IFAPP WORLD
International Federation of Associations of Pharmaceutical Physicians
KEEP IN TOUCH WITH IFAPP • WWW.IFAPP.ORG
II·2008·AUGUST

CONTENT



*President's Letter*

# Dear Colleagues

*Dr Luis F. Collia, IFAPP President*

Welcome to the second IFAPP World issue in 2008. Ethics in clinical research is a main focus of this edition just starting right beside with an article of Dr Greg Koski and an interview with the acknowledged expert in this field in theory and practice.

Dr Koski is an accredited speaker on this matter at ICPM 2008 in September in Amsterdam, the Netherlands.

The article and interview corroborate the evidence, that ethics has an eminent role in clinical research, that all investigators need to be well trained in this respect before they are permitted to engage in human studies and – very important as well – that certification is needed as a prove of being well trained – a prove not at last for oneself. It also becomes obvious once again, that both, ▶▶ page 10

*Questions & Answers*

# Ethical Excellence in Clinical Research: A Neglected Affair?

*The investigator is the individual best positioned to prevent harm to human subjects in clinical research, while at the same time being the individual most likely to do harm. This paradox, expressed by Henry K. Beecher (for details see below), can be resolved by well-trained and well-intentioned investigators.*

*Dr Greg Koski, President and Chairman of the Board of Trustees of the 'Academy of Pharmaceutical Physicians and Investigators' (APPI) and the 'Association of Clinical Research Professionals' (ACRP), Senior Scientist at the Institute for Health Policy and Associate Professor in the Department of Anesthesiology and Critical Care of the Massachusetts General Hospital at Harvard Medical School, Boston, USA*

*IFAPP WORLD • Dr Koski, how would you characterize a well-trained, well-intentioned investigator with regard to ethical, sound and safe clinical research for new medicines?*

Dr Greg Koski • The truly professional investigator, whether based in academia, private practice or industry, fully recognizes and accepts responsibility for the safety and well-being of study subjects as ones highest priority, along with preserving the integrity of the scientific process. In clinical research, the investigator assumes a moral responsibility to protect the interests of study subjects because one literally uses these individuals as a means to an end, to achieve the results of the clinical study, a goal that would otherwise be impossible. To use any individual as a means to an end would be disrespectful and unethical, were it not for the special covenant established between the investigator and the subject, through which there is established an inherent and unwavering commitment to always put the subjects' interests and ▶▶ page 10

*The International Perspective*

### From Beecher's Paradox to Beecher's Paradigm

# Achieving True Protection for Human Subjects in Clinical Research *By Dr Greg Koski*

Four decades ago, long before research ethics committees and institutional review boards were an accepted part of the clinical research landscape, Professor Henry Beecher, then chairman of the Department of Anesthesia at the Massachusetts General Hospital, wrote that the only true protection for the safety and wellbeing of human subjects in research is a well-trained, conscientious investigator [Beecher HK. Ethics and Clinical Research. New England Journal of Medicine 1966, 274:1354-1360].

Not long ago, I found myself recalling Beecher's remark in the city of Udon Thani, Thailand, where I was participating in a conference on developing quality systems for health research that brought together stakeholders from the entire Asia-Pacific region. The conference offered a very clear reminder of the rapidity with which clinical trials and other health research activities are growing in that part of the world and in such regions as Eastern Europe, Latin and South America, and the Middle East.

Having been invited to discuss the role of investigators in protection of human subjects, I was afforded an opportunity to note that Beecher's observation has, ▶ page 2

## The International Perspective

### Achieving True Protection for…

◀ page 1 regrettably, been largely ignored by much of the research community in the intervening decades. Much effort, time, and money have been devoted to building an elaborate process for review, approval, and oversight of human research by committees of individuals having no direct role in the research and, too frequently, no formal training in either research or ethics.

Few would deny that Institutional Review Boards (IRBs) and Research Ethics Committees (RECs) have reduced the likelihood that unethical, unsound, or unsafe research is done. However, many cite the lack of empirical evidence that the review process itself is effective in reducing harm to research subjects, and critics decry the excessive focus on procedural and regulatory compliance that characterizes the process today. Many in the research community, including investigators, view the process more as an obstacle to be overcome when trying to initiate research than as a critical part of its conduct.

The message delivered at the conference in Thailand emphasized Beecher's Paradox – that the investigator is the individual best positioned to prevent harm to human subjects in research, while at the same time being the individual most likely to do harm. This paradox is readily resolvable by simply adopting Beecher's Paradigm – that all investigators be well trained and well intentioned before they are permitted to engage in human studies.

At present, we are far from achieving this goal. Our medical school curricula offer little or no training in clinical research, and most investigators still learn as apprentices to experienced mentors who may themselves have had little or no formal training in the responsible conduct of research, regulatory requirements, or research ethics. Commonly, outside of academic centers, investigators learn by the seat of their pants with the help of a research monitor or coordinator at an investigator orientation visit – hardly a recipe for thoroughness and excellence. Only within the past decade have some institutions and sponsors required that investigators acquire even minimal training in how to conduct research or research ethics, and frankly, many sponsors and contract research organizations are more interested in finding investigators (and IRBs) who will do things quickly than in selecting investigators committed to doing things well.

Some sponsors and investigators may take offense at my characterization of the current state of affairs and react defensively. If you are among them, stop for a moment and reflect on how you got to where you are today. Dr Lou

*A 1962 portrait of Henry Knowles Beecher by the French painter Jean-Pierre Aloux*

Sherwood, the first president of the Academy of Pharmaceutical Physicians and Investigators (APPI), now deceased, once confided to me how, upon leaving a stellar academic career in medicine and research for a high position in the pharmaceutical industry, he was stunned and, yes, humbled to find out how little he knew about the discipline that has come to be known as Pharmaceutical Medicine. Indeed, it was because of his humbling experience that Lou became such an ardent advocate of investigator training and certification, a hallmark of professionalism in clinical investigation and an essential part of APPI's mission and one that all pharmaceutical physicians should embrace.

If you happen to be among those who felt that twinge of defensiveness when you read the paragraph above, take the challenge – that is, take the exam. Successfully sitting for certification exams is part and parcel of the life of medical professionals, so why not that of clinical investigators? Some who take the Certified Physician Investigator (CPI) exam will be rewarded to find that they know what they should and are able to apply that knowledge effectively; they will emerge from the process both confident and certified, having demonstrated their personal commitment to realizing Beecher's Paradigm.

Others may receive a needed wake-up call and opportunity to advance their knowledge while similarly demonstrating their commitment to achieving the highest standards of conduct in their activities. In time, both sponsors and the public will take note, and even greater rewards will ensue; but we must take the initial step toward excellence largely out of good will.

Pharmaceutical physicians have an opportunity to take a leadership role in bringing Beecher's Paradigm to fruition, and in doing so, showing the world that our commitment to responsible conduct of human research and protection of human subjects is aligned with the goals of RECs and IRBs. In this manner, we can work in concert to do more studies more efficiently without imposing more counterproductive regulatory impediments.

*This article is adapted from its original version published in 'The Monitor', the official publication of the 'Academy of Pharmaceutical Physicians and Investigators' (APPI) and the 'Association of Clinical Research Professionals' (ACRP), in February 2008.* ■

## IFAPP's Calendar

# 'ICPM 2008' in Amsterdam

### Developing Pharmaceutical Care – Medicines After the Blockbuster Area

The 'International Conference on Pharmaceutical Medicine 2008' – ICPM 2008 – in Amsterdam, the Netherlands, is almost here! This conference is specifically designed to address all aspects of Pharmaceutical Medicine in the current, rapidly changing environment; it is the biennial vaccination to improve your fundamental knowledge on different key topics in this specialty.

*For detailed information please take notice of pages 4 and 9 • See you in Amsterdam!*

## Notes from the Editor

# IFAPP's Website with New Design

Recently IFAPP launched its new shiny website design at www.ifapp.org with a logical content structure according to subjects and shown in the menu bars.

With the new menu bars, the browsing facilities have improved in an attempt to make it easier to find the information that interests visitors.

The design was conceptualized and programmed in a joint effort under the coordination of Dr John Lee, member of IFAPP's Executive Committee from Sweden.

The content of IFAPP's website will be updated on a regular basis, just as it has in the past. Your comments are always welcome; please transmit them to ifapp@planet.nl.

*IFAPP's Regional Update*

# Pharmaceutical Medicine: A Distinct Medical Specialty in Argentina

On 3 June 2008, the career of the Specialist Physician in Pharmaceutical Medicine was officially launched, approved by the University of Buenos Aires Resolution No. 3436/2007.

## What is the significance of this new medical specialty?

If we review what happened in the pharmacological-industrial field during the last 50 years and the physician's role within it, we can differentiate two distinct periods. The first period was characterized by the emergence of countless drugs – efficiency was the only concern while the evaluation of their risk-benefit ratio was minimal or limited.

Thalidomide is an example. The thalidomide crisis occurred when thousands of children with severe malformations resulted from the effects of their mothers taking thalidomide during pregnancy. This crisis forced heightened risk awareness and the application of regulatory rules for better therapeutic's risk-benefit evaluations before and after marketing approval, leading to the current methodological requirements.

Since this time, significant progress has been made with regards to drug safety, not only resulting in better and more complete pre-clinical assessments, but also in broader and more comprehensive rules being established for clinical studies. Now clinical studies are better controlled with a focus on the detection of potential risk groups. Thalidomide today is used to treat more diseases than originally indicated, but with much greater awareness of its risks.

In turn, this has driven the need for deeper and more integral knowledge of pharmaceutical products with a dependence upon specialized professionals within pharmaceutical companies and authoritative bodies. Today physicians play an irreplaceable role in the therapeutic development process. All of these facets have generated the demand for a different curricular group, which has emerged as the aforementioned career and the physician in Pharmaceutical Medicine.

The professional training of physicians in Pharmaceutical Medicine in Argentina is in line with a global trend. However, while there are multiple accredited curricular programs for graduation in Pharmaceutical Medicine, there are only five for specialization – in the United Kingdom, Ireland, Switzerland, Mexico and now in Argentina, where Pharmaceutical Medicine is a listed distinct medical specialty.

## Driving the development of the career

The development of the career of the specialist physician in Pharmaceutical Medicine mainly has been driven by two postgraduate courses:

- The postgraduate course of clinical pharmacology performed by the Argentinean Pharmaceutical Medicine Society (SAMEFA) in the 1980's together with Sociedad Argentina de Farmacología y Terapéutica
- The postgraduate SAMEFA course of Pharmaceutical Medicine, which began in the 1990's, first annually (128 educational hours) and then biannually (156 hours)

▶▶ page 5

*At the inauguration of the career of the Specialist Physician in Pharmaceutical Medicine in the Faculty of Medicine in Buenos Aires, 3 June 2008: (from left to right) Dr Juan Carlos Groppa, Secretary of the career and Secretary of SAMEFA, Professor Dr José Milei, Member of the Evaluation Committee, Professor Dr Alfredo Buzzi, Dean of the Faculty of Medicine, Dr Héctor J. Arenoso, Chairman of the certificated postgraduate course in Pharmaceutical Medicine in Buenos Aires, Argentina, and Dr Luis Collia, IFAPP President.*

*Questions & Answers*

# Recognition of Pharmaceutical Medicine in Argentina – a long and intricate process

*An interview with Dr Héctor Julio Arenoso, Chairman of the certified postgraduate course in Pharmaceutical Medicine in Buenos Aires, Argentina*

For quite some time, Pharmaceutical Medicine in Argentina has been a focus for Continuing Medical Education (CME) and Continuing Professional Development (CPD). Recently Pharmaceutical Medicine has been recognized in this country – the second in Latin America and the 5th worldwide – as a distinct medical specialty equivalent to cardiology or gynecology. Dr Héctor Julio Arenoso, Chairman of the certificated post-graduate course in Pharmaceutical Medicine in Buenos Aires, Argentina, was significantly involved in the efforts to obtain this recognition. Here he provides some insights into the process and its impact.

*Dr Héctor Julio Arenoso: "I am convinced that the recognition of Pharmaceutical Medicine as a medical specialty will be highly positive for everyone involved in pharmaceutical research and development as well as for the pharmaceutical industry as a whole, for patients and the society at large."*

*IFAPP WORLD • Dr Arenoso, was it just a formal step in Argentina to get Pharmaceutical Medicine recognized as a distinct medical specialty or a long and perhaps challenging process?*

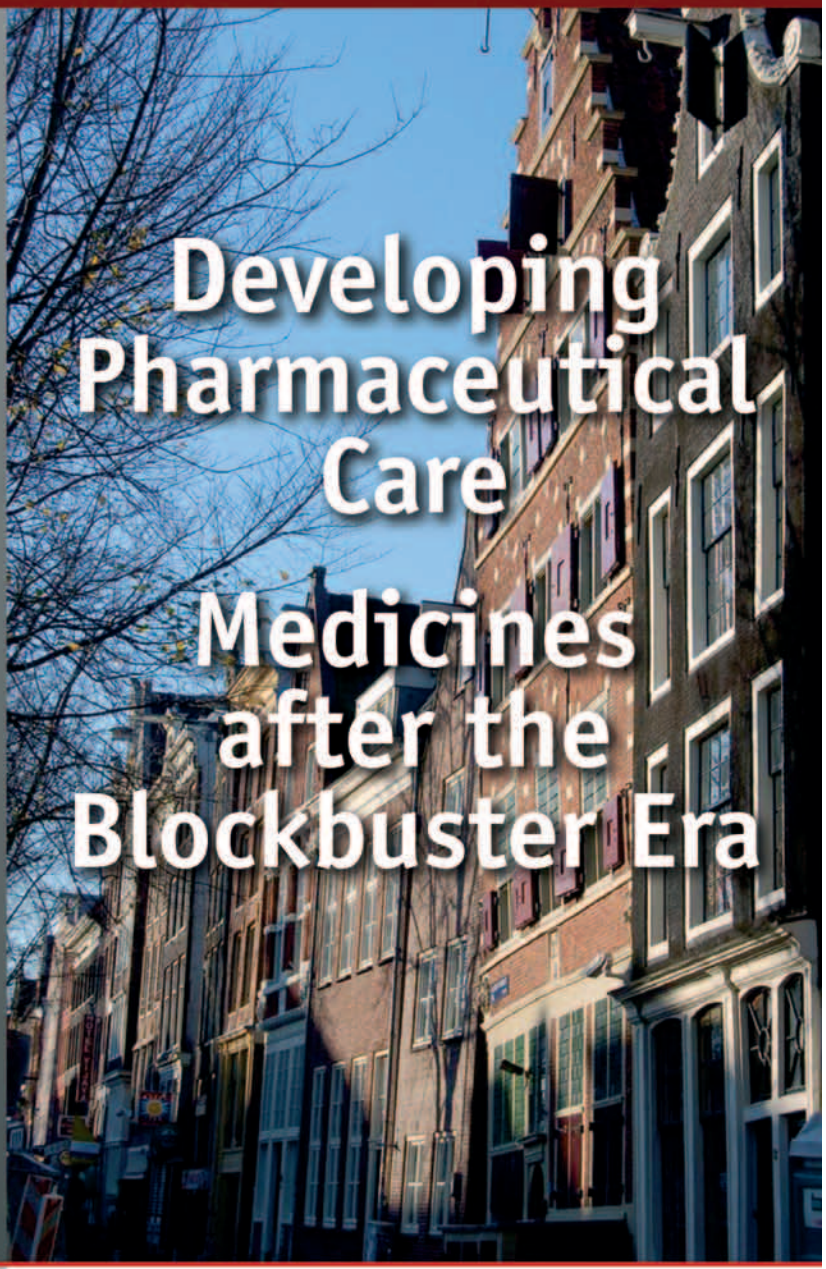
Dr Héctor Julio Arenoso • In fact, the process was long and difficult. Certainly throughout the process the Argentinean Pharmaceutical Medicine Society, SAMEFA, toured, consolidating its position within the medical society in general and the academic one in particular, joining with the professional quality of many of their associates, which was a very important factor in gaining this achievement.

In addition, SAMEFA's consolidated cooperation with the Asociación Médica

▶▶ page 5

# ICPM 2008, Amsterdam

## 7–10 September 2008




ICPM
2008
AMSTERDAM

The 15th International
Conference on Pharmaceutical
Medicine in
Amsterdam The Netherlands

www.icpm2008.org

Netherlands Association of
NEDERLANDSE
VERENIGING VAN
FARMACEUTISCH
GENEESKUNDIGEN
Pharmaceutical Physicians

IFAPP

## IFAPP's Regional Update

◀◀ page 3 In 2003 SAMEFA applied for the approval of its postgraduate course of Pharmaceutical Medicine as a career of the specialist physician in Pharmaceutical Medicine. It took exactly four years before the Faculty of Medical Sciences of the University of Buenos Aires (UBA) finally approved the career. During that time several modifications were made as suggested by the different technical areas of the Faculty and the UBA.

The career spans two years including 720 hours, of which 320 are spent in practice. The content of the curriculum is endorsed by IFAPP and harmonized with the different international curricula of IFAPP's member associations.

Currently, the first module of the career, themed Medicine Based on Evidences, with 32 regular students has just been completed. Among this group are physicians who already work in the pharmaceutical industry, others in contract research organizations (CROs) and the remainder in the field of care, but they all are interested in joining the pharmaceutical industry.

The recognition of Pharmaceutical Medicine as a distinct medical specialty favors those who are already working in the pharmaceutical industry and in CROs as it will allow them to obtain an academic "status" which they did not possess before. In addition, physicians from other medical specialties who want to join the industry could do so without losing their "status." Furthermore, the pharmaceutical industry will be able to achieve a better medical professional "status" while physicians will find a greater recognition as specialist physician in Pharmaceutical Medicine within the industry and the society.

The recognition of Pharmaceutical Medicine as a distinct medical specialty in Argentina is also a strong support for IFAPP, since it is another recognition of this distinct specialty, which supports the joint efforts to get Pharmaceutical Medicine recognized at an international level.

*Dr Héctor Julio Arenoso, Buenos Aires, Argentina* ■

*Buenos Aires (Photo: Marcelo Gerpe)*

## Questions & Answers

◀◀ page 3 Argentina, an institution with national and international prestige, was key. Contributing to this achievement were the various academic activities carried out over more than three decades: the course on clinical pharmacology together with Sociedad Argentina de Farmacología y Terapéutica, the postgraduate course on Pharmaceutical Medicine, the first Panamerican Congress of Pharmaceutical Medicine and the courses on monitoring in clinical investigations. Academic specialists were always invited to attend and they contributed to the high professional standard at these events as well as generating important background support.

*IFAPP WORLD • Clinical pharmacology and Pharmaceutical Medicine build an interdisciplinary relationship with experts working together closely. However, there is also competition between both disciplines. How is that relationship in Argentina, how did it influence the recognition process, and how will it change now that Pharmaceutical Medicine is also a recognized medical specialty?*

Dr Héctor Julio Arenoso • In Argentina, many clinical pharmacology professionals are working within the pharmaceutical industry, as it is in my personal case. This certainly helps in fostering a good relationship between clinical pharmacologists and physicians working within this industry.

Addressing those opposed to Pharmaceutical Medicine, our argument is that our specialty is much more comprehensive than clinical pharmacology. The performance of Pharmaceutical Medicine specialists within the pharmaceutical industry is primarily related to work in the fields of clinical trials, pharmacovigilance, regulatory requirements and marketing.

*IFAPP WORLD • What are the rules and prerequisites to gain a certification as a PM medical specialist in Argentina?*

Dr Héctor Julio Arenoso • The requirements to enroll in this career are having at least two years experience as a graduate physician. Then, an Evaluation Committee evaluates each applicant with a personal interview and an analysis of his CV. Having obtained any other clinical specialty or experience in issues related to Pharmaceutical Medicine or, of course, working in the pharmaceutical industry are important elements to get enrolled.

Later on, a ranking of all applicants is established, ordered according to the score they obtained in their interview.

*IFAPP WORLD • Will already certified "PM specialists", who completed the respective courses in Pharmaceutical Medicine earlier, immediately convert to "PM medical specialists?"*

*Dr Héctor Julio Arenoso: In Argentina, all CME and CPD courses of all medical specialties must be revalidated every five years. Physicians who obtain the certification as a specialist should also be recertified in regular terms.*

Dr Héctor Julio Arenoso • Physicians become specialists in Pharmaceutical Medicine once they have fulfilled the career requirements. In my case, by virtue of being the chairman of the career, I can use the title.

*IFAPP WORLD • What do you consider is the impact of the recognition of Pharmaceutical Medicine as a medical specialty?*

Dr Héctor Julio Arenoso • The certified specialist will obtain an academic "status," which he has not had previously, and this will enable him to interact with other colleagues on an equal footing. The pharmaceutical industry will benefit from these specialists, achieving better results in research and development and obtaining better products. This will benefit patients and the entire society.

*IFAPP WORLD • Could the recognition process in Argentina serve as a model for other countries?*

Dr Héctor Julio Arenoso • While all the countries experience difficulties to obtain recognition of Pharmaceutical Medicine as a distinct medical specialty, the challenges can be very different from country to country. However, our experience might serve as an example, at least as four particular points have proved to be most important. These are Continuing Medical Education (CME) and Continuing Professional Development (CPD), strong interaction at all academic levels, and a lot of work, which has to be completed.

*Dr Arenoso was interviewed by Eckhard Boettcher-Buehler from IFAPP World.* ■

## IFAPP's Vision Statement

„By 2011, IFAPP is recognized and accepted as an authoritative voice on the medical aspects of the pharmaceutical industry and education and standards within pharmaceutical medicine by governmental and regulatory authorities, pharmaceutical industry bodies, the public, healthcare providers, healthcare professionals, academic bodies and the media."

*Notes from the Editor*

# Personal Subscriptions to 'IFAPP World'

IFAPP is delighted to inform you of the latest augmentation to its information services: a personal subscription to IFAPP World tool has been implemented on the IFAPP website at www.ifapp.org/home/news/ifapp-world.

Upon entering their e-mail addresses into the personal subscriptions database, interested parties will get e-mail alerts with a hyperlink to the newsletter upon the availability of IFAPP World which happens three times a year. "IFAPP recognized that more individuals might be interested in global Pharmaceutical Medicine progress than can currently be reached by the existing information channels," said Dr Luis Collia, President of IFAPP. "We would like to establish a closer relationship to other scientific organizations, patient organizations, regulatory authorities, pharmaceutical industry associations, and non-governmental organizations than we have to date. By offering these personal subscriptions IFAPP also would like to strengthen the dialog between those in charge of providing healthcare solutions and those who are in need of those. IFAPP World could be an ideal platform serving that purpose." ■

*THE FLAG*

IFAPP World is a publication of the
**International Federation of Associations of Pharmaceutical Physicians (IFAPP)**
The Federation, founded in 1975, is a non-profit organization with 30 national member associations worldwide.
IFAPP acts as an international forum for all pharmaceutical physicians organizations worldwide by dealing with matters brought to its attention through national member associations.
**Editorial Board Representatives:**
Dr med. Johanna Schenk, FFPM (johanna.schenk@pharmaprojekthaus.com), Frankfurt/Main, Germany
Professor Dr Jean-Paul Deslypere (Jean-Paul.Deslypere@sgs.com), Singapore
Dr Stewart Geary (s2-geary@hhc.eisai.co.jp) Tokyo, Japan
**Editor in Chief:**
Eckhard Boettcher-Buehler (boebue@t-online.de), D-90562 Heroldsberg, Germany
**Associate Editor:**
Marie Gethins, Glenbrook, Cork, Ireland
**Design & Layout:**
Novum Verlag & Werbung GmbH, D-90542 Eckental, Germany

*Personal Snapshot*

# Committed to Human Subject Protection – Dr Greg Koski

*"I haven't run across another field where so many people are so passionate about what they do as in clinical research. Seeing the level of commitment they bring to what they are doing, the number of people who are willing to stand up and say, 'I'm going to do this right or I'm not going to do it at all,' gives me great hope for the future." Dr Greg Koski in an interview with Norman M. Goldfarb for the 'Journal of Clinical Research Best Practices' 2007, Vol. 3, No. 9, Sptember 2007.*

Greg Koski received his education and A.B., Ph.D. and M.D. degrees at Harvard University in Cambridge, Massachusetts, USA, one of the world's most prestigious academic centers. He completed his residency in anesthesia and intensive care, and fellowship training at the US National Institutes of Health (NIH) as a Pharmacology Research Associate. Today he is both, an anesthesiologist who has maintained a full-time anesthesiology practice at Harvard Medical School and the Massachusetts General Hospital since 1984, and an internationally respected expert in clinical research and in human subjects protection in particular.

Dr Koski's interest in research ethics grew strongly after joining the Subcommittee on Human Studies of the Massachusetts General Hospital in 1989. This Committee, established in 1963 under the leadership of Dr Henry Beecher, became his training ground for several new roles: He has served as Chairman of the Massachusetts General Hospital Institutional Review Board, Director of Human Research Affairs at Partners Healthcare System, Director of Henry K. Beecher Memorial Research Laboratories, before being recruited to serve as the first Director of the Office of Human Research Protections at the U.S. Department of Health and Human Services. Recently he was elected President of the Academy of Pharmaceutical Physicians and Investigators (APPI), the physicians affiliate of the Association of Clinical Research Professionals (ACRP), a US-based international organization promoting highest standards of professionalism in clinical research worldwide.

*"In anesthesia, there is a very real and necessary relationship of trust between the doctor and the patient. Once you receive that anesthetic, your life depends upon someone who is going to, above all other considerations, take care of you. That is exactly what an investigator ought to be doing for somebody in a clinical trial."*

## His vision

All people involved in clinical research should be committed, but moreover, certified as professionals in clinical research, pharmaceutical medicine and human subject protection issues. The Industry, beginning to see this demand, has the power and opportunity to facilitate this by simply stating that in five years it will not place a study with an uncertified investigator. Regulatory authorities could help move in that direction by subjecting non-certified investigators to greater scrutiny. Once the public begins to recognize the importance of having accredited human research protection programs and professionally certified research personnel, we are really going to move forward.

*Lively information regarding the person Dr Greg Koski and a detailed insight in how he has started, what are his goals and his passions are provided in the 'Journal of Clinical Research Best Practices' 2007, available at www.firstclinical.com/journal/2007/0709_Koski.pdf the internet, titled "Greg Koski on Human Subjects Protection". His view as an expert reflects the article and interview in this IFAPP World issue.*

*Eckhard Boettcher-Buehler* ■

*Quality Issues in Clinical Research*

# 10th IFAPP European Conference

## 30 January 2009
## London, United Kingdom

IFAPP is pleased to announce its 10th European Conference, which will be held in collaboration with the British Association of Pharmaceutical Physicians (BrAPP) and the British Association of Research Quality Assurance (BARQA) at 30 January 2009 in London, United Kingdom. It will cover 'Quality Issues in Clinical Research' with contributions from speakers representing EMEA, academia and industry.

For further details please take notice of the first announcement at the end of this IFAPP World issue or visit www.ifapp.org. ■

*Reports & Concepts*

**European Pharmaceutical Industry Association**

# Code of Practice on Relationships with Patient Organizations

The 'Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations' recently came into effect across Europe to ensure relationships between the pharmaceutical industry and patient organizations are transparent and ethical. Since 1 July 2008 it has been applying to the 2,200 companies that the 'European Federation of Pharmaceutical Industries and Associations' (EFPIA) represents directly and indirectly in 31 European countries.

The code requires that each company must make publicly available a list of patient organizations to which it provides financial support as well as significant indirect or non-financial support, including a description of the nature of this support. This information may be provided at a national or European level and should be updated at least once a year; it should be available (e.g. on company websites) for the first time by the end of March 2009.

The code, which also includes various other standard requirements, is available at www.efpia.eu/Content/Default.asp?PageID=367.

The code also includes standards requiring companies to have written agreements defining their support, to encourage multiple sources of funding for patient organizations, to obtain written permission for the use of patient groups' logos, not to seek to influence the content of sponsored patient organization material to favor commercial interests, and to limit hospitality to a reasonable level. The code reflects European Union law by prohibiting the advertising of prescription-only medicines to the public.

Implementation is carried out by the national industry associations, which must have procedures in place for receiving and processing complaints and imposing sanctions if necessary. Sanctions vary, and may range from publication and fines, to suspension from the national industry association. Non-industry stakeholders will be involved in the national bodies that will handle complaints. National industry associations may choose to impose extra requirements.

The 'International Alliance of Patients' Organizations' (IAPO) also lists patient-industry relations as a concern, which is addressed by IAPO 'Principles of Partnerships' including independence, openness and transparency, mutual benefit, accountability, respect and equal partnerships (available at www.patientsorganizations.org following the


menu "Patient-Centered Healthcare", "Policy Issues and Activities", "Patient-Industry Relations" and "Principles for Partnerships").

## Swallowing the best advice?

In fact, there is a long drawn-out, complex and controversial dispute on how patient groups might be influenced by industry and whether transparency can prevent it or not with publications causing provocative headlines. Some exponents believe that several patient groups are perilously close to becoming extensions of pharmaceutical companies' marketing departments while others say, without support many patient organizations could not even exist.

Good insight into this controversial matter is provided by two articles, which also specify further references:

- Marshall J, Aldhous P: Patient groups special: Swallowing the best advice? New Scientist 2006, 2575:18-22 (available at www.newscientist.com following the menue "Archive", "2006", "28 October 2006 No. 2575" and "Special Report")
- Mintzes B: Should patient groups accept money from drug companies? No. BMJ 2007, 334:935 (available at www.bmj.com/cgi/content/full/334/7600/935)

*Eckhard Boettcher-Buehler* ■

*IFAPP's Regional Update: Turkey*

# Less is More: Modest But Achievable ISMED Program

TURKEY • Since the foundation of ISMED, the Turkish Association of Medical Professionals in the Pharmaceutical Industry, in 2003, ISMED has been actively supported by IFAPP. Now IFAPP held an important role in assisting ISMED to overcome a crisis.

At a meeting of the European Association for Clinical Pharmacology and Therapeutics (EACPT) in Istanbul, Turkey, in August 2003, where IFAPP organized a full day course themed Clinical Research and Good Clinical Practice, IFAPP Delegates Dr Domenico Criscuolo from Italy and Dr Juan Lahuerta from Spain met some Medical Directors of pharmaceutical companies based in Istanbul. Dr Criscuolo and Dr Lahuerta offered IFAPP support to organize a Turkish association for professionals in Pharmaceutical Medicine. This offer was welcomed resulting in the foundation of ISMED in December 2003. ISMED organized its first scientific event in April 2004 with Dr Criscuolo opening this exciting event. Since that time ISMED and IFAPP have enjoyed a strong and stable relationship.

During the years that followed, ISMED membership grew with several scientific events held in Istanbul. However, later on ISMED faced serious challenges – while some of the ISMED membership declined to passivity, others maintained interest and thought about a new, dynamic organization.

Hoping to moderate in this difficult situation, in March 2008 Dr Criscuolo suggested a brainstorming meeting, which was organized by ISMED. Based on experience from other associations, which faced similar challenges stemming from limited time and available resources, ISMED executive committee members agreed at this meeting on a reactivation by planning a modest but achievable ISMED program.

*Dr Domenico Criscuolo, member of IFAPP's Executive Committee, Colleretto Giacosa, Italy*

*After the brainstorming session: (from left to right) ISMED President Dr Ilker Gelisen, IFAPP's Executive Committee member Dr Domenico Criscuolo, first ISMED President Dr Yesin Uresin, ISMED Vice President Dr Emrah Aras.*

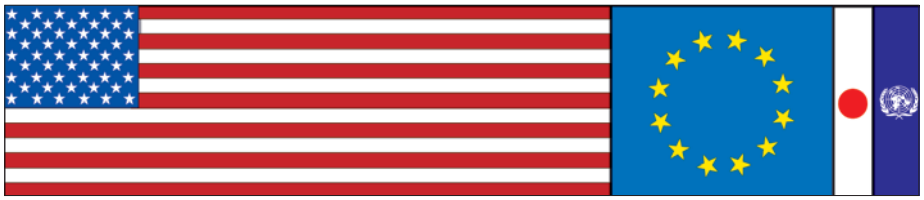
*The World in Brief*

# Pharma Invests More in R&D than Any Other Sector

The pharmaceutical industry accounts for no less than 19% of R&D global business expenditure; it is the sector with the highest ratio of R&D investment to net sales (15.9%). The industry employs more than 643,100 people in Europe of which 107,000 work in R&D units. These statistics are from the 2008 Edition of 'The Pharmaceutical Industry in Figures' released by the 'European Federation of Pharmaceutical Industries and Associations' (EFPIA) in June 2008.

Between 1990 and 2007, R&D investment in the United States grew 5.2 times whilst in Europe and Japan it only grew 3.3 and 2.3 times, respectively. There is also rapid growth in the research environment in emerging economies such as China and India. According to an EFPIA commentary, the current tendency to close R&D sites in Europe and open new sites in Asia will have dramatic effects in the next few years if nothing is done to maintain pharmaceutical discovery expertise in the EU.

The EFPIA industry figures are available at www.efpia.eu/content/default.asp?PageID=559&DocID=4883. ■



**65.2 % USA · 24.3 % Europe · 3.7 % Japan · 6.8 % ROW**

*Geographical breakdown (by main markets) of sales of new medicines launched during the period of 2002-2007. Note: new medicines cover all new active ingredients marketed for the first time on the world market during the period 2002-2007. Europe includes non-EU members and CIS markets (ROW – Rest of the World, CIS – Commonwealth of Independent States; Source: IMS Health MIDAS MAT December 2007). Reprint with kind permission of EFPIA.*

*IFAPP's Regional Update: Italy*

# SSFA's 11th National Conference on Pharmaceutical Medicine

ITALY • More than 200 members of the Società di Scienze Farmacologiche Applicate (SSFA), the Italian Association of Pharmaceutical Medicine, met in Rome in March 2008, attracted by a carefully prepared SSFA's 11th National Conference program. In addition to SSFA members, clinical investigators, regulators, scientists from academia as well as members of affiliate associations, e.g. pharmacologists and toxicologists, attended the conference and it proved highly successful.

The opening session was devoted to a discussion on new regulations. Dr Carlo Tomino from the Italian drug agency Agenzia Italiana del Farmaco (AIFA) illustrated the recently enacted Italian Clinical Trial Application law, which should become European standard and harmonizes the documents for submission to the Ethics Committees and the Competent Authorities. The conference continued with an update on Pharmaceutical Medicine and a significant contribution by Dr Umberto Filibeck, head of AIFA Inspectors, on clinical research quality assurance. Finally, two clinicians held enthusiastic lectures on innovative medicine in Alzheimer's Disease and stem cells transplantation.

At the conference the General Assembly of SSFA was held with many members contributing comments and suggestions for future association directions. At the Assembly, Dr Carlo Tomino and to Dr Umberto Filibeck, both from AIFA, were awarded with honorary SSFA membership which in fact is a form of diploma for distinguished scientists in the area of Pharmaceutical Medicine.

Rome was the fantastic site for this important event; the next meeting will be organized in Milano in 2011.

*Dr Domenico Criscuolo, member of IFAPP's Executive Committee, Colleretto Giacosa, Italy*

*Dr Luciano M. Fuccella (left) awarding Dr Carlo Tomino with the SSFA diploma and honorary SSFA membership*

*Dr Domenico Criscuolo (left) hand over the award to Dr Umberto Filibeck*

*IFAPP's Sponsors*

**IFAPP gratefully acknowledges generous sponsorships and financial support from the following companies:**

**Gold Sponsor: Pfizer** Inc. (www.pfizer.com)

Silver Sponsors (in alphabetical order): **Boehringer Ingelheim** GmbH (www.boehringer-ingelheim.com), **Cato Research** Ltd. (www.cato.com), **GlaxoSmithKline** plc. (www.gsk.com), **Eli Lilly and Company** (www.lilly.com), **Merck & Co.**, Inc. (www.merck.com), **PharmaProjekthaus** GmbH & Co. KG (www.pharmaprojekthaus.com).

As a not-for-profit organization IFAPP appreciates the support it receives from institutions with a passion for enhancing the knowledge, expertise and skills of pharmaceutical physicians worldwide. Information on sponsorship opportunities is available at www.ifapp.org, section sponsors.

*IFAPP's Regional Update*

# News from IFAPP's Member Associations

UNITED KINGDOM • We are proud to announce that the 'British Associaton of Pharmaceutical Physicians' (BrAPP) has a new Chairman: Dr Jane Barrett, elected on 13 March 2008. Dr Barrett will be well known to many IFAPP members as she has served as UK delegate for a number of years. Her current term of office will run for two years. She previously served as BrAPP Chairman between 1997 and 2001 and was the first holder of the post to serve for two consecutive terms of two years. Dr Barrett is a highly experienced pharmaceutical physician and runs a successful consultancy with particular interest in medical ethics, pharmacovigilance, medical law and clinical research fraud. She has also served as Registrar at the Faculty of Pharmaceutical Medicine. A frequent speaker at international meetings, Dr Barrett always finds time to encourage newly recruited physicians in the pursuit of a career in pharmaceutical medicine. Her own personal experience in large pharmaceutical companies, CROs and now consultancy means that she can offer members a broad spectrum of advice and leadership.

BrAPP is the world's first association of pharmaceutical physicians being first constituted in 1957. It seeks to pursue the objectives of its founders in encouraging the development of all pharmaceutical physicians regardless of the stage of their careers. This BrAPP does by producing a regular journal, offering training courses and educational meetings. In addition the association offers career advice and networking support to those aspiring to join industry and to all its members.

*Liz Langley, BrAPP Manager – info@brapp.org*

*Dr Jane Barrett, new Chairman of BrAPP, says that her vision for the future is "to make BrAPP as relevant and important to our members as it has ever been, and to forge stronger links with our colleagues in other IFAPP countries."*

ITALY • Dr Gianni de Crescenzo has been elected new President of the 'Società di Scienze Farmacologiche Applicate' (SSFA), the Italian Association of Pharmaceutical Medicine, during its General Assembly in March 2008 in Rome. He is successor of Dr Francesco de Tomasi.

*Dr de Crescenzo is Senior Regional Director at Wyeth Lederle S.p.A., responsible for clinical R&D in Italy, Greece, Turkey, Malta, Cyprus, and Middle East and North African countries. As SSFA President he is committed: "to promote clinical research and development in a fair and fruitful cooperation of all the relevant parties working in this field, respecting the different roles we all play, with the health and safety of the people as the ultimate goal. To provide and stipulate formal training for responsible and ethical conduct of clinical research is another crucial aspect I will promote. Rome was not built in a couple of days, but, day by day, I'm sure we will be able to create ever safer pharmaceuticals."*

BRAZIL • The new board of directors of the 'Brazilian Society of Pharmaceutical Medicine' (SBMF) was elected in December 2007 and Dr Gustavo Kesselring from the German Hospital Oswaldo Cruz in São Paulo and Member of IFAPP's Executive Committee has been re-elected as the president for the term 2008/2009.

*Dr Gustavo Kesselring: SBMF's vision is to promote the acknowledgment of Pharmaceutical Medicine as a medical specialty, with a specific body of knowledge, and distinct fields of professional responsibility. Recently the Pharmaceutical Medicine Specialization Course held in the Federal University of São Paulo was granted official accreditation from IFAPP's Council for Education in Pharmaceutical Medicine (CEPM).*

GREECE • The 'Hellenic Society of Pharmaceutical Medicine' (ELEFI) held its General Assembly in May 2008 with elections of the new President and the Executive Board.

Dr Dimitris Michailidis, Botania, is reelected ELEFI President, and Vice President is Miss A. Terzaki, Omega Mediation. ■

*Dates & Deadlines*

*7-10 September 2008 • Amsterdam, the Netherlands*

**ICPM 2008 – 15th International Conference on Pharmaceutical Medicine**

Please note the article " 'ICPM 2008' in Amsterdam" on pages 2 and 4 • www.icpm2008.org

*14-15 August 2008 • Chiang Mai University, Bangkok, Thailand*

**Thailand Towards Center of Excellence in Clinical Trials – The 8th Annual Update**

"Healthy and powerful infrastructures for clinical researches in Thailand"

*14-16 September 2008 • Philadelphia, PA, USA*

**ACCP's 37th Annual Meeting**

American College of Clinical Pharmacology (ACCP) • www.accp1.org

*5-8 October 2008 • Buenos Aires, Argentina*

**8th ISOP Annual Meeting**

International Society of Pharmacovigilance (ISOP) • www.isop2008.org

*20-22 October 2008 • Kuala Lumpur, Malaysia*

**CReaTE '08 – Clinical Research and Trials Excellence: Promoting Research Hubs in Asia**

CReaTE '08 creates an international opportunity to update research skills; it has evolved from NCCR '07 as the 2nd Annual International Conference & Exhibition on Clinical Research & Trials – the National Committee for Clinical Research (NCCR), Ministry of Health, Thailand • www.nccr.gov.my • http://create2008.net/index.htm

*21-22 November 2008 • Mumbai, India*

**2nd Asia-Pacific Clinical Trial Congress 2008 • Coping with the Expanding Scope of Clinical Trials: Destination Asia-Pacific**

Indian Drug Manufacturers' Association (IDMA) • www.idma-assn.org

*30 January 2009 • London, United Kingdom*

**The Tenth IFAPP European Conference – Quality Issues in Clinical Research**

The International Federation of Associations of Pharmaceutical Physicians (IFAPP) in collaboration with the British Association of Pharmaceutical Physicians (BrAPP) and with the British Association of Research Quality Assurance (BARQA) • For details see page 12.

## President's Letter

◀◀ page 1 training and certification constitutes professionalism and that professionalism in clinical research is an important part of the whole, which constitutes a particular discipline that is known as Pharmaceutical Medicine.

Pharmaceutical Medicine recently has been recognized as a distinct medical specialty in Argentina. How this has happened and what it all means is another subject in this IFAPP World issue, reflected by an article and a question and answer catalogue starting on page 3. Beside this you will find reports regarding various activities of IFAPP and IFAPP's member associations.

IFAPP's Executive Committee held two teleconferences since the release of the last IFAPP World issue. A main topic has been the continuing discussion of IFAPP's strategy and tactics in order to improve our profile and publicity, and to gain ever more influence on decisions in the world of Pharmaceutical Medicine as a distinguished stakeholder. The summary and conclusion on this ongoing discussion will be presented soon.

I also like to bring the 'International Conference on Pharmaceutical Medicine – ICPM 2008 in Amsterdam, the Netherlands, 7-10 September 2008 to your attention once again. The final program is now available at www.icpm2008.org where you also can register for the event and book hotel accommodation and tours. Your participation at the conference is highly appreciated.

During ICPM 2008 three important IFAPP meetings will happen, too – IFAPP's Executive Committee face-to-face meeting, the House of Delegates meeting and the General Assembly. I kindly invite all Presidents and Delegates from IFAPP's member associations to join these meetings. The agendas have been sent at the beginning of July.

It is my pleasure to congratulate all newly elected presidents of IFAPP's member associations, who took over these positions recently: Dr Jane Barrett from the 'British Association of Pharmaceutical Physicians' and Dr Gianni de Crescenzo from the Italian 'Società di Scienze Farmacologiche Applicate', Dr Gustavo Kesselring from the 'Sociedade Brasileira de Medicina Farmacêutica', and Dr Dimitris Michailidis from the 'Hellenic Society of Pharmaceutical Medicine' – in alphabetical order.

Last but not least, I would like to thank all of you who contribute to IFAPP operations and IFAPP World.

*Dr Luis Francisco Collia, IFAPP President, Medical Manager Merck Serono Argentina, Buenos Aires, Argentina* ■

## Questions & Answers

◀◀ page 1 safety first. If all investigators, and their sponsors, governed their activities accordingly, there would be little need for ethical review and regulatory oversight – as Albert Camus once said, "Integrity needs no rules." Regrettably, we are far from achieving this goal.

*IFAPP WORLD • How should investigators be well trained for excellent clinical research, and what needs to be done for a good intention and integrity?*

Dr Greg Koski • Too often, indeed, far too often, our system permits individuals with little or no formal training in the many dimensions of clinical research to be "investigators". In truth, such individuals are no more than technicians.

Clinical research and pharmaceutical medicine are professional activities that require mastery and application of an extensive body of knowledge and skill, and only individuals who have demonstrated such mastery should be permitted to serve as investigators. As in any true profession, standards should be established by the professionals themselves, and the profession should hold every member to those standards. Even more importantly, these standards should be minimalistic, but should be based upon excellence.

A well intentioned investigator has an opportunity to demonstrate both mastery and commitment by not simply endorsing, but by internalizing the principles and practices that characterize excellence in the profession, and by voluntarily subjecting themselves to objective assessment of their knowledge and skills through a process of professional certification. We have done this in medicine for nearly a century – it is time we do the same for clinical research and pharmaceutical medicine.

*IFAPP WORLD • Are you aware of certain areas, countries or continents where training deficit is particularly substantial?*

Dr Greg Koski • In many instances, the only training either received or required is a start-up visit or investigator meeting convened by a study sponsor. Many large contract research organizations openly confess that investigator training and qualifications are far less relevant than how rapidly one can enroll subjects into a study. Few competent authorities, including the U.S. Food and Drug Administration actually take the time to assess whether or not investigators are truly qualified by training and experience to conduct a particular study. This is an unacceptable situation that urgently needs correction. We simply must ensure that all investigators are qualified according to standards set by the profession.

One would think that every sponsor would issue such a requirement, but too often, the competing goals of getting a study up and running and completed quickly take precedence. This is a short-sighted and ill-conceived approach – one that the industry could easily change overnight if it so chose. Which will it be, professionalism and quality, or simple expediency? Interestingly, the rapid growth of clinical research in Asia, Eastern Europe and other regions seems to be driving expectations for proper training and certification of investigators. The need, of course, is equally great in countries with well-established traditions and infrastructure for clinical research, as would be the benefits.

*IFAPP WORLD • With regard to training deficits: are there already consequences in terms of ethical conduct failures?*

Dr Greg Koski • Every failure in clinical research, whether due to ethical lapses or performance by research teams has consequences, mostly negative. The erosion of public confidence and trust in the clinical research process and in the pharmaceutical industry generally is readily apparent and stems directly from failures of the industry and investigators to conduct their activities according to the high ethical and professional standards we have mentioned. Every failure not only undermines public trust, but also evokes calls for ever increasing regulation. One would have thought we would have learned our lesson from this already.

*IFAPP WORLD • Is ICH GCP E6 an adequate outline or concept of what is ethics in clinical research globally or do we need an expansion of the ICH initiative or a new global approach?*

Dr Greg Koski • ICH GCP E6 is an adequate outline, but nothing more – it is an outline, a skeleton that needs further elaboration and guidance for all parties. Simply put, it needs more meat on its bones. My colleagues and I envision a harmonized global approach toward establishing a shared international infrastructure for safe, high-quality and professional conduct of clinical research, a system not unlike the international air-transportation safety system. ▶ page 11

## Questions & Answers

◀ page 10 Such a system would establish an international network of fully accredited research sites, operating under the approval and oversight of accredited human research protection programs, with professionally certified research teams, connected by a robust, common or at least inter-connected information technology platform supported by harmonized standard operating procedures. This system could be supported by user fees and contributions from governments, industry, and even private foundations. Investment of even a small fraction of monies currently devoted to marketing and promotional activities could easily underwrite such a system and the payoffs would be huge.

Imagine being able to efficiently start and conduct a clinical trial at 600 sites in 60 countries in just 4 weeks, with all sites performing their work according to the highest standards of quality and excellence established by the profession. This approach could dramatically facilitate the conduct of studies while reducing costs, improving efficiency, reducing risks, enhancing safety through more effective reporting and monitoring of adverse events, and could get new products to market sooner, all with a better safety profile. This approach has worked well for the airline industry – it is hard for me to imagine why we have not yet done this for clinical research.

My hope is that organizations like IFAPP, APPI and others can take the lead in working with industry and government to develop and implement such a system over the next 5 to 8 years. Certainly, this is where I will be investing my time and effort.

*IFAPP WORLD • What's about education and training of REC and IRB members? Do we also need new standards and a global harmonization?*

Dr Greg Koski • Research ethics committees and institutional review boards are a critical part of the clinical research system, and their performance must be similarly knowledge-based and professional. Our current approach of relying largely upon well-meaning but inadequately trained volunteers is simply out of touch with reality and in need of immediate attention, as many are now recognizing. Our current approach is often more operational than substantive, too idiosyncratic, and terribly inefficient. Furthermore, there is little evidence that it actually does much good, and increasing evidence that it may actually be more harmful than helpful. This is an area of critical need for improvement, and this quality improvement should be based upon empirical data about what works and what doesn't.

There is no reason why we can't achieve a much higher degree of global harmonization in this area, and while ICH GCP E6 is a start, we can go much further. For instance, the World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS) have already developed and issued harmonized ethical guidelines for clinical and epidemiological research and standard operating procedures for ethics committees, including procedures for surveying and assessing their performance. They have been translated into several languages and have been adopted in several countries, particularly in the Asia-Pacific region. We need to put these tools to work for the benefit of all, and we need to get industry, government and academia behind these initiatives

*IFAPP WORLD • Actually clinical research is facing an ongoing transition from pharmaceutical to biological medicine with potentially high-risk medicinal products; also more and more new investigational medicines are designed for individualized indications, and at the same time investigators need to conduct clinical trials faster and faster. How can ethics in clinical research cope with all that?*

Dr Greg Koski • As science marches forward in the "omics age", and translational medicine fosters increasingly individualized medicine with potent, potentially high-risk agents, we need to be sure that ethical considerations remain at the forefront. The way to do this is to make sure that the scientists and sponsors are themselves properly trained and engaged in the ethical dimensions of their work. This goes back to the issues of personal responsibility and professionalism that I mentioned earlier.

Too often, investigators and scientists have focused excessively on the science and business aspects of their work, all too willing to leave the ethics to the IRBs and ethics committees. Indeed, our approach to ethical review has promoted this abdication of ethical responsibility. We can and should change this by ensuring that all investigators are properly trained in all aspects of pharmaceutical medicine and clinical investigation, including the ethical domain. All scientists must be cognizant of their social and ethical responsibilities, and it is long past time for the pharmaceutical and biotechnology industry to do the same.

*IFAPP WORLD • What would you consider is the role of Pharmaceutical Medicine, its associations and their individual members with regard to research ethics and the respective training of clinical investigators?*

Dr Greg Koski • Establishment and global recognition of pharmaceutical medicine as a specialty within the practice and teaching of medicine would go a very long way toward realizing the goals we have discussed here. Indeed, the curriculum for training professionals in pharmaceutical medicine must include knowledge domains in ethics and related fields as part of an integrated, interdisciplinary approach. In this regard, our organizations of pharmaceutical physicians around the world have a great opportunity and responsibility to make this happen – the big question that remains is whether or not we have the will and the energy to take the lead.

*IFAPP WORLD • Do clinical investigators have an adequate voice in Pharmaceutical Medicine organizations and in pharmaceutical R&D overall? Or do sales persons and managers, administrators and officers dominate research for new medicines?*

Dr Greg Koski • I sense from your question that you are asking whether we all focus too much on procedural and regulatory compliance and too little on conscientious clinical research practice. Frankly, yes, we do, but as I mentioned earlier, those of us in roles as investigators and sponsors have been all too willing to yield our positions in the ethical realm to those outside of the scientific domain – indeed, the entire approach has largely devolved to one focused on regulatory compliance as the floor of professional conduct.

The simple fact is that we have all too willingly crawled down to the point that if we stoop any lower, we're criminals! We'd be breaking the law. This is not where we want to be, and it is not where we should be.

Restoring professionalism in clinical research requires acceptance of our personal and collective responsibility for achieving excellence in all that we do, not just conducting our activities in concert with legal requirements. Who is better prepared or more appropriately positioned to lead this transformation to a professional paradigm than the physicians engaged in clinical research and pharmaceutical medicine. The time has come for us to pick-up the torch and proudly carry it forward, and I am looking forward to being part of this revolution.

*Dr Koski has been interviewed by Eckhard Boettcher-Buehler from IFAPP World.* ■

International Federation of Associations
of Pharmaceutical Physicians
*founded 1975*

# THE TENTH IFAPP EUROPEAN CONFERENCE

London, Friday, 30 January 2009

# Quality Issues in Clinical Research

*in collaboration with the*
*British Association of Pharmaceutical Physicians (BrAPP)*
*and with the*
*British Association of Research Quality Assurance (BARQA)*

Marriott Hotel West India Quay – Canary Wharf
22, Hertsmere Road • E14 4ED London, United Kingdom
Phone +44 (0)20 70931000 • Fax +44 (0)20 70931001

| • Scientific Committee |
|---|
| Dr Jane Barrett • Dr Luis F. Collia • Dr Domenico Criscuolo • Prof Dr Gerfried Nell |

| • IFAPP Secretariat | | |
|---|---|---|
| Kuipersweg 2T | Phone +31 (0)348 489305 | e-mail: ifapp@planet.nl |
| 3449 JA Woerden | Fax +31 (0)348 489301 | website: www.ifapp.org |

| • CPD Credits |
|---|
| This conference has been awarded with 5.75 CPD credits from the<br>Faculty of Pharmaceutical Medicine of the Royal Colleges of the United Kingdom |

# • Programme

| | | | |
|---|---|---|---|
| 08h 15 - 08h 45 | • Registration | | |
| 08h 45 - 09h 00 | **Introductory Remarks** | *Domenico Criscuolo* | *IFAPP* |
| | **• Morning Session**<br>**Looking for a Quality System** | | |
| | *Chairs: Fergus Sweeney (EMEA) and Domenico Criscuolo (IFAPP)* | | |
| 09h 00 | **GCP Inspections: Role of EMEA** | *Fergus Sweeney* | *EMEA* |
| 09h 30 | **Role and Activities of Italian Inspectorate** | *Umberto Filibeck* | *AIFA* |
| 10h 00 | **Major Quality Issues in Clinical Research** | *To be announced* | *BrAPP* |
| 10h 30 | • Coffee | | |
| 11h 00 | **The Role of Audits in the Quality Process** | *Anna Piccolboni* | *Zambon Group* |
| 11h 30 | **Are Auditors Properly Trained?** | *David Butler* | *BARQA* |
| 12h 00 | **Discussion** | | |
| 12h 30 | • Lunch | | |
| | **• Afternoon Session**<br>**EU and Quality** | | |
| | *Chairs: Jane Barrett (BrAPP) and Matt Jones (BARQA)* | | |
| 13h 30 | **EU Focus on Quality** | *To be announced* | *MHRA* |
| 14h 00 | **Experiences in Regulatory Inspections** | *Matt Jones* | *BARQA* |
| 14h 30 | **The Experience of Roche QA** | *Beat Widler* | *Roche* |
| 15h 00 | **Quality and CRO: an Example** | *Angela Del Vecchio* | *AIFA* |
| 15h 30 | **Computerized Systems Validation: a Risk-Based Approach** | *Chris Montgomery* | *BARQA* |
| 16h 00 | **Discussion** | | |
| 16h 30 | **Concluding Remarks and End of Meeting** | *Matt Jones*<br>*Jane Barrett* | *BARQA*<br>*BrAPP* |

## • Contents of the Conference

The 2009 Conference will cover a very relevant topic: how to ensure and how to control Quality of Clinical Research. IFAPP Scientific Committee believes that this issue needs a full day debate, with contributions from all players in clinical development, and from speakers representing EMEA, Industry and Scientific Associations. And it is easy to anticipate that this Conference will be very fruitful for all interested parties.

## • Target Audience

The conference is addressed to pharmaceutical physicians and quality assurance managers: in addition all professionals involved in clinical research and regulatory affairs as well as regulators and clinical investigators, and all those involved in the development of medicinal products, will benefit from this up-to-date review of quality issues.

## • Language

The conference language is English.

## • Conference Venue

The conference will take place at:

Marriott Hotel West India Quay
22, Hertsmere Road
E14 4ED London
Phone +44 (0)20 70931000
Fax +44 (0)20 70931001

For your information please note that London City is the closest airport. If you want IFAPP to reserve your hotel accommodation, please complete the en-closed hotel reservation form and return it to the IFAPP secretariat as soon as possible. We reserve a number of rooms for attendees until 1 December 2008.

## • Hotel Accommodation

On the enclosed hotel reservation form you will find information about several hotels. If you want us to reserve your hotel accommodation, please mention your hotel preference.

## • Certificate of Attendance

The IFAPP will grant a Certificate of Attendance to all delegates. The conference is awarded with CPD credits from the Faculty of Pharmaceutical Medicine of the Royal Colleges of the United Kingdom.

## • Registration Fee

You can register for this conference by filling in the enclosed registration form and returning it to the IFAPP secretariat. Registrations will be accepted only upon receipt of payment.

The registration fee is **EUR 800.00**
BrAPP and BARQA members **EUR 700.00**

You should pay the registration fee by bank transfer to:

Account no. 55.84.60.739
ABN AMRO BANK
P.O. Box 2007
3440 DA WOERDEN
The Netherlands

BIC: ABNANL2A
IBAN: NL30ABNA0558460739

## • Lunches and Coffee Breaks

Coffee and lunch are included in the registration fee.

## • Confirmation

After receipt of your registration form you will receive a confirmation and an invoice.

## • Cancellation

In the event of cancellation on or before **1 December 2008** the fee will be reimbursed by deduction of a 20% (EUR 160.00 or respectively EUR 140.00) administration fee.

In case of cancellation after 1 December 2008 there will be no reimbursement on the registration fee.

Replacement of a delegate can occur at any time without additional charge.

## • Further Information

For further information please contact:

**IFAPP Secretariat**
Kuipersweg 2T
3449 JA WOERDEN
The Netherlands
Phone: +31 (0)348 489305
Fax: +31 (0)348 489301
E-mail ifapp@planet.nl
Website www.ifapp.org