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International Conference
on Pharmaceutical Medicine

Hybrid Meeting 19-21 October 2022 SNFCC, Athens – Greece

What lies ahead in Pharmaceutical Medicine

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Investigational Drug Supply for Seriously Ill Patients in Time of War



War is the most tragic condition humanity can face. Lives are lost or deranged. Human contacts are destroyed. Even after the ending of a war, it takes a long time until normal social, cultural, economic and health care related interactions can be reorganised. Now in Europe we are again in an irrational and savage war initiated by an unscrupulous leader. The war and its aftermath will cause a prolonged disruption of health care in Ukraine due to the destruction of hospitals and the death or dislocation of the medical personnel. For a long time to come the primary goal will be to provide basic medical care and essential medicines. Experienced international organisations manage these tasks, usually supported with generous donations from the industry. However, it is also necessary to consider problems associated with investigational drugs needed for patients with serious diseases.

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Many patients enrolled in various clinical trials are affected in Ukraine and Russia. This is an important ethical problem for the organisers and sponsors of such trials. They will not be able to reach the war zone; however, they should make all possible efforts to find those patients who could flee to safety outside the war region in Ukraine or to foreign countries.

Significantly impaired international clinical trial operations can be expected also in Russia as the result of the sanctions affecting scientific cooperation, communication, economic transactions and travelling. Many sponsor companies have already stopped recruiting patients into their ongoing trials in Russia. It is essentially a humanitarian issue whether to continue experimental treatment for seriously ill patients, irrespective of whether Russia is condemned for initiating this war and committing serious war crimes in Ukraine. It will not be easy to fulfil this ethical need due to the interruption of the normal channels. One possible approach might be that pharmaceutical companies, with humanitarian organisations, jointly develop a secured limited drug supply chain needed for these patients.

With this short communication several members of the Ethics Working group of IFAPP wish to call the attention of the IFAPP national organisations and of all pharmaceutical medicine experts to this special ethical aspect of ongoing clinical trials at times of human conflict. Our suggestion follows essentially the humanitarian ideals of Henry Dunant, founder of the Red Cross movement, stating that all war victims should be protected. Similarly, seriously ill patients involved in clinical trials should not be abandoned during wars and accompanying economic warfare. It should be also considered that the trial data will also help other patients worldwide.

We hope that this cruel war will be ended soon, and the patients of the region will again benefit from full access to medicine research.

Members of the IFAPP Working Group of Ethics:

- Sandor Kerpel-Fronius, Semmelweis University, Budapest, Hungary
- Varvara Baroutsou, Independent Medical & Pharmaceutical Medicine Consultant, Athens, Greece
- Brigitte Franke-Bray, Independent Consultant, Basel, Switzerland
- Chieko Kurihara, National Institutes for Quantum and Radiological Science and Technology, Chiba, Japan
- Kotone Mutsuyama, Nippon Medical School, Tokyo, Japan
- Shehla Naseem, Ferozsons Laboratories Ltd, Karachi, Pakistan
- Johanna Schenk, PPH plus GmbH & Co. KG, Hochheim am Main, Germany

IFAPP Board Secretary: Anna Jurczynska

As a member of the Executive Committee of the Spanish Association of Pharmaceutical Medicine (AMIFE), I was elected as Delegate to IFAPP in 2010. Although I learned a lot about IFAPP from my colleagues at AMIFE, my first direct contacts with IFAPP members were in Amsterdam, during the IFAPP Science2Business Conference “Academia-Industry Collaboration for New and Better Medicines: From Partnership to Trust” held in 2011. This interesting event allowed me to meet a number of professionals from different countries and participate in PharmaTrain sessions.



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I studied Social Science at the University of Warsaw and gained my PhD with specialisation in Healthcare, followed by an MBA at the same university. My first job at a pharmaceutical company as Clinical Research Associate was in the Medical Department of The Upjohn Company in Madrid. My main commitments were related to local and international clinical operations, with responsibility for timely submission of clinical trials dossiers, correct performance and adequate outcomes and results of the trials. After 5 years I was promoted to the position of Adjunct to Regulatory Affairs Director and was accountable for the supervision and development of new product registration dossiers for submission to Spanish Health Authorities and/or to EMA.

While at the Regulatory Department at Serono I was involved in the supervision of registration dossiers for advanced therapy drugs and had direct contacts with the Spanish Medicine Agency. A substantial change came when I decided to join the Marketing Department at Rhone-Poulenc with responsibilities related to contacts with Key Opinion Leaders, development of clinical trial protocols for post-authorisation studies and organisation of congresses, conferences and similar events.

In the last years of my professional career, I joined Parexel International as General Manager of Business Administration, being its legal representative in Spain and overseeing all clinical and business operations in the country.

AMIFE became a member of IFAPP in 1978 and organised the 7th International Conference of Pharmaceutical Medicine (ICPM) in 1990 in Madrid. When I joined IFAPP as AMIFE's Delegate, I actively participated in the organisation of the 16th ICPM in Barcelona, with Dr Rudolf van Olden as the IFAPP President.

Last year I re-joined the IFAPP Board of Officers as Secretary after two years of absence due to professional challenges in my company, ANMAR Clinical Services. New National Member Associations (NMAs) and Individual Affiliates joined IFAPP at that time, and now we have a large number of members from Europe, Asia, Africa, America and Australia. It is a real pleasure and honour to be part of the IFAPP Board and collaborate with excellent professionals from around the world.

Anna Jurczynska, PhD, MBA

Executive Board, AMIFE, Spain



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History and Activity of the Pharmaceutical Medicine Section (PhMS) of the Hungarian Society for Experimental and Clinical Pharmacology



HUPHAR

Hungarian Society for Experimental and Clinical Pharmacology

The Hungarian member association of IFAPP works as a section of the Hungarian Society of Experimental and Clinical Pharmacology. This structure was developed to provide a scientific and organisational framework for several important specialisations in pharmacology. It is very helpful for keeping good communication between the various member scientists and for supporting the management of the sections. Usually, several sections organise their meetings together. Presently the following sections are registered in the Society:

- Clinical Pharmacology
- Experimental Pharmacology
- Extracellular Vesicles
- Immunopharmacology
- Innovation in drug research
- Pharmaceutical Chemistry and Molecular Informatics
- Pharmaceutical Medicine
- Pharmacokinetics and Drug Metabolism

The place of the Pharmaceutical Medicine Section in the complex scientific environment of drug development in Hungary is quite unique. Hungary has a well-developed pharmaceutical industry with a long tradition dating back to the end of the 19th century. During the socialist period all the Hungarian pharmaceutical companies were nationalised and operated in a large state-controlled pharmaceutical association. In 1967, the Ministry of Health and the Hungarian Association of the Pharmaceutical Industry organised jointly a clinical pharmacology network for performing clinical drug evaluation at a high scientific level. Essentially, the system was based on small clinical pharmacology units located in leading university and large community hospitals.

These units worked under the supervision of the clinical head of the clinical departments. At its peak, the network comprised 21 clinical pharmacology units employing 134 trained clinical pharmacologists and additional technical staff. At the end of the socialist system the clinical pharmacology network was dissolved. However, the knowledge remained; the experts continued to work at the clinical sites or joined the medical department of the new independent pharmaceutical companies. (For more details see: Kerpel-Fronius S. The Development of Pharmaceutical Medicine in Hungary. *Pharm Med* 27:289–295, 2013. doi: <https://doi.org/10.1007/s40290-013-0031-5>)

The partly overlapping clinical drug development activities of the various societies in Hungary originate from this historical background. The Clinical Pharmacology Section of the Hungarian Society of Experimental and Clinical Pharmacology was organised to further scientific high-level drug development and to coordinate clinical pharmacology education and board examinations at the universities. The clinical pharmacology board examination was introduced in 1979. It is a secondary specialisation based on any primary medical specialisation. Phase I studies can be performed only by specialists in clinical pharmacology. For other phases of clinical trials, a valid Good Clinical Practice certificate issued by a university-accredited course is necessary.

In 2000 a Clinical Trial Management Society was established to focus on the specific interests of the personnel dealing with the management and monitoring of clinical trials. Its members are mainly working in the pharmaceutical industry and CROs. They focus primarily on the scientific and legal



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aspects of trial management and play an essential role in harmonising the changing trial requirements with the legal framework of the Hungarian health care system. The Society joined IFAPP in 2004. Soon it became clear that this new professional group needed specific training in pharmaceutical medicine. The organisation of the international Cooperative European Medicine Development Course (CEMDC) at the Semmelweis University in Budapest fulfilled this requirement. The programme received the PharmaTrain (1) course of excellence accreditation. Unfortunately, the members of the society felt that their professional needs were not represented adequately by IFAPP. Therefore, some years ago they decided to leave IFAPP.

Due to the decision of the Clinical Trial Management Society the Hungarian scientists lost their official contact with the scientific pharmaceutical medicine programme of IFAPP. For re-establishing this important scientific liaison, it was decided to organise a Pharmaceutical Medicine Section (PhMS) within the Hungarian Society of Experimental and Clinical Pharmacology. The Section was officially inaugurated in 2018 and was accepted as an IFAPP National Member Association in the same year. Since clinical pharmacology and pharmaceutical medicine represent the medical and the industrial sides of clinical drug development, it was logical to establish immediately a close cooperation with the Clinical Pharmacology Section. The PhMS joined the annual meeting of the clinical pharmacology sections organised yearly since 1998. This meeting has a mixed programme with educational review lectures and short scientific contributions. It is very advantageous that the Hungarian Regulatory Agency is a co-organiser of the meeting, providing an extensive overview of recent regulatory developments each year. The PhMS will also continue its engagement in the pharmaceutical medicine training programme. Presently, the CEMDC is under reorganisation for providing a complete Master programme at the Semmelweis University, Budapest.

At the recent, virtually held clinical pharmacology meeting in December 2021, the PhMS organised a small section dealing with specific scientific problems of trial management during the COVID-19 pandemic. Two lectures discussed the organisation of trial management centres in university clinical complexes and hospitals. The aim of these reorganisations is to increase trial efficiency and quality by organising central trial management for all clinical units. Earlier trial activities were usually managed independently in the various clinical units. Another participant analysed the practical problems associated with the use of the new EMA “Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products” (20 July 2017 EMEA/CHMP/SWP/28367/07 Rev. 1). It is important to point out that all three above-mentioned organisations dealing with clinical trials participated at the congress providing opportunities for interaction. It was stimulating to learn that more than 100 colleagues followed the lectures of the PhMS according to the data of the computer team.

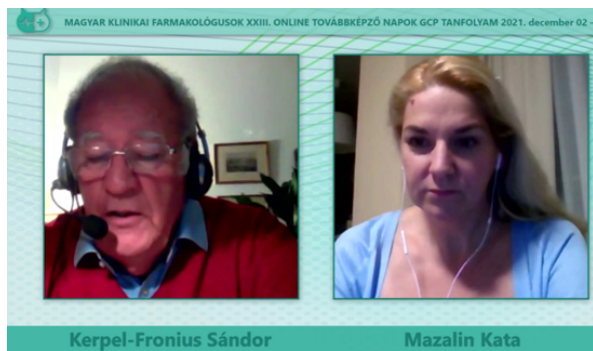
The PhMS had difficult times building up its organisation during the first year of the pandemic. Nevertheless, it remained active and carried out its work in close cooperation with the clinical pharmacologists and the clinical trial managers. We hope that, following this approach, we can further develop successfully our pharmaceutical medicine programme in Hungary.

1) PharmaTrain: <https://www.pharmatrain.eu/>



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Dr Sandor Kerpel-Fronius and Dr Kata Mazalin moderating the online session of the PhMS, 2021

Dr Sandor Kerpel-Fronius, MD, DSc, FFPM

Secretary of the Hungarian Section of Pharmaceutical Medicine
Professor of Clinical Pharmacology
Semmelweis University Budapest, Hungary

Dr Kata Mazalin, MD

Deputy Secretary of the Hungarian Section of Pharmaceutical Medicine
Head of Medical Oncology, Novartis
Budapest, Hungary

The HEART Approach for Clinical Trial Leadership

Project management vs Project leadership

New drug development remains highly risky and costly despite the fact that approval success rates increased to 62% in 2017 (Galson et al., Nature, 2021). Galson et al. name poor execution and inadequate project management as one of the factors causing every third study to fail in phase III.

We believe that the success of clinical trials can be improved by executing strong project leadership in addition to traditional project management techniques. One of the biggest challenges for life-science start-ups and small biotech companies is the development of a clear strategic path that will successfully bring their product to market. Hence, clinical development leadership addresses this very issue by identifying the products strongest advantages in terms of market needs and value and developing a streamlined clinical trial programme that helps these companies succeed.

Based on extensive knowledge of the regulatory environment, the clinical project leader establishes a high-level project vision, can identify alternatives, and proposes new approaches. The project leader also takes ownership for the study as part of the whole drug development programme by stepping out of visionless execution and being able to see the long-term perspective of their decisions.

In modern clinical development, there is an urgent need for a stronger project leadership mindset implemented in the early stages of clinical trials.



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We suggest applying the HEART approach for leading drug and device development programmes successfully:

- o High-level vision: understanding and reviewing regularly where the sponsor’s expectations meet market needs.
- o Expert: profound clinical and regulatory knowledge should be a prerequisite. However, it is a valuable trait to recognise in time whether it is necessary to involve an expert, as this can be a decisive moment for the success or failure of the clinical trial. Inadequate selection of biomarkers or selection of the wrong target population could thus be easily avoided in hundreds of clinical trials.
- o Adaptive approach: staying open-minded and flexible. Every clinical trial is similar and unique at the same time. Propose new approaches in routine tasks.
- o Responsibility: responsible project leaders are expected to account for multiple constraints and demands from a range of stakeholders. It includes not only sponsor, clinical operations, and study team, but also patients and the health care system in general. Bring solutions to the market and fill the gaps.

And last, but not least

- o Team: strong communication and coordination skills play a crucial role in a complex and dynamic process of drug development. Good project leadership possesses full integrity and commitment to the team. K. Murray in his book Charismatic Leadership states that a team under charismatic leadership is 24 percent more likely to give discretionary effort. Listen and do what was said.

Project managers learn from the outside in mastering techniques and skills. Project leaders develop themselves from the inside out investigating their weak and strong traits; emotional intelligence, adapting their communication to the need of the team and stakeholders. While management is the process of working with others to ensure the effective execution and accomplishment of a chosen set of goals, leadership is about developing what the goals should be. It is about driving change, whereby the journey is as important as the outcome.

Can the clinical trial succeed with an application of solely project management? Yes, definitively. However, under a discrete project leadership, the pathway from idea to market would be rationalised, streamlined, and sustainable.

HEART Approach

for Clinical Trial Leadership



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- S. Galson et al. Nature Reviews Drug Discovery 20, 259-260 (2021) doi: <https://doi.org/10.1038/d41573-020-00167-0>
- K. Murray Charismatic Leadership: The Skills You Can Learn to Motivate High Performance in Others. Kogan Page (2020).

Kerstin Peschel-Credner, PhD (Senior project manager at Gouya Insights KG, member of GPMed [Austrian Association of Pharmaceutical Medicine]);

Kateryna Uspenska, PhD (Senior project manager at Gouya Insights KG; member of the IFAPP Young Professionals WG, member of GPMed [Austrian Association of Pharmaceutical Medicine]).

IFAPP Education and Certification Working Group (ECWG) Reaches First Milestone

The ECWG is working on the delivery of education and training courses for professionals within the field of Pharmaceutical Medicine/Medicines Development Sciences (PM/MDS) and just finalised a Concept Paper which can be found here: https://ifapp.org/2022mar25_ecwg_concept_paper-2

As an important news, IFAPP will continue to offer the award of the title Global Fellow in Medicines Development (GFMD) to those colleagues who already have many years of experience in Pharmaceutical Medicine and who can demonstrate their expertise. To apply for this award, a specially designed questionnaire should be completed, as used previously. The results of a recently conducted survey have shown clearly that this title is highly appreciated by the IFAPP membership. A call for applications will be sent out during the course of 2022.

The scope of the Education and Certification WG is based on IFAPP's overall strategy and mission to promote Pharmaceutical Medicine with regard to the discovery, development, research and use of medicines. As a basis for training programmes, the PharmaTrain Syllabus v2.0 (1) is used.

Birka Lehmann, MD PhD GFMD

ECWG Chair

(1) PharmaTrain Syllabus v2.0 <https://ifapp.org/about/pharmatrain-syllabus>



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Dr Ellen Evelaar New NVFG President

'In memory of the recent International Women's Day of 8 March 2022, IFAPP celebrates the election of Dr Ellen Evelaar to be the new president of the Dutch association and the first woman in this position for 60 years.'

Dr Evelaar expands on her new role and her background as follows:

I am honored to take on this role and contribute to the committee's mission together with the board. After obtaining a PhD and 15-year practicing as a clinical Gynecologist, I specialised in Pharmacovigilance for various medicinal products (e.g., gene therapy, immunotherapy/cancer vaccines) and medical devices. I developed to a senior professional executive with global experience as (1) EU-QPPV (e/o USA)* and (2) director of Pharmacovigilance departments of several small to big-size Pharmaceutical and Biotech companies.



During those years, I gained experience in all aspects of medical, clinical (drug/device) and pharmacovigilance process developments and management in close collaboration with the medical affairs, clinical and regulatory departments (including food and vaccines) in the Life Sciences industry. As an Auditor I performed several professional services (health inspections and audits) successfully.

Dr Ellen W. Evelaar MD PhD

President of the Dutch Association of Pharmaceutical Medicine in The Netherlands (NVFG)

*EU-QPPV: European Qualified Person Pharmacovigilance, also in the USA under certain conditions

Training as a Specialist in Pharmaceutical Medicine at Swissmedic

Swissmedic, the Swiss Agency for Therapeutic Products, announced on 20 January 2022 that it had been certified as a category A training institution in Pharmaceutical Medicine (<https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/weiterbildung-facharzt-pharmazeutische-medizin-bei-swissmedic.html>).

IFAPP TODAY took the opportunity not only to extend its congratulations but to address some questions to Dr Stephanie Juritz, Senior Clinical Assessor, Dept. Clinical Assessment, Swissmedic, and member of SGPM, the Swiss Society of Pharmaceutical Medicine, one of the two IFAPP National Member Associations (NMAs) from Switzerland, the other being SwAPP (Swiss Association of Pharmaceutical Professionals).



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IFAPP TODAY: Dr Juritz, could you please kindly explain what the definition of category A training institution means?



Dr Juritz: The training as a Specialist in Pharmaceutical Medicine lasts five years, comprising three years of specialist training in pharmaceutical medicine and two years of patient-focused

clinical training (non-specialist training). The three years of specialist training can be preceded by an elective year at a recognised institution providing advanced training in clinical pharmacology and toxicology, or in prevention and public health. Up to one year of research activity or MD/PhD training can also be credited. The advanced specialist training is provided at recognised training institutions in Switzerland which, depending on their certification (category A-D), offer specialist training lasting between six months (category D) and the full three-year specialist training programme (category A). Swissmedic meets all the requirements for the full advanced specialist training programme (<https://www.siwf.ch/weiterbildung/facharztstitel-und-schwerpunkte/pharmazeutische-medizin.cfm#>).

IFAPP TODAY: Will this new certification make Swissmedic an even more attractive employer for physicians on their career path to becoming a Specialist in Pharmaceutical Medicine than it already is? And – vice versa – do you expect that pharmaceutical physicians will become even more attractive candidates for demanding positions in the pharma and biotech industry with a background of specialty training at a regulatory body?

Dr Juritz: Yes, we do believe that recognition as a category A training institution makes Swissmedic considerably more attractive as an employer for people seeking to qualify as a Specialist in Pharmaceutical Medicine. Physicians with at least two years of patient-focused, non-specialist clinical training receive comprehensive advanced training at Swissmedic (see below) and can acquire the nationally recognised title Specialist in Pharmaceutical Medicine after three years of advanced specialist training at Swissmedic. We expect the career prospects in pharmaceutical medicine to be very good for these individuals who combine clinical experience with advanced specialist training provided by a regulatory authority culminating in the title of Specialist.

IFAPP TODAY: In which year was pharmaceutical medicine accepted as a distinct medical specialty in Switzerland, and when did Swissmedic start participating in the corresponding specialist training? How many colleagues have benefited from training at the Swiss authorities since it began, and how many are currently involved?

Dr Juritz: The title Specialist in Pharmaceutical Medicine has been recognised in Switzerland since 1 January 1999. Swissmedic was recognised as a category B training institution until 2014. It was recertified as a training institution in 2019, when it was provisionally classified as category A. Following a successful visit in 2021, during which we presented an updated and expanded advanced training concept, the Swiss Continuing Education Commission confirmed our status as a category A institution.



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Swissmedic can accommodate two people on the training programme at any one time. The conditions for inclusion in the advanced training programme are a licence to practise medicine and at least two years of patient-focused post-graduate clinical training. The trainee must also be employed by Swissmedic.

Both training places are currently filled. One physician who has completed the training has applied to the post-graduate medical training institute (SIWF) to be awarded the title of Specialist, and we hope that will happen soon.

IFAPP TODAY: Which competences constituting the specialty training can be gained at Swissmedic, and which are left to other institutions, presumably pharma and biotech companies and certain academic settings? Are training participants required to rotate among various departments?

Dr Juritz: The advanced training provided by Swissmedic is very wide-ranging, and the content is taught in the Authorisation, Licensing and Market Surveillance organisational units. The focus is on the core areas of discovery and early-stage development, registration and authorisation, pharmacovigilance and risk management, ethics and patient protection, and communication and management.

The training content is taught at Swissmedic through day-to-day activities in the corresponding organisational unit (e.g., Registration and Authorisation) and additionally through work shadowing in other organisational units at Swissmedic. The advantage of work shadowing over rotation is that shadowing is more flexible, and the tasks performed, and time involved can be tailored individually based on existing knowledge and skills. Practical advanced training at Swissmedic is rounded out by theoretical training. The content of these diploma courses is based on the IFAPP/PharmaTrain syllabus for the diploma (base) course in pharmaceutical medicine (www.siwf.ch).

Training participants who have at least two years of patient-focused, non-specialist post-graduate clinical training can acquire all the specialist knowledge and skills required for the title of Specialist in Pharmaceutical Medicine through the comprehensive advanced training opportunities offered by Swissmedic.

IFAPP TODAY: Do Swiss institutions certified for specialty training in pharmaceutical medicine have a common platform for further development of the discipline at the national educational level? Do you exchange programmes, experience and thoughts with other regulatory agencies, particularly in the United Kingdom and Ireland, the other two European countries where pharmaceutical medicine enjoys specialty status?

Dr Juritz: The institutions that provide specialty training in Switzerland exchange information regularly at the national level. Regular meetings are held to revise relevant training documents (e.g., advanced training programmes), exchange views and author publications. We have recently started organising workshops at the training institutions. This enables training participants to gain experience of other training institutions which have a different focus and to cover additional aspects of the training objectives. There are currently no direct exchange programmes with training institutions in other countries. One aspect of the work done by Swissmedic and the advanced training it provides that deserves to be mentioned,



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though, is the specialist exchange and joint activities pursued with other regulatory authorities. These include active membership of ICH and WHO working groups, collaboration with other regulatory authorities (TGA in Australia, Health Canada, HSA in Singapore, MHRA in the United Kingdom) in the Access Consortium and active participation in the assessment of oncological applications under Project Orbis (an initiative of the Oncology Center of Excellence run by the US Food and Drug Administration). These opportunities provide training participants with insight into and in-depth knowledge of the principles of drug development (ICH working groups) and of the assessment and regulatory requirements of authorisation bodies in other countries.

IFAPP TODAY: Do you know why there is only a handful of countries worldwide that acknowledge pharmaceutical medicine as a distinct medical specialty, while at the same time the spectrum of tasks for which physicians are responsible over the life cycle of medicines and medical devices has become significantly broader in recent decades? Is there a potential conflict with other medical specialties?

Dr Juritz: A separate title Specialist in Pharmaceutical Medicine is currently only recognised in a few countries: UK, Ireland, Mexico, and Switzerland; Nell, 2017 (1). Some countries also have specialist diplomas, but these do not confer separate medical titles.

In our experience there is a great need for this training, not least because specialisation is also increasing in drug development, and the corresponding scientific and regulatory expertise and skills are therefore a decisive aspect in the successful development of a medicinal product.

In Switzerland, the content of the advanced training programmes for specialists in Prevention and Public Health and Clinical Pharmacology and Toxicology overlaps to some extent. This is why up to one year of advanced training at a correspondingly accredited training institution that teaches these courses can be credited towards the advanced training for Specialists in Pharmaceutical Medicine.

Furthermore, the Swiss Society of Pharmaceutical Medicine is part of the Swiss Society of Pharmacology and Toxicology (SSPT) and is closely allied with the Swiss Association of Pharmaceutical Professionals (SwAPP). Knowledge is shared across these organisations at annual conferences, for example.

IFAPP TODAY: And finally, as a pharmaceutical physician with experience of working in both industry and regulatory functions, what advice would you give to colleagues worldwide concerning education and training on the way to specialist recognition or equivalent?

Dr Juritz: The basis for advanced training as a Specialist in Pharmaceutical Medicine is a licence to practise medicine and at least two years of post-graduate clinical training. The advanced training provided by the training institutions is linked to the professional activities performed there. The candidate therefore needs to focus on both the specialist qualification and the job description issued by the training institution. Advanced training at a category A training institution is advantageous for candidates because these institutions offer comprehensive insight into the specialty, and training participants are able to spend their entire training period at one institution. As a category A training institution and, in particular, an internationally networked regulatory agency, Swissmedic offers the opportunity to work in different relevant areas of the advanced specialist training (e.g., registration and authorisation or licensing/clinical trials) and to acquire additional knowledge through work shadowing in other organisational units.

1. Nell G: The Specialty of Pharmaceutical Medicine. In Vohora D, Singh G: Pharmaceutical Medicine and Translational Clinical Research, 2017, pages 3-15, Elsevier, <https://doi.org/10.1016/C2014-0-01796-0>



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The interview on behalf of IFAPP TODAY was conducted by **Dr Johanna Schenk FFPM GFMD**, Hochheim am Main, Germany, Member of the IFAPP Communication Working Group, and IFAPP President from 2000-2002.

Dr Stephanie Juritz, Senior Clinical Assessor, Dept. Clinical Assessment and Head of Further Education Pharmaceutical Medicine, Swissmedic, Bern, Switzerland, in cooperation with Dr **Mario Iovino, Clinical Assessor**, Dept. Clinical Assessment and Deputy Head of Further Education Pharmaceutical Medicine, Swissmedic, Bern, Switzerland.

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Pharmaceutical Medicine Modules



EL.E.F.I., the Hellenic Society of Pharmaceutical Medicine, in collaboration with Deree - The American college of Greece, are organising a 32-hour (8 meetings) course for scientists and early-career researchers who wish to develop their understanding of ethics in research and publication processes.

The course is delivered by an accomplished group of international and national academics, biomedical researchers, legal & research ethics experts, biolaw & bioethics experts, academic clinical investigators, medical consultants and members of ethics committees of research institutions.

The programme will help participants understand the ethical principles and standards required in research

projects and will cover related issues such as researcher responsibilities, subjects' rights, research publication standards based on ICJME & COPE guidelines, research regulation and ethics committees, open science, conflict of interest and ethical challenges in advanced therapies and use of new technologies.

The course is designed for researchers from a wide range of sciences including recent PhDs, Postdocs, Academics, R&D scientists, BSc, MSc, MDs, Biomedical Scientists, PharmDs, MPH.

May 5 - June 23, 2022 | EET 15:00-19:00

(a total of 32 hours)

live-online in English, via Zoom

For more Information please click [here](#).

To register please click [here](#).



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Pharmaceutical Medicine Modules

Patient Safety Surveillance:
Pharmacovigilance & Pharmacoepidemiology

Enhance your knowledge & skills in cutting-edge patient safety aspects!

Participants will learn how to design and manage patient safety aspects and to assess research safety in light of new technological tools used for monitoring patient safety, current pharmacovigilance frameworks, modern Pharmacoepidemiology methodology research & guidelines, and COVID-19 medicines and vaccines.

The course is designed for researchers from a wide range of disciplines including Biomedical and Pharmaceutical Sciences. It is appropriate for recent PhDs, BSc, MSc, MDs, PharmDs, MPH and young professionals interested to advance their career in Pharmacovigilance.

MAY 4 – JUNE 22, 2022 / EET 15:00-19:00

(A TOTAL OF 32 HOURS)

LIVE-ONLINE IN ENGLISH, VIA ZOOM

For detailed information and to participate: Register [here](#).

Brigitte Franke-Bray, Treasurer IFAPP, Elected to PharmaTrain Board and Executive Committee



The IFAPP Board wishes to congratulate Brigitte Franke-Bray, MD PhD FFPM GFMD, Treasurer IFAPP, to her recent election to the Board and, subsequently, to the Executive Committee of PharmaTrain <https://www.pharmatrain.eu/> as one of two Vice Presidents.



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The International Federation of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) and the Hellenic Society of Pharmaceutical Medicine (EL.E.F.I.) invite you to the 20th International Conference on Pharmaceutical Medicine - ICPM 2022 “What lies ahead in Pharmaceutical Medicine” (October, 19th-21st, 2022 ||Book Castle, Stavros Niarchos Foundation Cultural Center - Athens, Greece).

At a critical moment of war and humanitarian crisis in Ukraine with the hope for its swift resolution and beyond pandemic uncertainties, EL.E.F.I. and IFAPP remain dedicated to deliver the long awaited ICPM 2022, as an exceptional hybrid educational experience.

Due to current circumstances that might impact educational activities in 2022 and, as many of our guest speakers from Greece and abroad may face difficulties travelling to an in-person conference, we have already included the opportunity for online participation of congress faculty members and attendees.

The ICPM 2022 will present the latest advances in modern Pharmaceutical Medicine with a wealth of Biomedical & Clinical Research sessions. IFAPP & EL.E.F.I. are committed to making new scientific data on New Technology Development Platforms, Precision Medicine, Advanced Clinical Medicine, Career Development and Professional Competencies in Pharmaceutical Medicine accessible to all professionals working in Pharmaceutical Medicine.

We are optimistic that the virtual and in person experience format of the Conference will facilitate opportunities for networking and interaction with our members, the academic community, researchers, clinical investigators, stakeholders and trigger lively discussions, either onsite or in online forums.

Mark your calendar, register now and don't forget to submit your abstract before the 12th of June 2022.

We are excited to welcome colleagues and attendees in live plus ICPM 2022!

Visit our ICPM 2022 [website](http://www.icpm2022.gr) for detailed information.

THE FLAG

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IFAPP Communication Working Group

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