IFAPPWORLD
INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS & PHARMACEUTICAL MEDICINE

CONTENT

Testimonials about the IFAPP-Rutgers-PT Programs

Supporters for the IFAPP-Rutgers and PharmaTrain Certification and Specialization Programs in Medical Affairs and Clinical Development have offered testimonials about the value of this program for health care professionals and pharmaceutical companies:

Michael Rosenblatt, M.D., Executive Vice President and Chief Medical Officer, Merck & Co. Inc., New Jersey, USA: "We are pleased to be supporters of the new IFAPP-Rutgers Certification Program in Medical Affairs and Clinical Development. The physicians and other professionals who serve in these areas are positioned at a dynamic and critically important interface between the biopharmaceutical industry and the medical community.

Their role is to communicate data-driven findings to the medical world while obtaining input from physicians and leaders in medicine about clinical issues and the direction that medicine is taking. Critically important to their success and contributions will be training in the sciences fundamental to medicine and the principles of medical affairs as a discipline. The IFAPP-Rutgers collaboration is an important offering in this regard for people choosing a career in medical affairs and for the biopharmaceutical industry."

Rory O'Connor, M.D., Senior Vice President, Head of Global Medical Affairs, Pfizer Inc., New York, USA: "I would say that building and maintaining colleague skills is probably the most important element in managing a large complex pharmaceutical organization, and medical colleagues have particular needs in this regard. Through its relationships with [IFAPP's] National Member Organizations, and connections with other professional bodies such as the Drug Information Association (DIA), IFAPP plays a central role in supporting appropriate educational programs. >>>

LEAD STORY

IFAPP-Rutgers and PharmaTrain Certification and Specialization Programs in Medical Affairs and Clinical Development

Certification refers to the confirmation of certain characteristics of an object, person, or organization. This confirmation is often, but not always, provided by some form of external review, education, assessment, or audit. One of the most common types of certification in modern society is professional certification, where a person is certified as being able to competently complete a job or task, usually by the passing of an examination. On the other hand, specialization is a type of certification, usually required for licensure (for professional practice).

In spite that fostering the development and international recognition of pharmaceutical medicine as a separate medical specialty has been one of the key goals for IFAPP since its inception, the objective has been only partially met. A number of possible explanations (not enough advocates, lack of awareness of the discipline among the country decision makers, no established need for licensure since pharmaceutical medicine does not involve clinical practice, limited recognition to new medical specialties at the country level) can be attributed to such lack of success.

IFAPP (with the support of the BioPharma Educational Program at Rutgers University) and PharmaTrain are entitled to provide professional certification to its membership in a two-step process. The *level I Certification in Medical Affairs and Clinical Development* (covering the cognitive aspects of the core competencies) will be offered worldwide by IFAPP-Rutgers through online continuing professional development (CPD). The *level II Certification* (*Specialist in Medicines Development* award) includes a vocational program (aimed to developing skills and behaviors) to be offered by PharmaTrain (with the support of IFAPP and its national member associations) on country-by-country bases. Pilot experiences will be run in Italy and Japan in 2016. Details of the *Specialist in Medicines Development* (SMD) program have already been published in IFAPP WORLD [1- 4].

Medical affairs organizations have emerged over the past half century in response to federal regulations around the separation of medical and commercial activities within drug companies. Medical affairs organizations aim to provide patient- and physician-centered services as part of a new business model aimed to provide value in healthcare. Many companies also chose to focus research and development (R&D) resources on developing new products and moved post-launch activities, such as finding new indications for existing drugs, into the medical affairs function.

Continued pressures from regulatory agencies and public sentiment have >>>

>>> The IFAPP-Rutgers Certification Program in Medical Affairs and Clinical Development will materially enhance this impact and influence."

Karel Verkoelen, M.D., Vice President Medical Education and Training – Global Medical Affairs, Sanofi, France: "At Sanofi Medical Affairs we have decided to support the IFAPP-Rutgers Certification Program in Medical Affairs and Clinical Development because we firmly believe that there is a need for excellent educational programs in support of *excellence* in the practice of medical affairs. We also love the fact that this program will be conceived from the onset as an online program facilitating a global implementation within Sanofi's medical affairs community. In addition the collaboration with Rutgers University & IFAPP adds robust credibility to the certificate."

Michael Devoy, M.D., Head of Medical Affairs & Pharmacovigilance and Chief Medical Officer at Bayer Pharma AG, Germany: "The topic of medical education and training is one that we feel passionate about at Bayer. There is a lack of consistent, high-quality training options in the biopharmaceutical industry for physicians and other professionals across the world that are developing medicines to help patients. The new IFAPP-Rutgers Certification Program in Medical Affairs and Clinical Development is aimed to equip professionals interested in this sector with the fundamental knowledge necessary to guide medical innovation while upholding the highest ethical standards. By supporting the IFAPP-Rutgers program in collaboration with other industry partners, we seek to not only promote a culture of clinical excellence and scientific rigor in the biopharmaceutical industry but also to inspire people to embark on a career in medical affairs. We hope that you will take full advantage of this opportunity." ■

>>> pushed more and more activities into medical affairs organizations. Today, these organizations commonly involve the following medical activities: medical education, medical field teams, post-launch clinical trials, medical information services, medical communications, medical strategic activities, medical grants, publications, health economics, and outcomes research. These functions make relevant contributions in the decision-making process among key medical stakeholders and customers by facilitating coordination and integration of medical data and knowledge.

The competencies to perform effectively in medical affairs are aligned with the overall competencies in medicines development and the needs to acquire and develop the talent through education and training are emerging worldwide. Some specific functions, such as medical science liaisons may benefit from a formal training in the discipline.

The *Professional Certification in Medical Affairs and Clinical Development* program has been designed to meet such emerging needs. This program will be offered by IFAPP in strategic alliance with Rutgers University and includes six highly interactive online CPD modules to be offered on quarterly bases and thus the certification could be achieved in a 6-to-12-month period. The learning outcomes will be aligned to the core competencies. Assessments will be conducted at the end of each module. The professional certification will be granted afterwards.

The initiative has received the support from major pharmaceutical companies (please note the testimonials on the left side) and national member associations and will be launched in the Q4'2016.

The biopharmaceutical and device industry has seen major changes over the past decade. As market pressures have intensified and commercial practices have come under closer scrutiny, there has been a marked increase in scientific rigor across the industry. A renewed emphasis on the importance of proper education and training aimed to provide an integrated perspective of medicines development and its related functions have been underscored by the public and private sectors. The new cadre of professionals is expected to understand business issues impacting the biomedical sciences and be able to interact and develop relationships with a broad range of stakeholders, including payers, patients and advocacy groups. The certification programs described above are expected to be part of the solution.

References

IFAPP WORLD
[1] February 2015 page 1-3;
[2] April 2015 p. 1-3
[3] August 2015 p. 3-4
[4] October 2015 p. 1-2.

Dr Honorio Silva,
IFAPP President Elect,
USA

The Spanish Association of Pharmaceutical Medicine (AMIFE)

40th Anniversary of AMIFE

The year 2015 was of special relevance for the Spanish Association of Pharmaceutical Medicine (AMIFE) – we celebrated our 40th anniversary!

Founded in 1975 by a group of pharmaceutical physicians, it was meant to create a platform for education, training and exchange of knowledge, skills and information. Currently a large number of pharmaceutical professionals, physicians, pharmacists, biologists, biochemists, dedicated to clinical research, regulatory affairs, market access, pharmacovigilance, medical science liaison, medical information, etc. are an essential and active part of our Association.

For this special event we invited two important guests:

Dr Ignacio Hernández Medrano, neurologist, graduated at the Singularity University (NASA Silicon Valley), CEO-Founder of Savana, a start up focused on artificial intelligence in electronic medical records and currently coordinator of clinical research in a first-line hospital in Madrid.

Dr Ignacio Hernandez Medrano developed a very interesting and highly impacting presentation on "The Future (not so far away) of Medicine", where science, technology, artificial intelligence, big data, nanotech, social networking, crowd sourcing, and computer science were all present and provided a novel insight into medicine. Bioprinting of human tissues, drones to bring drugs closer, fighting malaria through video games, organ on a chip, traditional drug discovery vs. recursion drug discovery, human genome project, DNA mapped at birth, cosmetogenomics, nutrigenomics for disease prevention and intervention are examples of current and future ideas and projects to be developed and delivered to people worldwide.

We were also honored by the presence of **Dr Honorio Silva**, IFAPP President Elect, Director, PharmaTrain Federation, Brussels, Adjunct Assistant Professor, Rutgers University School of Health Related Professions, Newark, NJ, USA. He elaborated on the current challenges pharmaceutical medicine and medicine development are facing as a >>>

>>> discipline and a profession, the emergence of outcomes-based education and the use of professional competencies to overcome such challenges.

Dr Silva compared traditional education versus competency-based education (CBE). CBE is emerging as a standard for undergraduate, and postgraduate education as well as for continuing professional development. Competencies are defined as the sum of knowledge, skill, behaviors and attitudes necessary for a particular set of tasks or objectives in a specific function. The competency-based educational programs offered by both IFAPP and PharmaTrain are an integrated and specific way to meet the worldwide needs for education and training in medicines development and its effective integration into the health care systems.

As discussed and agreed during the 40th AMIFE anniversary meeting and general assembly, AMIFE's strategic plan for 2016 to 2018 includes knowledge/recognition of the work performed in the pharmaceutical industry based on educational programs for pharmaceutical professionals, creation of new projects/activities, increase of visibility, with the final goal to achieve sustainability and growth of the Association.

Dr Anna Jurczynska
AMIFE Delegate to IFAPP, Spain

apms ASSOCIATION OF PHARMACEUTICAL MEDICINE (SINGAPORE)

1ST APMS SYMPOSIUM
Bridging the Gap in Medical Affairs

After two years of baby steps, the Association of Pharmaceutical Medicine Singapore (APMS) took a giant leap by organizing its first 1-day symposium focused on medical affairs. Close to 100 participants gathered at this interactive forum on October 30, 2015.

Senior leaders engaged with the audience on industry updates, not only via lectures but also debates on controversial issues, panel discussion and workshop.

These sessions brought to life the very real challenges that we face in our industry in Asia. Changes in the healthcare environment, highlighted by Rhenu Buller (Frost & Sullivan), have reinforced the necessity for medical affairs professionals to evolve from a support function to take a more proactive role. Ajay Tiku (GlaxoSmithKline – GSK) noted that the medical affairs function often exists within a matrix organization, reporting lines are spread across the traditional country, functions, and product group silos. A panel from GSK, Takeda, Novartis, and ProClinical then discussed traits that define "competence" and "talent" in medical affairs in Asia. Publication planning, a key competence of medical affairs function was described in the workshop led by Arti Dhar (MediTech Media).

John Lim (Duke-NUS Graduate Medical School) highlighted current efforts in regulatory harmonization by the Association of Southeast Asian Nations (ASEAN) Consultative Committee on Standards and Quality (ACCSQ) working groups, which have resulted in several recommendations, such as the ASEAN Common Technical Dossier (ACTD) and ASEAN Common Technical Requirements (ACTR). However, pragmatically, regulatory excellence should be aimed for through greater convergence across the region, rather than regulatory perfection through complete harmonization.

Hot debates took place with the participants voting their views on polemical issues such as "honoraria and conference sponsorship", "should medical affairs report to comercial?", "should medical affairs be involved in promotional activities?". Duels took place between respectively: Chern Seam Lim (Shire) vs. Priyanka Bhatia (GSK), Jayanti Visvanathan (Novartis) vs. Amar Kureishi (Alcon), Abhishek Bhagat (AbbVie) vs. Aileen Dualan (Novartis).

The APMS Faculty at the symposium (above)

A sea of hands during the debate as the audience actively engaged and took sides (right)

Drawing together the themes of the day, Sam Lim (AstraZeneca-JADE) emphasized that the future of the pharmaceutical industry is science, performed and communicated by highly skilled clinical scientists. Thus, a new collaboration, JADE (Janssen Asia-Pacific and Duke-NUS Education Initiative) has been forged to design and develop a high quality educational program for medical affairs professionals in the Asia Pacific region.

The APMS intends to be at the forefront of adapting to this changing landscape in Singapore and in Asia, by promoting pharmaceutical medicine as a distinct scientific discipline through training of young professionals and providing a platform for sharing experiences and best practices. This symposium is a stepping-stone for the APMS in its endeavor.

Dr Aileen Dualan,
APMS President, Singapore

Ethical Considerations Concerning Comparator Medication
A Response on "ETHICAL QUANDARY"

Under the heading "Ethical Quandary" IFAPP WORLD (December 2015 page 2-3) has asked their readers: *„Placebo-Controlled Clinical Trials in Low-Resource Settings – How Much Standard of Care is Necessary?"*

Professor Dr Hans-Dietrich Heilmann from Freiburg, Germany, has responded: "I think it may be absolutely acceptable ethically to use as comparator the optimal therapy that is locally available. This would also avoid persuasion or coercion of patients to participate in the study.

However, it may happen that FDA, EMA, or other agencies in high-standard countries would not accept such study for licensing the test product for the markets they regulate due to the lacking comparison with the best standard available there, in particular since the cost of a new therapy (influencing its availability to all patients) in high-standard countries might be comparable to or even higher than that of the best standard.

Thus it might be commercially (not ethically!) advisable to use the best standard overall as comparator in all countries." ■

The Disaster of Bari Harbor

A Case of Medical History by Domenico Criscuolo and Corrado Gallo Stampino

The toxic effects of yperite gas on lymphoid tissue, observed during one of the most important chemical disasters of the World War Two, laid the foundation for the development of modern anti-cancer chemotherapy.

"Over 600 mustard gas casualties occurred following the release of mustard gas in Bari Harbor on December 2, 1943".

The first words of the medical report written by Colonel Steward Alexander immediately suggest the severity of this episode.


THE MILITARY SURGEON

Original medical report by Colonel Steward Alexander

On December 2, 1943 a German air strike caused the destruction of an entire allied convoy in the harbor of Bari, Italy. It lasted only twenty minutes, but the raid was especially violent. The report speaks of 16 ships sunk and four very seriously damaged. One of these was the US cargo ship John Harvey and its bombing was responsible for one of the most serious disasters caused by chemical weapons during the World War Two. The US ship was loaded with hundreds of tons of bombs containing yperite, a highly lethal gas. The explosion produced a toxic cloud with an odor similar to that of garlic, according to the reports at the time, and which stayed in the area for several days. Furthermore, the yperite, mixed with naphtha and oil, created a slick on the surface of the water.

The newspapers of those days reported the event without ever mentioning the nature of the explosion. G. B. Infiel, in his essay "Disastro a Bari", sustains that Sir W. Churchill himself gave order that no mention was to be made of the presence of yperite on the allied ships and to attribute all deaths from burns as consequences of enemy action.

Immediately after the explosion hospitals were filled with hundreds of wounded who came into contact with the dense cloud of smoke formed by the gas mixed with naphtha. The contamination later hit also emergency workers who, while aboard boats trying to save the wounded or to recover bodies, were overcome by the yperite fumes that came from the sea surface. The healthcare workers first treated the victims for shock characterized by decrease in blood pressure, serious burns over the whole body, and lacerated and contused wounds.

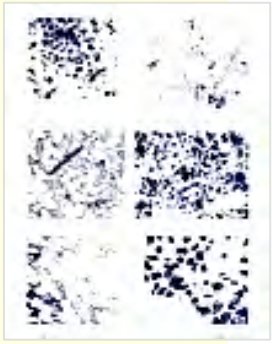
Twenty-four hours later the first deaths occurred, which alarmed the doctors and led them to their initial suspicions about the cause of the events. The first patients who presented extensive burns of various degrees and hypovolemia, progressively became more complicated with damages to the respiratory tract caused by the inhalation of gas vapors.

The US cargo ship John Harvey, loaded with mustard gas bombs, on fire

The intervention of a chemical consultant, Colonel Steward Alexander, sent by the American Headquarters, ascertained the nature of the agent, which was causing hundreds of victims. The rigorous military censorship of the time blocked the spread of the news regarding the consequences of the bombing, and not even the Italian civil and health authorities were informed. In his final report Alexander writes that 617 soldiers were exposed to the yperite gas and that 83 died.

An important issue was the documented aplasia of the bone marrow, and especially of the lymphoid tissue. A few decades earlier, in 1919, E. B. Krumbhaar, a researcher at the University of Pennsylvania, reported in The Journal of Medical Research the effects produced from exposure to military gases. Yperite was widely used during World War One, especially in Ypres, Belgium, the city which gave the name to the gas. Krumbhaar's publication contains interesting observations concerning the alterations of the lymphoid and hemopoietic tissues. Even though the same type of alterations which were observed following the bombing in Bari were noted, at that time there were no investigations about the potential activities of nitrogenous mustard gases for therapeutic purposes.

With the event of World War Two – especially after the episode in Bari – scientific research realized the therapeutic potential of nitrogenous mustard gases in the regression of tumor tissues.



Histologic sections of bone marrow with cellular alterations caused by yperite gas

The marked effect of nitrogenous mustard gases on lymphoid tissue prompted further investigation on the effects of these compounds, and suggesting their therapeutic use in the treatment of cancer. Bypassing obstacles of purely chemical nature and utilizing chloride salts of nitrogenous mustard gas, it was possible to administer by parenteral route what would become the first reference drug for treating tumors. One of the first clinical trials was conducted on a group of six cancer patients in terminal phase. The most marked effects were found in patients affected by Hodgkin's disease. The treatment was repeated at intervals varying from one to eight months. The preliminary evaluations conducted on a small number of patients were considered of interest and in 1946 there were already 150 cancer patients treated with nitrogenous mustard gas. Marked side effects, such as nausea, vomiting, neutropenia, anemia, and thrombocytopenia, complicated the first administrations of the drug. It has only recently been possible to correct these adverse reactions by the use of growth factors and the introduction of antiemetic drugs.

Since World War Two a lot of progress has been made in the discovery and development of anticancer drugs. Sometimes, however, scientific research takes advantage of discoveries that occur by serendipity. In this event the wartime development of a dreadful weapon, together with the clever observations of some physicians, turned into the basis for modern anticancer chemotherapy. ■

The Flag

IFAPP WORLD is a publication of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine.

IFAPP, a non-profit organization founded in 1975, acts as an international forum for all pharmaceutical medicine professionals' organizations worldwide by dealing with matters brought to its attention through national member associations.

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18th | International Conference on Pharmaceutical Medicine

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Program Summary

18 April 2016 (Monday)

Nobre auditorium

09:00 - 09:45	**Opening Ceremony**	
09:45 - 10:30	Keynote session **Integrating clinical research into healthcare**	
10:30 - 11:00	Coffee Break	
11:00 - 12:30	Panel **The future of Medical Affairs organizations in pharmaceutical companies**	
12:30 - 13:30	Lunch Break	
	São Paulo auditorium	**Brasil auditorium**
13:30 - 15:00	Concurrent sessions 1 **Social media and its impact on the pharmaceutical business**	Concurrent sessions 2 **Biosimilars: challenges in drug development and pharmacovigilance**
15:00 - 15:30	Coffee Break	
15:30 - 17:00	Concurrent sessions 3 **Global perspectives for Medical Science Liaison professionals**	Concurrent sessions 4 **Challenges in Health Technology Assessment (HTA) with new drugs**
17:00 - 18:00	Late sessions 1 **The future of professional development in Clinical Research and Drug Development Sciences: Professional Certification, Accreditation and Specialization**	

19 April 2016 (Tuesday)

Nobre auditorium

09:00 - 10:30	Plenary session 1 **The future of education in Drug Development Science and Pharmaceutical Medicine**	
10:30 - 11:00	Coffee Break	
11:00 - 12:30	Plenary session 2 **Ethics in Medicines Development: where we stand and where we go**	
12:30 - 13:30	Lunch Break	
	São Paulo auditorium	**Brasil auditorium**
13:30 - 15:00	Concurrent sessions 5 **Drug development in the emerging markets: challenges to reach the global market**	Concurrent sessions 6 **Research institutes in private hospitals and Brazilian clinical research**
15:00 - 15:30	Coffee Break	
15:30 - 17:00	Concurrent sessions 7 **Preclinical studies and Drug development in Brazil: A joint session with Brazilian Society of Pharmacology and Experimental Therapeuthics (SBTFE)**	Concurrent sessions 8 **The future of clinical development: trends and challenges**
17:00 - 18:00	Late sessions 2 **Rare Diseases: access, marketing and ethics challenges**	
18:00 – 18:30	Final remarks	