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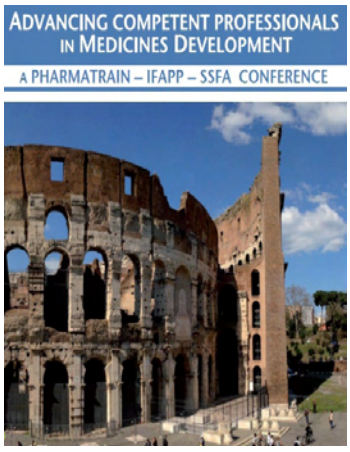
IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS & PHARMACEUTICAL MEDICINE

CONFERENCE REPORTING



ADVANCING COMPETENT PROFESSIONALS IN MEDICINES DEVELOPMENT

– Reports from a PharmaTrain – IFAPP – SSFA* Conference held in Rome, Italy, 10th -11th June 2015 –

* SSFA: Societá di Scienze Farmacologiche Applicate – Society for Applied Pharmacological Sciences, the IFAPP member association in Italy

The presentation slides of this conference are available to download on SSFA's website [click here]

REPORT I

CELEBRATING THE FIRST 40 YEARS OF IFAPP

CHAIRPERSONS: Dr Honorio Silva (IFAPP) & Dr Marco Romano (SSFA)

Forty years ago the life of physicians in the pharmaceutical industry was not particularly enviable because there were not many physicians employed in each company and jobs in the industry came to be regarded as having a low status by others in the profession. Today the biopharmaceutical industry has become an interesting employment opportunity for biomedical professionals involved in medicines development. Pharmaceutical medicine is an established discipline and the profession has emerged as a solid career path comparable to that of serving the community in academic institutions, research centers, regulatory agencies or clinical practice.

Significant efforts and contributions have been made since the initial conception of the founders of IFAPP to the current network of 30 National Member Associations (NMAs) involving around 7000 professionals all over the world. Education has been the cornerstone of IFAPP activities, evolving from informal educational programs to postgraduate education and established Continuing Professional Development (CPD) activities, including international conferences. The role of the Faculty of Pharmaceutical Medicine (FPM) in establishing the first examination for certification in the United Kingdom (UK) as well as maintaining and raising the standards and guidelines for the medical practice of pharmaceutical medicine has been invaluable.

Executives from IFAPP, IFAPP Member Associations, and PharmaTrain at the Conference in Rome, Italy, 10th -11th June 2015

IFAPP adapted the initial syllabus prepared by the FPM and established an accreditation process for the growing number of academic institutions willing to offer postgraduate education in Europe, Latin America and Asia. IFAPP has worked closely with the NMAs to ensure the scientific and lay public that the development of medicines is in the hands of appropriately trained and up to date professionals.

The need for to build a more collaborative infrastructure for pharmaceutical R&D in Europe and to speed up the development of more effective and safer medicines was shared by the European Commission and its Innovative Medicines Initiative (IMI). The efforts of Prof Dr Fritz Buhler in Switzerland with support from other colleagues at the IFAPP Board led to the creation of the European Federation of Course Providers in Pharmaceutical Medicine (EFCPM). Both IFAPP and EFCPM were the core founding members of PharmaTrain, a consortium of academic institutions, learned societies and pharmaceutical companies sponsored by the IMI, which joined efforts to provide a European comprehensive solution to the education and training needs of professionals involved in medicines developments. PharmaTrain deliverables were an updated and harmonized syllabus, curriculum and quality standards for teaching pharmaceutical medicine across academic institutions in Europe.

PharmaTrain became the educational arm of IFAPP and a close collaboration has been developed over time. A working group from both institutions defined the core competencies (knowledge, skills, and behaviors) to perform effectively as a pharmaceutical physician in the development of better medicines.

In addition to be the foundation for outcomes based education, competencies can be used to define job descriptions, job portfolios, and career paths. The learning outcomes of the PharmaTrain program are effectively aligned with the core competencies, and thus the PharmaTrain program can provide the cognitive aspects of the core competencies. The skills and behaviors can be gained through a special on-the-job-based vocational program (Specialist in Medicines Development) recently developed by the PharmaTrain Federation, the successor organization to PharmaTrain, to be piloted in Italy and Japan in 2016.

The NMAs are consistently focused in providing services to the growing list of new members and are eager to participate more actively and collaborate with IFAPP in the implementation of educational programs and share best experiences. A positive response to the new initiatives and the concepts of certification and specialization has been granted. The perspectives for further advancement of pharmaceutical medicine as a discipline and profession look very optimistic, including strategic alliances and collaboration with key stakeholders. A long-term plan involving IFAPP's leadership and that of the NMAs has been put in place and hopefully would be achieved within the expected timelines.

This vision was fully shared by Dr Keith Bragman, FPM President, UK, who commented that only a large cooperation from all involved parties will achieve the ambitious target of a globally harmonized education.

Dr Honorio Silva,
IFAPP President Elect, USA

REPORT II

MEDICINES DEVELOPMENT – THE GLOBAL ENDEAVOR DEMANDS A GLOBAL E&T APPROACH

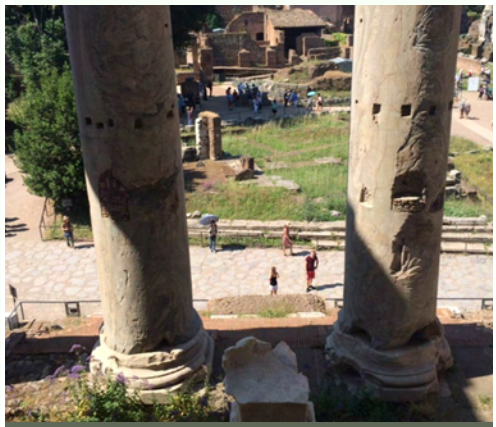
'BACK TO THE FUTURE' ROUND TABLE WITH IFAPP PAST PRESIDENTS

The PharmaTrain – IFAPP – SSFA Conference held in Rome on historic grounds from 10th -11th June 2015 started with the celebration of IFAPP's 40th anniversary. Five of the sixteen IFAPP past-presidents to date were invited to participate in a 'Back to the Future' session highlighting the evolution of pharmaceutical medicine (PM) as fostered by IFAPP and allied societies, as well as the pertinent IFAPP milestones.

Dr Luciano M. Fuccella, IFAPP President from 1990 to 1994, today Honorary SSFA Member, underlined IFAPP's vision of a global drug development commitment, the main theme of the International Conference on Pharmaceutical Medicine (ICPM) held in Rome in 1994. "Think global" was the way to go after medicines development had taken place piecemeal at national levels, frequently leading to diverging outcomes and labeling. Global development efforts demand, however, a common understanding of education and training (E&T) needs of the players and how to satisfy these.

Thus, the IFAPP program executed from 1996 to 1998 under the leadership of its President, Prof Dr Peter Stonier, United Kingdom, had – as highlighted by him at the current Rome conference – education already high on the agenda. It read:

- Encourage E&T of pharmaceutical physicians to a recognized high standard of competence for work in the global pharmaceutical industry.



The PharmaTrain – IFAPP – SSFA Rome Conference, a memorable meeting on historic grounds

- Strive towards a common standard of training, through introduction of a core syllabus of pharmaceutical medicine and development of structured training courses with their respective examinations and qualifications.
- Seek specialty recognition of pharmaceutical medicine.

In Dr Johanna Schenk's presidency (2000 to 2002) two IFAPP bodies were "built to last", one being the Working Party on Ethics, later renamed to PM Ethics Council (PMEC), and the Council on Education in PM (CEPM). The latter had its roots in the earlier Working Party on Education in PM, composed of IFAPP representatives and PM course providers. From its foundation in 2001, the CEPM has been a body constituted of national IFAPP member associations (NMAs) only closely cooperating with both established and emerging course providers and allied societies.

From the 1998 Boston ICPM, IFAPP's efforts to become a truly global federation were reflected by IFAPP meetings at the II Pan-American Conference in Buenos Aires, Argentina, in November 2001 and the 2002 ICPM held in Cancún, Mexico. Four of seven IFAPP presidents since that time came from the Americas or Asia, three only from Europe.

One of the latter, Dr Domenico Criscuolo, IFAPP President from 2002 to 2004, today Head of the IFAPP WORLD Editorial Board and the Italian member of the IFAPP House of Delegates, strengthened the educational cooperation with the European regulatory authorities in annual EMEA- (earlier acronym for European Medicines Agency) IFAPP Conferences during his term. He engaged himself in the recruitment of new member associations, thus, enlarging the platform for common standards in PM matters and, particularly, E&T.

Prof Dr Gerfried Nell, Austria, the fifth past-

president in attendance who was at the IFAPP helm from 2008 to 2011, has been a strong supporter of IFAPP's constitutional aims of fostering the development of training and continuing educational programs in PM. This is mirrored by his active engagement in the collaboration effort between IFAPP and PharmaTrain.

As highlighted in this Back-to-the-Future session E&T is the foundation for the entire value chain in medicines development. IFAPP has been pursuing this path with patience and persistence from its foundation. E&T is now more than ever before a core IFAPP activity driven by currently 30 national member associations from all continents. For good reasons it includes E&T of medicines development scientists nowadays.

Moving forward and going beyond E&T, deployment of professional social media for efficient, real-time and cost-effective global communication on PM and IFAPP matters, as well as a PMEC revitalization, were strongly recommended. "Who if not pharmaceutical physicians should have a primary responsibility for ethics in PM operations?" asked Dr Schenk in her concluding remarks.

Dr Johanna Schenk, IFAPP Editorial Board Representative, Germany

REPORT III

EDUCATION IN PHARMACEUTICAL MEDICINE: PRESENT AND FUTURE

CHAIRPERSONS: Dr Ingrid Klingmann (PTF) & Dr Gustavo Kesselring (IFAPP)

This session was fully devoted to what has been done in the last decade regarding education and training in pharmaceutical medicine (PM) by multiple stakeholders in academia and in the pharmaceutical industry.

Dr Mike Hardman from AstraZeneca gave an overview on how the Innovative Medicines Initiative (IMI) has been conceived by the European Commission that looked forward to accelerate drug development mainly in Europe through all research and educational platforms and institutions already established in this region. In this context he has explained the IMI-Train as a European partnership of the public and private sector to provide education and training solutions in the medical, biomedical and pharmaceutical sciences, which meet the needs of the pharmaceutical industry, of regulatory agencies, academic institutions, and healthcare systems through its global training course offers and training services. An interesting example on how the same concept works in other industries is the recently opened (September 2014) University Technology College Model for engineers in the auto industry.

Dr Ingrid Klingmann, PharmaTrain Federation, (PTF) presented PharmaTrain's main objectives:

- «To provide a Europe-wide comprehensive solution to training needs of integrated medicines development (sciences) for all professionals involved, incl. physicians, pharmacists, pharmaceutical scientists, biologists, biometricians, health economists, safety and regulatory scientists from universities, regulatory agencies, all industry as well as research ethics committees and investigators.

- To create (new) and integrate existing multi-modular programs of advanced studies in pharmaceutical medicine/ medicines development sciences leading to a postgraduate Diploma or Master of Science, based on the Bologna credit and title system with 30, respectively 60+ ECTS [European Credit Transfer System] credits.
- To establish the concept for on-the-job-based competence development, leading to a "Specialist in Medicines Development" for physicians and non-physicians.»

This ambitious long-term program is being fully supported by IFAPP.

Dr Antonio Torsello, University of Milano-Bicocca, and Dr Francesco de Tomasi, Università Cattolica del Sacro Cuore in Rome, explained how the two master courses in drug development, accredited by PharmaTrain as Centers of Excellence in Italy, are organized. Those courses have been running in Italy since 2007 and have already graduated 490 students with a high satisfaction and a high degree of employment for all graduated students.

Prof Dr Peter Stonier from the PTF has described the concept of a Specialist in Medicines Development (SMD). Currently, academically in medicine or life sciences qualified persons working in medicines development are trained on the job and undertake continuing professional development (CPD) or participate in university training courses to achieve a secondary diploma and/or master degree. All this leads to a certain individual array of competencies across multiple domains. So far, there is no qualification, degree or award available in most countries, which certifies the successful training described, and the PharmaTrain SMD certification concept and program aims to fill this gap.

An SMD program has started in 2015 in Italy and Japan with a joint collaboration between the IFAPP National Member Associations in both countries and the PTF. According to Dr Heinrich Klech, PTF, this program is overseen by a Global Certification Board with members from Europe, Japan, USA, Latin America and South Africa.

Dr Kyoko Imamura from the Japanese Association of PM (JAPhMed) has illustrated how the SMD certification program is being implemented in Japan in close collaboration with the Osaka University as a PharmaTrain Center of Excellence. Their plan is

to raise awareness of the value of education, training and certification by a third party in Japan, to develop a consortium of relevant parties for wider recognition in the society and realize joint recognition of SMDs in industry, academia and regulatory authorities.

Prof Dr Sandor Kerpel Fronius, Semmelweis University, Hungary, has focused on aspects of education and training needs in medicines development, regulation and clinical research in low- and middle-income countries. He concluded that local experts and organizations should coordinate education in such countries. However, international cooperation is recommended and the internationally accredited educational material should be tailored in content and complexity to local needs.

Dr Honorio Silva, IFAPP President Elect, has presented the global perspective of competencies for the clinical research enterprise. Describing the inefficiencies in clinical research he has addressed the value of professional competencies and the results of the Joint Task Force (JTF) on clinical trials core competencies and the international validation of JTF competencies and educational needs assessment. This competency approach is being developed in all educational programs of PharmaTrain and IFAPP.

Finally Dr Jean-Marie Boeynaems from the European Clinical Research Infrastructures Network (ECRIN) presented the Clinical Investigator Course (CLIC) program as a clinical investigators training. Despite its hurdles it is making progress and has inspired European initiatives in France, Portugal, Hungary and had an impact in Japan.

All presentations clearly showed that only a joined effort with all stakeholders – industry, academia and regulators – will win the challenge of education and training needs in the clinical research enterprise.

Dr Gustavo Kesselring, IFAPP President, Brazil

REPORT IV

ADVANCING COMPETENT PROFESSIONALS IN MEDICINES DEVELOPMENT

CHAIRPERSONS: Dr Peter Stonier (PTF) & Dr Domenico Criscuolo (SSFA)

The last session of the Conference was entirely devoted to the analysis of the Italian status of training in pharmaceutical medicine, as this can be appreciated from different points of views. The first two speakers illustrated their opinions in their role of regulators. Prof Dr Sergio Bonini, European Medicines Agency (EMA), remarked that many training initiatives are currently ongoing, both at the EU level and the national level. He mentioned the efforts put in place by the Faculty of Pharmaceutical Medicine (FPM), by IFAPP, by the PharmaTrain Federation (PTF), and finally he underlined the key role played by several EU universities, which have established master courses in pharmaceutical medicine/medicines development sciences many years ago. He stated that for the EMA as well training is a priority, and in fact a lot of support is offered to several educational activities. As an example to reinforce the key role of a higher education of pharmaceutical medicine professionals, he mentioned that the EMA is fully committed to grant adaptive licensing to innovative drugs, but this approach requires well-trained professionals, able to capture any signal arriving from patients' experience. He concluded stating that the ideal training should be delivered by a joint network of universities, regulators, scientific associations and the pharmaceutical industry. His suggestions were immediately reinforced by Dr Sandra Petraglia from AIFA, the Italian Medicines Agency, who noted that in Italy there is still a significant lack of training in particular for clinical investigators participating in highly complex clinical trials with most innovative drugs.

Dr Mariapia Cirenei from AICRO, the Italian network of contract research organizations (CROs), underlined that training of professionals employed in CROs became mandatory in Italy by law in November 2011, which clearly defined training obligations of most professionals working in drug development within CROs (strangely enough, not a similar requirement is in place for people working in the pharmaceutical industry). She commented that the quality of CRO services and deliverables in Italy definitely increased after implementation of this law. Today, CROs in Italy are well prepared for future challenges, which certainly will arise from the new EU Clinical Trial Regulation, she concluded.

The last two speakers were representatives of two learned societies, which are highly committed to education. Prof Dr Luca Steardo, Italian Society of Pharmacology, underlined once again the significant dedication to education in pharmaceutical medicine demonstrated over several years by specialized bodies like IFAPP, the FPM and the PTF. Prof Dr Massimo di Maio, Italian Association of Medical Oncology, reported that oncology should lead the way of education, as nearly 40 percent of clinical trials involve cancer patients. He commented that significant progress was made in the last two decades with the formation of networks of collaborative groups, able to recruit large patient populations in a short period of time, and at the same time disseminating the culture of education in clinical trials. He also reported that the association of oncologists is working hard on several programs, from the certification of clinical sites to guarantee quality and competence to the institutional recognition of key professional roles, like the ones played by clinical research coordinators, research nurses and data managers.

In closing the session, both chairpersons expressed high appreciation for the messages delivered by all speakers, who made a continuous reference not only to the pioneer role in education played by IFAPP, the FPM and the PTF, but even more to the need for a better educational approach for all professionals involved in medicines development, from clinical investigators to regulators, and to professionals working in the pharmaceutical industry and CROs.

Dr Domenico Criscuolo, IFAPP Delegate, Head of IFAPP WORLD Editorial Board, Italy

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The Flag

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