's ongoing mission to advance healthcare by supporting the professional development of pharmaceutical physicians and professionals and promoting the highest standards in research and practice. The IFAPP community is encouraged to engage actively with the new initiatives arising from this partnership and to contribute to the shared goal of improving global health outcomes through science and collaboration.

For further details about the partnership, please visit the official IFAPP (ifapp.org) and Frontiers (frontiers.org) websites or contact the IFAPP secretariat (secretariat@ifapp.org)for more information.

Author:
Robert Lins, MD, PhD, Specialist in Clinical Pharmacology and Pharmaceutical Medicine,
Head of IFAPP External Affairs Working Group (EAWG)

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Launching the Young Professionals Working Group (YPWG) Initiative “Grow with the Experts” Webinar Series

We are thrilled to announce the launch of the new YPWG initiative, Grow with the Experts, Webinar Series! This initiative is dedicated to supporting the next generation of leaders in Pharmaceutical Medicine by bridging the gap between academic knowledge and real-world career paths.

The WG’s flagship project is a dynamic webinar series designed specifically for early career professionals. The series operates under the powerful tagline: "Real voices. Real journeys. Real inspiration."

This initiative will focus on interviewing seasoned experts in Pharmaceutical Medicine about the diverse challenges, strategic pivots, and essential skills that can benefit those starting their careers. The core mission is to provide actionable insights and candid perspectives that aren't typically found in textbooks.

The idea for the webinar series was conceived by Kateryna Uspenska, who was recently elected as the new Chair of the YPWG.

The inaugural webinar is scheduled for 28 January 2026 and features a respected figure in the field:

- **Guest Speaker: Nikos Tsokanas**, Managing Director/Medical Consultant at Lean Pharma Services and IFAPP Treasurer
- **Topic: "Career Pivots: Switching Roles Within Pharma"**

Join us to hear Nikos discuss his journey and provide practical advice on navigating career transitions, highlighting the varied opportunities available within the complex and rewarding world of Pharmaceutical Medicine.

Author on behalf of the YPWG:

Yasmin Nagaty
Regional Manager | The Middle East Association of Pharmaceutical Medicine Professionals CIO (MEAPP) | Visiting Lecturer, CPMR, King's College London

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IFAPP YOUNG PROFESSIONALS WORKING GROUP INVITES YOU TO JOIN

LIVE-MEETING SERIES "GROW WITH THE EXPERTS!"

REAL VOICES. REAL JOURNEYS. REAL INSPIRATION

WEDNESDAY
JAN 28, 2026

TIME
12:00 CET

Guest: Nikos Tsokanas,
Managing Director at Lean Pharma Services

JOIN NOW

Career Pivots: Switching Roles Within Pharma (And How to Do It)

Moderator: Kateryna Uspenska,
Senior Clinical Project Manager at Gouya Insights

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Dutch Association on Pharmaceutical Medicine (NVFG) Annual Congress 2025: Nuclear Medicines and ATMPs

The NVFG Annual Congress 2025 was held on 09 October 2025 at the Postillion Hotel in Bunnik, The Netherlands. The sessions were opened by the chairperson Rudolf van Olden, former IFAPP President and former chairman of the NVFG and focused on Nuclear Medicines and Advanced Therapy Medicinal Products (ATMPs).

The first speaker was Marnix Bogert, Manager Innovation and Programme Development at NRG / Pallas Reactor. In his presentation "Nuclear Medicine Development: From Nuclear Reactor to Clinic," he provided a fascinating overview of the development and production of nuclear medicines, as well as the logistical and regulatory challenges involved. The demand for radioactive isotopes in the use of diagnostic and therapeutic applications is increasing rapidly. The current nuclear reactor, now sixty years old, will be replaced by a new reactor, which is expected to be operational by 2030. The Dutch government is supporting the new construction, while the original reactor was established at the time with funds from the European Community.

The second speaker, Prof. Dr Marnix Lam, Professor and Head of Nuclear Medicine at Universitair Medisch Centrum (UMC) Utrecht, spoke about “Nuclear medicine in the clinic”. He outlined the development of the use of radioactive substances in medical practice, which is now indispensable for both diagnostics and therapy. Thanks to nuclear medicine, great strides have been made in the treatment of cancer. At the same time, he warned about the increasing complexity of regulations and stricter requirements, making it increasingly difficult to develop new therapies from academia and bring them into clinical practice.

After the break, during which attendees as well as speakers and sponsors had time to exchange their thoughts on the first two presentations, Dr Lourens Bloem, Assistant Professor of Clinical Therapeutics at Utrecht University, presented on ATMPs and regulations. In his lecture he explained what ATMPs actually are, and how they differ from biologicals and small molecules. He then discussed the regulations and procedures for approval, both for research and for clinical use.

The closing presentation was given by Wiebe Cnossen (Volunteer Patient Advocate, on behalf of Hematon) and Prof. Dr Ton van Meerten (UMC Groningen). Their joint presentation on “ATMPs bedside: value-driven financing through the national expert panel CAR T (1) cell therapy” offered both the patients and clinical perspectives. Wiebe Cnossen explained what Hematon stands for: optimal treatment, aftercare, guidance, and information for patients and their loved ones. He emphasised that many barriers still exist that hinder these goals.

Afterwards, Prof. Van Meerten took the audience through recent developments in CAR T therapy. He discussed the impressive progress, but also the challenges, including the high costs and long production time of personalised therapies. Unfortunately, many patients in an advanced stage of their disease do not have that time. Currently, an important study is underway, co-funded by the Dutch government, which investigates whether the CAR T therapy developed at UMC Groningen is comparable to the commercially available treatment considered the gold standard. The results are still under investigation, but the initial findings suggest that academic production and administration proceed significantly faster.

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After the lectures, there was ample opportunity for questions and discussion, led by the conference chair Rudolf van Olden. The lively exchange of ideas continued enthusiastically during the closing reception. The NVFG Annual Congress 2025 once again offered an inspiring and educational afternoon, with plenty of knowledge sharing and valuable encounters.

Author: Rita Lobatto, MD, MPH, Pharmacovigilance Executive, RP & L Consultancy and **Faizel Ghazi**, Commercial Director Ualise

1) Car T cell: Chimeric Antigen Receptor cell

Rita Lobatto

Faizel Ghazi

Celebrating the Success of the Capacity Building Programme in Egypt

On 03 November 2025, a special ceremony marked the successful completion of the Capacity Building Programme for Enhancing Clinical Research and Drug Development in Egypt, a collaborative initiative between King's College London (KCL), Future University in Egypt (FUE), and the Middle East Association of Pharmaceutical Medicine Professionals (MEAPP), funded by the British Council's Going Global Partnerships Programme.

From left: Dr Tamer Elhosseiny, Vice Chairman for the Egyptian Drug Authority, Prof. Azza Ahmed, Dean of the Faculty of Pharmacy, FUE, Prof. Abdel Wahab El-Ghandour, Vice President, FUE, Prof. Ebada Sarhan, President, FUE, Prof. Stuart Jones, Director of CPMR (1), KCL, Dr Assem el Baghdady, MEAPP President, and Prof. Hanan Refaat, Dean of International Affairs, FUE, during playing the anthem of Egypt.

The programme, which spanned the year 2025, represents one of only ten successful projects awarded under the British Council's Transnational Education (TNE) Call 2024. This milestone reflects the shared vision of fostering sustainable, high-impact collaborations between the UK and Egyptian higher education institutions.

A total of 131 participants out of 133 enrolled, successfully completed the programme requirements and graduated from three specialised modules: Clinical Drug Development, Drug Development Statistics and Data Management, Health Technology Assessment and Pharmacoeconomics, earning certificates jointly endorsed by KCL, FUE, MEAPP, and the British Council.

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This initiative addresses a critical need for capacity building in medicine development, an area essential to advancing public health, ensuring access to innovative and affordable treatments, and strengthening national security. It reflects a vision strongly upheld by MEAPP's President and all its members.

By training scientists, researchers, regulators, and industry professionals, the programme directly contributes to positioning Egypt as a regional hub for pharmaceutical research, innovation, and education. This aligns perfectly with MEAPP's mission since its inception.

Prof. Stuart Jones, Director of the CPMR, delivers King's College London Speech

Being part of the organising team, I witnessed the tremendous effort that went into every detail, from drafting the grant proposal to reaching today's celebration, and soon, to preparing the final report. The journey has been filled with careful planning, coordination, and countless discussions, all aimed at making this learning experience truly meaningful.

Beyond the organisation, I also joined the programme as a student, completing all three modules and meeting all assessment requirements successfully. I was fortunate to learn from an exceptional faculty from King's College London and industry experts, gaining insights that bridge science, regulation, and practice.

The graduation ceremony, hosted by Future University in Egypt, celebrated not only academic achievement but also the spirit of collaboration that drives progress in global health. Participants and partners reflected on a shared commitment to bridging academia, industry, and policy to accelerate medical innovation and improve patient outcomes.

Dr Dina Khaled, Dr Nouran Omar (FUE), and myself, Yasmin Nagaty (MEAPP), receiving trophies in recognition of our contributions as Steering Committee members of the project.

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Honouring the legacy of the late Prof. David Morgan, who contributed to Module 2

MEAPP President, Dr Assem el Baghdady, MD, FFPM, FRCP, ending his speech with a thank you message written over a striking background of Egyptian hieroglyphs

The atmosphere was truly celebratory, a moment of pride for all participants who completed this transformative learning journey.

As the programme concludes, MEAPP and its partners look ahead to expanding such initiatives across the Middle East and Africa, empowering the next generation of professionals who will shape the future of medicine.

Author:
Yasmin Nagaty
Regional Manager | The Middle East Association of Pharmaceutical Medicine Professionals CIO (MEAPP)
Visiting Lecturer, CPMR, King's College London

1) CPMR: Centre for Pharmaceutical Medicine Research

A group photo of the graduates who attended the ceremony

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Building Professional Identity in Pharmaceutical Medicine: Insights from IFAPP's October 2025 Webinar

On 30 October 2025, IFAPP hosted an engaging webinar entitled 'Professional Identity in Pharmaceutical Medicine and Medicines Development'.

The event brought together global experts to discuss the evolving concept of professional identity within the discipline, with a focus on collective contributions to education, continuing learning, and best practices that are generating trust and commitment to patients and the public. Career development was identified as a key factor in fostering a sense of professional identity, emphasising its role in cultivating ethical, competent and collaborative professionals within the life sciences sector.

Our guest speakers from PharmaTrain (Dr Ingrid Klingmann) and the GMDP Academy (1) (Dr Pravin Chopra and Professor Sam Salek) participated in an interactive dialogue with our audience, discussing how their organisations perceive and contribute to shaping professional identity in Pharmaceutical Medicine and Medicines Development.

The speakers defined professional identity as the internalised values, beliefs and norms that guide behaviour and decision-making in a professional context. It is not just about what professionals do, but who they are in their roles. In the field of Pharmaceutical Medicine/Medicines Development (PM/MD), where science, ethics, regulation and patient care converge, a robust professional identity is crucial for practitioners to uphold integrity, prioritise patient safety and meaningfully contribute to global research and innovation.

The panelists' insightful discussion about the core competencies and values that are essential in the PM/MD domain emphasised scientific rigour, evidence-based thinking, ethical responsibility, regulatory compliance, collegiality, collaboration across multidisciplinary teams, and commitment to lifelong learning and patient-centred outcomes.

It is important to note that professional identity is not static; it evolves through education and training, mentorship and role modelling, reflective practice, and real-world experience.

The speakers highlighted the challenges of navigating complex global regulations, managing commercial pressures while upholding ethical obligations and adapting to rapid technological change. However, these experiences also serve as opportunities to strengthen identity through resilience, consistency, and adaptability.

PM/MD professionals are encouraged to actively shape their professional identity by engaging with our communities of practice, seeking feedback and ensuring that their personal values align with their professional goals.

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Professional identity is a dynamic concept that requires adaptability in the face of new technologies, regulatory changes, and a focus on patient-centric approaches.

Global standardisation of curricula, competencies, continuing education and certification is required to ensure the credibility and mobility of professionals worldwide.

Pharmaceutical Medicine as a medical discipline has been recognised in a few countries only. These include the UK with the Faculty of Pharmaceutical Medicine, Ireland with Trinity College, and Switzerland (Swiss Society of Pharmaceutical Medicine), also for biomedical scientists (Diploma from the European Center of Pharmaceutical Medicine). In Belgium, the Ministry of Health has formalised this recognition through a Royal Decree, incorporating it into the regulated medical specialties published in the Belgian Official Gazette in 2023.

Our community should advocate strengthening Pharmaceutical Medicine's visibility and acceptance globally. I would like to thank our guest speakers, Dr Ingrid Klingmann (PharmaTrain), Dr Pravin Chopra (GMDP Academy) and Professor Sam Salek (GMDP Academy), for sharing their insights on competency-based education and continuing professional development and career growth.

Similarly, I would like to thank our colleagues who attended for their contributions to the dialogue session. They addressed practical and ethical comments and questions concerning the implementation of competency frameworks in various regulatory environments, as well as the increase in decentralised trials and the requirements of Artificial-intelligence-driven drug development.

In conclusion, the webinar emphasised that professional identity is not static. It is shaped by science, ethics, and societal needs. IFAPP's initiatives, in collaboration with organisations such as PharmaTrain and the GMDP Academy, aim to establish a global network that fosters professional identity in PM/DM. This network is grounded in science, integrity, research ethics and innovation within the discipline. Our work in the research and development of medicines, medical devices, and new technologies touches the lives of everyone. Our work is interdisciplinary, complex, and diverse, with outcomes that differ greatly from those of other specialties. Professional identity in PM/DM represents a trust-generating promise, reflecting a commitment to patients' and the public's interests. I hope that this summary serves as a thoughtful reflection on how cultivating a strong professional identity can elevate both individual careers and the broader impact of PM/DM on society.

Author: Dr Varvara Baroutsou
IFAPP Immediate Past President

1) GMDP Academy - Academy for Global Medicines Development Professionals https://gmdpacademy.org


Varvara Baroutsou


Ingrid Klingmann


Pravin Chopra


Sam Salek

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"Opportunities and challenges in implementing the European AI Regulation: Overview of content and status of implementation from a regulatory perspective"

"Regulation (EU) 2024/1689, commonly referred to as the "EU AI Act," is considered the world's first comprehensive regulation of artificial intelligence (AI). The webinar will be given by Professor. Dr Folker Spitzenberger who will examine the background, scope, and risk categorisation of AI systems. Opportunities and challenges of the EU AI Act, such as fostering trust in human-centred AI solutions while avoiding overly stringent regulation, will be discussed, as well as the actual requirements for conformity assessment of AI systems and the interfaces with vertical product regulations such as the European Union Medical Device Regulation (EU MDR) and the European Union In Vitro Diagnostic Regulation (EU IVDR)."

Speaker: Professor Dr Folker Spitzenberger

Register here for this webinar

After registering, you will receive a confirmation email containing information about joining the webinar.

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Summary

Professor Folker Spitzenberger is a graduate chemist and received his PhD in molecular biology from the Institute of Pharmacology at Heidelberg University in Germany. After postdoctoral work at the Medical Faculty of the University of Dresden, Germany, and at Yale University (CT, USA), he worked from 2002 to 2016 in the area of assessment and implementation of quality assurance systems in the field of medical devices at the ZLG (1), the RKI (2), and the German accreditation body DAkkS (3).

With the additional qualification as a Master of Drug Regulatory Affairs, Folker Spitzenberger advises international organisations such as the WHO and the EU in the field of QM/QA (4) and Regulatory Affairs. In 2016, Folker Spitzenberger joined the University of Applied Sciences Luebeck (TH Luebeck, Germany) as Professor for Regulatory Affairs for medical devices. He also continues his work as quality assessor for DAkkS and ZLG. Folker Spitzenberger is an active contributor to various standardisation committees and is a co-author of many standards in the field of quality management, Regulatory Affairs, biomedical engineering and, lastly, AI.

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(1) ZLG: Central Authority of the Laender for Health Protection with regard to Medicinal Products and Medical Devices in Germany (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten)
(2) RKI: Robert Koch Institute, Germany's public health institute
(3 DAkkS: Deutsche Akkreditierungsstelle (German Accreditation Body)
(4) QM/QA: Quality Management/Quality Assurance

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2026

IFAPP *Free webinar*

The webinar will be given by **Todor Darakchiev**, M. Pharm., Head of Division Medical Devices Department, Market Supervision and Inspections,, Bulgarian Drug Agency (BDA), who will examine the background, scope and implementation of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Regulation (EU) 2017/746 lays down the rules concerning the placing on the market, making available on the market, or putting into service of in vitro diagnostic medical devices for human use and accessories for such devices in the European Union. This Regulation also applies to performance studies concerning such in vitro diagnostic medical devices and accessories conducted in the European Union.

Todor Darakchiev is Head of Division "Medical Devices" in the department Market Supervision and Inspections at the BDA. He has been working in the field of medical devices regulation since he started to work for the BDA in 2000. During his career in the BDA he gained regulatory experience as a chief expert for issuing of marketing authorisations of medical devices (till 2006), and as a chief inspector for medical devices and medicinal products (since 2007). Todor Darakchiev participates in the meetings of the EU Competent Authorities for Medical Devices as BDA representative. During the period 2007 – 2017 he attended several workshops for medical devices organised by TAIEX (1). In the beginning of the Bulgarian EU membership, he was a member of a working group responsible for transposition of the European legislation for medical devices. From 2011 to 2012 Todor Darakchiev participated in an interdepartmental project "Creation of digital database of medical devices paid with public resources" as a coordinator. After adoption of the EU Regulations for Medical Devices and In vitro Diagnostic Devices he was designated as a member of the Medical Device Coordination Group (MDCG) in the EU. Todor Darakchiev has also become a member of a working group for amendment of the Bulgarian Law on Medical Devices in connection with the implementation of the new legislation in the sector.

(1)TAIEX: Technical Assistance and Information Exchange, a key European Union instrument for institutional capacity-building worldwide, providing targeted and rapid support to public administrations in EU candidate countries and beyond

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Fellows and Rising Stars

In 2025 the following Rising Stars and Fellows were acknowledged by IFAPP:

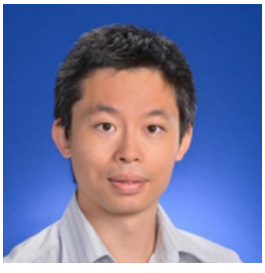
Rising Stars, Early Career in Pharmaceutical Medicine

Keiko Fukino

Cardiologist with over 25 years of frontline clinical practice, now expanding into Pharmaceutical Medicine to integrate clinical insights with evidence generation. In Japan, where the discipline is still emerging, working to promote understanding and inspire interest among younger physicians through education and mentorship.

Tsunehisa Yamamoto

Graduated from Keio University School of Medicine, Japan in 2009. Received a Ph.D. (Medicine) in 2016. Postdoctoral researcher at the University of Pennsylvania (Metabolism in heart failure, Daniel P Kelly lab) from 2018 to 2021. Joined BMS Japan Medical Affairs in 2021. Moved to BMS Japan Clinical Development in 2024.



Ko Nakajo

Director of Global Epidemiology at Johnson & Johnson Innovative Medicine, with over a decade of experience in pharmacoepidemiology, drug safety, and medical affairs. Holds advanced degrees in Epidemiology from Hokkaido University and LSHTM, with multiple peer-reviewed publications on infectious disease modeling and public health.

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Róisín Flynn

Róisín joined Pfizer in 2019 and worked in multiple Medical Affairs roles of increasing responsibility across the Hospital and Vaccines Business Units, including for the launches of Pfizer's COVID vaccine and antiviral nirmatelvir. She completed a MSc in Pharmaceutical Medicine in Trinity College Dublin in 2023 and subsequently moved to Eli Lilly to take up a Senior Director role in ExploR&D, a full-service autonomous R&D unit within Lilly that specialises in proof-of-concept clinical development. Róisín is currently Vice-President of the Pharmaceutical Managers' Institute in Ireland (PMI) and Vice-Chair of Association of Pharmaceutical Physicians in Ireland (APPI).

Senior Fellows of Scientific Leadership in Pharmaceutical Medicine

Dr Brandon M. Henry

Dr Henry is a physician–scientist and global leader in cell, gene, and RNA therapy, recognized for high-impact translational research, regulatory strategy, and clinical trial innovation. Named by Clarivate among the Most Influential Researchers in the World (top 0.1%), he has also appeared on the Stanford/Elsevier World's Top 2% Scientists list for five consecutive years and was independently ranked #3 globally in medicine by ScholarGPS and Stanford/Elsevier in 2024. Dr Henry has led or co-led dozens of advanced therapy programs for rare and ultra-rare diseases, including AAV gene therapies, RNA therapeutics, and genome-editing platforms, across neuro-developmental, neurodegenerative, and neuromuscular disorders, as well as inborn errors of metabolism. His work spans the full clinical development continuum–from IND-enabling studies and first-in-human trials to pivotal programs–focused on complex, high-need indications. Author of more than 400 peer-reviewed publications with over 26,000 citations, Dr. Henry has received numerous national and international awards. He is dedicated to advancing the next generation of curative genetic medicines, translating cutting-edge science into transformative clinical outcomes. His career is defined not by traditional pathways, but by vision, execution, and an unwavering commitment to treating the untreatable.

Dr Sander Becker

Sander has dedicated more than 43 years to Pharmaceutical Medicine, with a career strongly focused on ethical practice, professional standards and IFAPP's strategic development. He contributed to IFAPP's Ethical Code of Conduct and later Ethics Framework, helped lead "Shaping IFAPP's Global Strategy", and has recently examined "Linking the Declaration of Helsinki and Taipei - Ethics Research".

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Graduating in South Africa in 1978, he began working in Pharmaceutical Medicine in 1982, holding senior roles at Sandoz, ICI/AstraZeneca in South Africa and the UK, and Abbott in Australia. Since 1999 he has served as CEO of Consultants in Pharmaceutical Medicine, advising industry and regulators in pharmacovigilance, expert testimony and advertising control. Internationally, he served on the IFAPP Board, co-chaired the Pharmaceutical Medical Ethics Council, helped launch the World Ethics Corner, and was a founding chair of IFAPP's Ethics Committee, Council of Education and Global Strategy Working Party. In Australia, he served as President of APPA (2000–2002) and later on its Executive, leading initiatives to support members and chairing several international conferences. He is a life member of SAAPP, BrAPP and APPA, and an honorary editor of Pharmaceutical Medicine and Frontiers of Medical Science.

Mariangela Amoroso

Over the last two decades, Mariangela has gained extensive professional experience in pharmaceutical companies in positions of increasing responsibility at both Italian and international level. A medical doctor and specialist in obstetrics and gynaecology, she spent 8 years in clinical practice at the Department of Gynaecological Oncology at the Catholic University and Campus Biomedico in Rome. Since 2003, she has worked in clinical development and new drug launches in virology, immunology and neuroscience at BMS, where she has held several leadership positions, including European Associate Medical Lead and Medical Head Virology in the UK. In 2015, she assumed the role of Medical Director Italy & Europe at Allergan (AbbVie Group) and since 2021 she has held the role of Medical Director at Sanofi. Member of the SIMEF Council since 2023, member of the Board of Directors of the Nat. Foundation of Gene Therapy, active member of several scientific societies, visiting professor at the PhD course - University of Perugia. She consistently demonstrates strengths in strategic leadership, motivating and successfully managing people and has developed a reputation for cross-functional collaboration, direct communication and high-performance leadership. In her spare time, she enjoys reading and travelling. She is very interested in leadership issues, especially for professional women and young people.

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Marco Costantini

Marco is a clinical biostatistician with nearly twenty years of experience in the pharmaceutical industry. He currently serves as Director of Biostatistics at GlaxoSmithKline's Siena site, a role he has held since July 2022. In this capacity, he is responsible for the quantitative strategies supporting several vaccine development programs and oversees all associated statistical activities. His remit spans the entire development continuum, from preclinical research through clinical trials to market authorization. Marco leads a multinational team of statisticians and provides strategic guidance on statistical methodologies and quantitative frameworks, and he contributes to talent acquisition and development initiatives within the Biostatistics organization.

Throughout his career, Marco has contributed to the marketing authorization of several medicines and vaccines and has participated in more than 50 clinical trials across multiple phases and therapeutic areas. He is the Coordinator of the Italian Biostatistics Group (IBIG) and an elected member of the Executive Board of the Italian Society of Pharmaceutical Medicine (SIMeF). He has also served as the Italian delegate to EFSPI for five year. His scientific contributions include numerous publications in the fields of vaccine and statistics.

Victor Gallego

With 20+ years across multiple global pharma companies, Victor brings experience in Medical Affairs, Clinical Pharmacology and Pharmaceutical Development, spanning early drug discovery to Phase I–IV clinical trials. Proven track of leading national and international teams, driving medical transformation, and delivering successful launches across various therapeutic areas. Passionate about cross-functional collaboration to improve patient outcomes gathering collective efforts between Research & Development and launches team. Committed to continuous learning and professional development, with a strong interest in emerging trends such as digital transformation, artificial intelligence, and innovative medical models.

Brigitte Franke-Bray (MD PhD) FFPM GFMD

Brigitte is an independent consultant with special expertise in Pharmaceutical Medicine. She is a former member of the Executive Board (Secretary) of the PharmaTrain Federation and currently still a member of the Advisory Board of ECPM (European Center/Course of Pharmaceutical Medicine) Basel.

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From September 2018 to June 2023, she was Treasurer of IFAPP. She is also a member and auditor of the Swiss Society of Pharmaceutical Medicine (SGPM), of EUPATI Switzerland, and a member of the Advisory Board of the Bulgarian Association for Drug Information (BADI) and of the Swiss Round Table on Antibiotics. She started her career as a hospital physician in internal medicine, respiratory diseases and allergology in Germany before she worked as a medical expert/director in big pharma (Ciba-Geigy, Sandoz, Novartis) and small pharma (Drossapharm) in Switzerland. She also has ample experience in a big CRO (Quintiles) as founder and head of the office in Switzerland and she additionally headed two of the three German Quintiles offices. Brigitte was Director DIA Europe, Middle East, Africa and, additionally, the DIA's Global Training Officer for about eight years and, in the Swiss Medicines Regulatory Authority Swissmedic, she gained experience as a Clinical Reviewer in the department of Marketing Authorisation. Brigitte was an instructor in a diploma course of the University of Basel and has been an examiner for the ECPM training course and the physicians' specialisation in Pharmaceutical Medicine, Switzerland (FMH) for many years.

Hidenori Komori

Hidenori is graduated from medical school in 1995, started his career as clinical physician at Kyoto University Hospital. He specialized in Cardiovascular medicine after 3 years of training for general internal medicine. He proceeded with his research for atherosclerosis at Kyoto University Graduate School of Medicine based on molecular biology and was awarded a degree of Ph.D. In 2010 he joined global mega pharma to suspend his experience and acknowledgement in industry. He has worked both at global mega pharma and local pharma during his career, functionated in clinical development, safety and medical affairs. He joined the Japanese Association of Pharmaceutical Medicine (JAPHMED) and have been active for 15 years, including the 15th Chairman of JAPHMED annual meeting held on 2024. He contributed to the organization as a director and the head of Kansai Committee with colleagues to activate this field of academy.

Elisa Crovato

Biostatistician by Degree, Elisa has dedicated the past 15 years to Market Access and RWE both in Pharmaceutical Companies and Consulting. Understanding and disseminating how evidence can support Drugs' Value in Regulatory, HTA and pricing discussions has been her preferred focus, especially in addressing stakeholders' needs in diseases where uncertainty is high and payers need to be reassured. The willingness to raise awareness on these topics led her to SIMeF and to mentor young professionals.

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Erik Present

Eric graduated as medical doctor and has 25 years of experience in bringing innovative drugs to patients through various roles in medical affairs. Erik is a strong advocate of Medical Affairs and his expertise is wide-ranging including medical affairs, market access in the BeNeLux, medical education and strategic portfolio/program management, early access and clinical trials. Erik has had different roles in Medical Affairs at AstraZeneca, JnJ, Galapagos and Alfasigma. He is currently Head of Medical Affairs at Kintiga, a consultancy company in market access, medical affairs and regulatory affairs.

Over the years, Erik has been very active as industry representative in the set-up of the new specialty title for physician-specialists in Belgium: physician-specialist in Pharmaceutical Medicine and Clinical Pharmacology; which was created in 2023. Belgium is now the 4th country in Europe to recognize this specialty title for physicians; but Belgium is the only country in Europe to have this title combined Pharmaceutical Medicine and Clinical Pharmacology. He has now the vice-chair the recognition commission in Belgium. Erik was instrumental in the creation of Healixia; and is President from the start in 2000 onwards. Healixia is the result of a convergence between 4 associations in Belgium: ACRP.be, BAPU, BeAPP and BRAS and is now, with over 700 members, the largest Belgian association of professionals in life sciences. Healixia is a member of IFAPP.

Francesco Butti

After graduating in Biotechnology, Francesco began working in the pharmaceutical industry, holding increasing roles and responsibilities in Research & Development and Medical Affairs. For several years, Francesco has been volunteering for scientific associations (including SIMeF and IFAPP), as well as teaching in various post-graduate Master's programs. He currently serves as Head of Clinical Development & Operations at Boehringer-Ingelheim Italy.

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AGENDA

Free Webinars

- 28 January 2026 - Career Pivots: Switching Roles Within Pharma (and How to Do It)
  Click here to register.
- 4 February 2026 - Opportunities and challenges in implementing the European AI Regulation: Overview of content and status of implementation from a regulatory perspective
  Click here to register.
- 19 February 2026 - EU In Vitro Diagnostic Regulation (IVDR) implementation. State of play and challenges
  Click here to register.

THE FLAG

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