2014 March

# IFAPPWORLD

INTERNATIONAL FEDERATION OF ASSOCIATIONS OF PHARMACEUTICAL PHYSICIANS & PHARMACEUTICAL MEDICINE

PRESIDENT'S LETTER

## Dear Colleagues

I am pleased to present you the first issue of IFAPP WORLD in 2014. While reading this issue you will perhaps be surprised that reports ending incomplete with a forwarding link to the IFAPP Website, where you find the continuation ... ▶ page 2

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WWW.IFAPP.ORG

Dr Yil-Seob Lee, IFAPP President, South Korea

"Our goal is to strengthen our community, to improve communication, and to make IFAPP membership even more useful and valuable for all connected members."

President's Letter

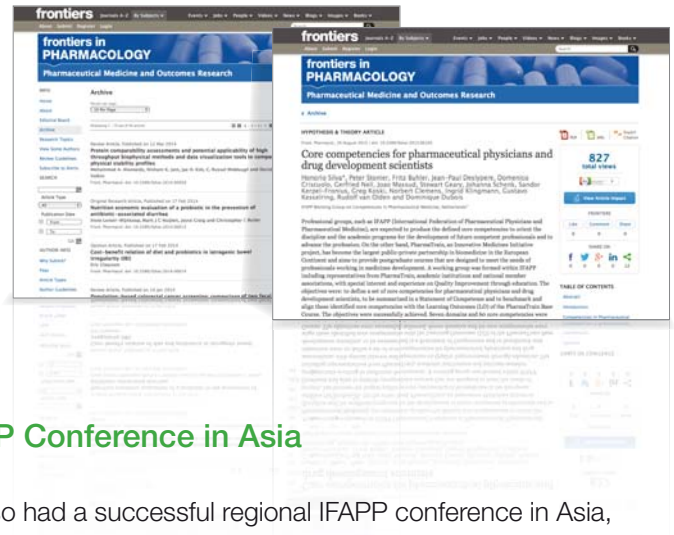
# Dear Colleagues

**I am pleased to present you the first issue of IFAPP WORLD in 2014. While reading this issue you will perhaps be surprised that reports ending incomplete with a forwarding link to the IFAPP Website, where you find the continuation of the report. Our intention is to keep the circulating IFAPP WORLD PDF file short, concise, and to the point, while we still put our emphasis on completeness and comprehensiveness. For this purpose we provide the full information on our IFAPP website. We are optimistic that this approach could encourage and accelerate the information exchange between IFAPP member associations and IFAPP WORLD readers.**

To build up the IFAPP community and make communication even faster and straight forward we strongly recommend that you subscribe to the IFAPP RSS feed here or join the IFAPP mailing list option here.

## Core Competencies in PM

Looking back on 2013, I conclude that it was another successful year for IFAPP. We could reconnect to most of our national member associations. Further on, IFAPP developed the "Core Competencies in Pharmaceutical Medicine" with cooperative effort by the CEPM Working Group V, which included representatives from IFAPP and PharmaTrain. I really appreciate the hard work of the CEPM Working Group. The Core Competencies were accepted and endorsed by IFAPP national member associations and have been published in the journal "Frontiers in Pharmacology" [Front. Pharmacol., 26 August 2013; doi: 10.3389/fphar.2013.00105] which is available here online in full length. The 60 Core Competencies from seven domains are a fundamental guidance for the planning of graduate and continuing professional development programs.




## IFAPP Conference in Asia

We also had a successful regional IFAPP conference in Asia, being the "Collaboration for Innovation in Drug Development" Conference in Seoul, Korea, in September 2013. This conference was organized in collaboration with the Drug Information Association (DIA), IFAPP, the Korea National Enterprise for Clinical Trials (KoNECT), and the Korean Society of Pharmaceutical Medicine (KSPM). Approximately 500 participants from all over the world have joined and discussed how to achieve innovation in drug development through collaboration with stakeholders. We were happy to welcome representatives of our IFAPP national member associations in the US, Japan, Singapore, Philippines and Korea. Experiences were shared during the meeting, which has been very useful, in particular for the younger associations. A conference report you find in this IFAPP WORLD issue on page 6. ... ...

Read More ▶

Dr Kyoko Imamura, JAPhMed President, Japan

"One can make a breakthrough as a group, even if this is difficult as a lonely individual in the office."

The International Perspective: JAPAN

# Topics in Pharmaceutical Medicine in Japan Today

**by Dr Stewart Geary, Director of JAPhMed, Japan**

**The Japanese Association of Pharmaceutical Medicine (JAPhMed – www.japhmed.jp) strives to provide leadership in the field of pharmaceutical medicine in Japan. Since its foundation over 40 years ago, JAPhMed has undergone many changes, most recently – in 2010 – opening membership to professionals in pharmaceutical medicine who are not physicians, but it has consistently stood for the advancement of the skills and knowledge of those working in the field for the ultimate benefit of patients.**

## Medical Affairs – an Area of Interest

Medical Affairs is one area of recent interest in Japan. This function has long had a different character in Japan, in part because of the relatively low numbers of physicians working in the pharmaceutical industry in Japan, but also because the role of Medical Representatives in that country has included roles in safety data collection and management of post-marketing observational studies not seen in other countries. Recently there have been more moves to establish Medical Affairs departments at companies headquartered in Japan.

JAPhMed has an active Medical Affairs Committee (see the box for details) which has been involved in highlighting issues related to medical affairs in that country including the transparency of funding of academic physicians' clinical research by pharmaceutical companies, the role of Medical Science Liaison (MSL) in Japan, and industry funding of continuing medical education.

### JAPhMed's Medical Affairs Committee

"Compliance has been increasingly an important issue in pharmaceutical industry, and clear distinction should be made between medical/scientific activities and promotional activities.

Our Medical Affairs Committee is dedicated to contribute improvement of current status by promoting discussions of the issues such as implementation of investigator initiated studies and post-marketing clinical trials in order to develop scientific evidence in Japan, and activation of scientific exchanges among industry, academic researchers and opinion leaders based on compliance."
[from JAPhMed Website http://japhmed.jp/english/ in the menu "Sub Committee > Medical Affairs Committee"]

## Transparency in Research Funding and International Standards in Training

The management of conflicts of interest and transparency in research funding is tied directly to the importance of ... ...

Read More ▶

Continuation from IFAPP WORLD – APRIL 2013

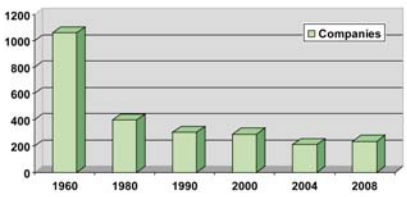
# Physicians and Non-Physician Pharmaceutical Medicine Professionals – How are IFAPP Member Associations dealing with it?

## The International Perspective: ITALY

## SSFA Celebrating the 50th Anniversary

**SSFA is the acronym of the Italian Association of Pharmaceutical Medicine – Società di Scienze Farmacologiche Applicate (www.ssfa.it), which more precisely translates to Society for Applied Pharmacological Sciences.**

Someone might ask: why this name? In order to better understand its origin, we should go back to the year 1964, when SSFA was founded. In the '60s the Italian pharmaceutical industry was in great shape: there were more than 1,000 companies (figure) which had a very prosperous time, supported by a powerful economic environment and a significant internal growth. This scenario was in fact also encouraged by the lack of a patent law on drugs, which has been enforced only in 1978: Therefore many Italian companies were making significant profits by simply copying the drugs discovered and developed by others, or introducing minor chemical modifications. In those days, the most represented scientific professions in the Italian pharmaceutical companies were pharmacologists and toxicologists, as the vast part of research on new drugs was a laboratory exercise. And indeed the founders of SSFA were mainly pharmacologists and toxicologists. This short story clearly explains the origin of the name of the Italian association.




However, in the relatively short period of the '80s and '90s, the Italian scenario has changed drastically. ... ...

Read More ▶

## The International Perspective: AUSTRALIA

## APPA Membership Extended

**The Australian Pharmaceutical Physicians Association (APPA – www.appa.net.au) is an organization of approximately 80 members with a majority being pharmaceutical physicians, employed in "medical" and "scientific" functions of the pharmaceutical and biopharmaceutical industry in Australia.**

However, those who may fit the member profile for an Associate APPA Member as per the current APPA Constitution are carefully considered by the APPA Executive Committee upon the request for APPA membership.

For instance, a person, who is employed as a Medical Science Liaison in a pharmaceutical company and his or her professional background is science rather than medicine, would be eligible for an Associate APPA Membership.

Associate APPA Members do not have voting rights when it comes to electing the Executive APPA Committee at the Annual General Meeting. However, the APPA Executive Committee has been pondering over a revision of our current constitution, which describes the above mentioned conditions. Currently, the APPA Executive Committee has commenced the revision of the APPA Constitution. Consultation with members will be part of this revision and one of the questions which will be considered is whether full APPA membership should be opened to non-physician members.

*Dr Beata Niechoda,*
*Executive Committee Member APPA, Australia*

Dr Marlene Llopiz, AMEIFAC Ex-President, Mexico

"AMEIFAC formed the Mexican Chapter of the Association of Clinical Research Professionals (ACRP), which has successfully held two courses for the certification in PM and already scheduled two other courses."

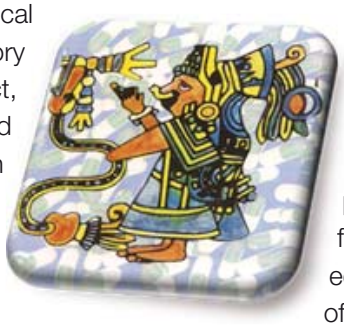
The International Perspective: MEXICO

# AMEIFAC, ACRP and IFAPP: A Combination of Knowledge for the Betterment of Pharmaceutical Medicine Worldwide

by Dr Marlene Llopiz, AMEIFAC Ex-President, Mexico

**AMEIFAC, the initials of the Asociación de Médicos Especialistas en la Industria Farmacéutica, A.C. (Association of Medical Specialists in the Pharmaceutical Industry) was founded over 45 years ago when a group of Medical Directors working at several pharmaceutical firms decided they would form a group called ADIMED (Asociación de Directores Médicos – Association of Medical Directors). This original association grew into what AMEIFAC is today.**

AMEIFAC is an organization committed to promoting and sustaining the development of pharmaceutical medicine (PM) as a medical specialty and training in clinical research at all levels. Its interest lies in providing constant and continuous education in the fundamentals of clinical research, certification of monitors and investigators, as well as the training of new generations of members of the pharmaceutical industry in important areas related to regulatory affairs, pharmacovigilance, clinical trial conduct, etc. AMEIFAC is the primary and certified resource in Mexico for clinical research professionals working for the pharmaceutical and biotechnological industry, for medical device manufacturers, for hospitals, academic medical centers and physician office settings. It is recognized by the National Chamber for the Pharmaceutical Industry (CANIFARMA) and the Ministry of Health of Mexico (Secretaría de Salud).



As is known, pharmaceutical medicine is a medical discipline concerned with the discovery, development, evaluation, registration, monitoring and dealing with the medical aspects of marketing medicines and medical devices for the benefit of patients and public health. During the past 50 years, PM as a discipline has gone through an important evolution on a worldwide scale. However, in Mexico and Latin America, its development has been recent, yet nevertheless very satisfactory, both on an organizational level, as well as academically.

## Pharmaceutical Medicine in Mexico

In Mexico pharmaceutical medicine has reached a level of development that needs to be reinforced and perfected in order to maintain the regional leadership of the country in a competitive global environment. Mexico's current level of development in PM can be measured by the new empowerment of undergraduate and specialist educational programs for those interested in PM at both public and private universities. Mexico was the first country in Latin America to offer this kind of educational programs, which have obtained official recognition and support by one of two of the utmost prestigious upper education and postgraduate institutions in the country. ... ...

Read More ▶

Dr Greg Koski, President and Co-founder of ACRES – Alliance for Clinical Research Excellence and Safety

"To hear members of industry, government and academia engage in conversation about actually collaborating was truly novel and inspiring".

The International Perspective: KOREA

# Collaboration for Innovation in Drug Development

**A Report from the Conference at September 9-10, 2013 in Seoul, Korea, made available by KoNECT and supplemented by Eckhard Böttcher-Bühler**


**The Collaboration for Innovation in Drug Development Conference was successfully held on September 9-10, 2013, at the Sheraton Grande Walkerhill Hotel in Seoul, Republic of Korea. Under the formidable leadership of the current IFAPP president, Dr Yil-Seob Lee, GSK vice president Korea, and with the ardent support of DIA, IFAPP, KoNECT and KSPM, this regional north-east Asia meeting came to fruition after months of hard work and planning. Approximately 500 attendees descended on the conference venue over the two days of the event, with a thoughtful public relations campaign leading to significant international attention, with attendees arriving from China, Hong Kong, Japan, The Netherlands, The Philippines, Singapore, Taiwan and the USA. The venue with state-of-the-art facilities has offered a vibrant atmosphere set against a beautiful panoramic backdrop of the Han River.**

## Organizers and Supporters

The ambitious event was jointly hosted through close cooperation involving four major organizations: the Drug Information Association (DIA), IFAPP, the Korea National Enterprise for Clinical Trials (KoNECT), and the Korean Society of Pharmaceutical Medicine (KSPM). [More details on these organizations presented below]

The event was also generously supported by the Korean government through the Korean Ministry of Health and Welfare (KoMHW), the Korean Ministry of Food and Drug Safety (MFDS) and Korea Health Industry Development Institute (KHIDI). The organizing committee would like to extend their deep gratitude to these organizations, as well as to all of the attendees and supporters who helped contribute to a highly successful and innovative conference. ... ...

Read More ▶

Laurent Auclert, European Federation of Pharmaceutical Industries and Associations (EFPIA), Chairman of the PharmacoVigilance Committee, France

"An informed patient is one of the best safeguards against medication errors."

Reports and Concepts

# Tackling Medication Errors – an EMA Workshop

**by Dr Domenico Criscuolo, SSFA Delegate to IFAPP. Italy**

Photo © Fotolia

**More than 200 European experts in drug development, regulatory affairs and pharmacovigilance convened at the European Medicines Agency (EMA) to take part in the EMA Workshop on Medication Errors, an issue which is frequently underestimated.**

## A Major Public-Health Burden

"Medication errors with medicinal products are a major public-health burden and generally refer to mistakes in the processes of prescribing, dispensing, administering or monitoring medicinal products in clinical practice. In Europe, the medication error rate in ambulatory care is estimated at 7.5% at prescription and 0.08% at the dispensing stage, whereas in the hospital setting the rates vary between 0.3–9.1% and 1.6–2.1% respectively." This scope EMA has provided in the introductory note to the program for this workshop, which was held in London, United Kingdom (UK), on February 28th to March 1st, 2013. It continues:

"At national level, various systems are in place to allow for medication-error detection, reporting and prevention, and the collaboration between organisations such as patient-safety institutions, pharmacovigilance centres and poison-control centres in one Member State can inform other Member States and inform work at European Union (EU) level. Since July 2012, the EU pharmacovigilance legislation explicitly foresees reporting of suspected adverse reactions associated with medication errors and liaison with national patient-safety organisations to improve public health [Directive 2001/83/EC Articles 1(11), 101(1) and 107a(5)]. The aim of this workshop is to facilitate the implementation of these new legal provisions at EU level." ... ...

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## The Flag

IFAPP World is a publication of the

### International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP)

IFAPP, founded in 1975, is a non-profit organization with 30 national member associations representing ca. 5,500 pharmaceutical medicine professionals worldwide.

IFAPP acts as an international forum for all pharmaceutical medicine expert's professional's organizations worldwide by dealing with matters brought to its attention through national member associations.

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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 medicine professionals worldwide.

IFAPP is in search of further Gold and Silver Sponsors.

Detailed information on sponsorship opportunities is available at www.IFAPP.org, section "sponsors" in the menu. ■


www.icpm2014.com

## IFAPP International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine

Our Federation is a non-profit organization founded in 1975. The aim of the federation is to act as an international forum for all the organizations of pharmaceutical physicians and pharmaceutical medicine world-wide by dealing with matters brought to its attention by our National Member Associations.

IFAPP fosters the development and international recognition of Pharmaceutical Medicine as a specific medical specialty and the development of training and continuing education programmes in pharmaceutical medicine. It stimulates a closer relationship between the professionals working in the field of pharmaceutical medicine: professionals working in industry, academia, regulatory bodies, authorities and policy makers. The IFAPP has 30 national member organizations.

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## DGPharMed Deutsche Gesellschaft für Pharmazeutische Medizin e.V.

The German Society of Pharmaceutical Medicine (DGPharMed) is a scientific-medical association with around 1.500 individual members active and committed to promote and develop all scientific areas of pharmaceutical medicine as ...

· drug discovery
· preclinical and clinical development
· risk, quality and safety assessment
· methodology of clinical trials
· legal and regulatory affairs
· market authorization
· continuous supervision
· health economics

The DGPharMed is focused on pharmaceuticals, medical devices and biotechnology products and related information, expertise, education and knowledge transfer.

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Phone: +49 89 4520843-0 | info@dgpharmed.de | www.dgpharmed.de

## Interview with the Presidents of IFAPP and DGPharMed e.V., Dr. Yil-Seob Lee and Dr. Axel Mescheder

As President of International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP), what do you consider as the most important goal to be achieved by International Conference of Pharmaceutical Medicine (ICPM) 2014?

**Dr. Yil-Seob Lee:** As we do in other ICPM meetings I hope we can share our knowledge and experiences in pharmaceutical medicine, improve our competencies in pharmaceutical medicine and learn the up to date information at the ICPM 2014. And I hope we can have better relationship and communication with each national member associations.

Germany is hosting the next ICPM, why did you decide to have the ICPM 2014 in Berlin?

**Dr. Axel Mescheder:** "The World Is Our Partner": Berlin's motto already indicates its truly international spirit which makes the German capital the place of choice for the ICPM 2014. Berlin is Germany's largest city, with a population of about 3.4 million. It is a vibrant place with partnerships linking 17 cities and including many joint enterprises with places all around the world. Berlin is one of the most dynamic economic regions in Europe. Its well-developed infrastructure, modern telecommunications structure and excellent science and research community provide ideal conditions for business and scientific meetings.

Which is the idea behind the title of ICPM 2014?

**Dr. Axel Mescheder:** Drug development aiming for true innovations has become even more challenging in the past decade. The investments needed further increased, hurdles for approval and reimbursement became more demanding. In a globalized environment all economic regions are directly competing for R&D leadership in drug development. This conference will focus on the major framework conditions in that field. Beyond assessment of the status quo the presentations will provide the participants with an outlook on what it will take to stay on top of drug development. High caliber international experts will address the key topics relevant for smart development of better drugs. However, the meeting structure will also allow for exchange and networking with peers to discuss presentations and new topics.

Dr. Axel Mescheder
*President of DGPharMed*

Dr. Yil-Seob Lee
*President of IFAPP*

## Thursday, 20 March 2014

| | | |
|---|---|---|
| 9.10 | Welcome | |
| 9.30 | Keynote Speech: Globalisation of high impact Clinical Research | |
| 10.00 | The new EU Regulation for clinical trials 1 | |
| 12.00 | Lunch Break | |
| 13.30 | Global scope regulations in Pharmacovigilance 2A | New collaborative models for the pharmaceutical industry 2B |
| 15.00 | Coffee Break | |
| 15.30 | Global education in pharmaceutical medicine and drug development sciences 3A | Clinical Outcome Assessments: concepts, instruments and regulatory perspectives 3B |
| 20.00 | Evening event at Arminiushalle, Berlin<br>See page 13 for details | |

## Friday, 21 March 2014

| | | |
|---|---|---|
| 8.30 | Laudatio | |
| 9.00 | Keynote Speech: Outlook for the future of medicine | |
| 9.30 | Intellectual Property: case studies around the world 4A | Smart clinical operations and monitoring 4B |
| 10.30 | Coffee Break | |
| 11.00 | The role of health care professionals in the future of drug development 5A | Impact of health care systems on the quality of care 5B |
| 12.00 | Lunch Break | |
| 13.00 | Hot regulatory topics: Focus on audits and inspections 6A | Ongoing issues in drug development: the international experience 6B |
| 15.00 | Coffee Break | |
| 15.30 | Round Table: Data protection in drug development | |

## Dinner at the Congress Hotel
## Wednesday, 19 March 2014, 19.30 h

We invite you to join our get together and evening buffet with conference participants, speakers and members of the scientific and executive committees.

The dinner takes place at the hotel restaurant “Le Bouveret” between 19:30 h and 22:00 h.

Please consider that a separate registration is required.

| | |
|---|---|
| 8.00 Uhr | Registration – near the entrance of the venue |
| 9.10 Uhr | **Welcome**<br>Yil-Seob Lee, President of IFAPP, South Korea and Axel Mescheder, President of DGPharMed, Germany |
| 9.30 Uhr | **Keynote Speech: Globalisation of high impact Clinical Research**<br>Bernard Munos |
| | **The new EU Regulation for clinical trials** SYMPOSIUM 1<br>Chair: Domenico Criscuolo, Italy \| Vincenzo Salvatore, Italy |
| 10.00 Uhr | **The new regulations for clinical trials – initial comments and amendments**<br>Vincenzo Salvatore, Università Insubria, Italy |
| 10.30 Uhr | Coffee Break |
| 11.00 Uhr | **Are EU ECs using the same approach to evaluate clinical protocols?**<br>Petra Knupfer, Ethics Committee, Medical Assosiation Baden-Württemberg, Germany |
| 11.30 Uhr | **How to promote clinical trials education among clinical investigators**<br>Jean-Marie Boeynaems, Université Libre de Bruxelles and Erasme Hospital, Belgium |
| 12.00 Uhr | Lunch Break \| Hotel restaurant and dining area |

## Global scope regulations in Pharmacovigilance Patient's safety beyond regulatory requirements?

SYMPOSIUM 2A

Chair: Thomas Bethke, Germany | Stella Blackburn, United Kingdom

## New collaborative models for the pharmaceutical industry

SYMPOSIUM 2B

Chair: Honorio Silva, United States | Sandor Kerpel-Fronius, Hungary

| | | |
|---|---|---|
| 13.30 Uhr | Quantitative and qualitative benefit risk evaluation – A new approach to measure risk<br>Xavier Luria, Senior Consultant, Spain | Transcelerate in discovery and early development<br>Paulo Moreira, EMD Serono, United States (USA) |
| 14.00 Uhr | A glance at the Global Pharmacovigilance Landscape – some practical aspects<br>Sabine Jeck-Thole, Boehringer Ingelheim, Germany | Academia and Pharmaceuticals': New models: The IMI<br>Kenneth I. Kaitin, Tufts Center for the Study of Drug Development, United States (USA) |
| 14.30 Uhr | Risk management and risk minimization – How to monitor success?<br>Stella Blackburn, European Medicines Agency, United Kingdom | Collaboration beyond pharmaceuticals: ACRES<br>Greg Koski, ACRES, United States (USA) |
| 15.00 Uhr | Coffee Break | Coffee Break |

## Global education in pharmaceutical medicine and drug development sciences

SYMPOSIUM 3A

Chair: D. Dubois, Belgium | João Massud, Brasil

## Clinical Outcome Assessments: Concepts, instruments and regulatory perspectives

SYMPOSIUM 3B

Chair: Ute Marx, Germany | Thomas Kohlmann, Germany

| | | |
|---|---|---|
| 15.30 Uhr | The global Specialist in Medicines Development: PharmaTrain<br>Ingrid Klingmann, Pharmaplex BVBA, Germany | COA in specific indications<br>Monika Bullinger, University Clinic of Hamburg-Eppendorf, Germany |
| 16.00 Uhr | Competency based job profiles and career path in medicines development<br>Peter Stonier, Faculty of Pharmaceutical Medicine, United Kingdom | COA: What Do the Regulatory Authorities expect?<br>B. Arnauld, HEOR & Strategic Market Access Mapi, France |
| 16.30 Uhr | Alignment of competencies for Inter Professional Education<br>Honorio Silva, Inter American Foundation for Clinical Research, United States (USA) | COA: What is the point of view of IQWIG?<br>Stefanie Reken, Institute for Quality and Efficiency in Health Care (IQWiG), Germany |
| 20.00 Uhr | Evening event at Arminiushalle, Berlin<br>Arminiusstrasse 2-4, 10551 Berlin-Tiergarten/Moabit | See page 13 for details |

8.30 Uhr
Laudatio: Prof. Fritz Bühler – The Great Educator
Gerfried Nell, NPC Nell Pharma Connect, Austria

9.00 Uhr
Keynote Speech: Outlook for the future of medicine: Where Research, Medicine and Care will Converge
Michael Rosenblatt, Merck & Co., Inc., United States (USA)
Chair: Greg Koski, United States (USA)

## Intellectual Property: Case studies around the world — SYMPOSIUM 4A

Chair: Christoph Gleiter, Germany | Alexander Denoon, United Kingdom

9.30 Uhr
Intellectual Property: The legal view
Alexander Denoon, Lawford Davies Denoon, United Kingdom

10.00 Uhr
Impact on pharmaceutical medicine and clinical research
Dr. Peter R. Roth, Novartis Pharma AG, Switzerland

## Smart clinical operations and monitoring — SYMPOSIUM 4B

Chair: Greg Koski, United States (USA) | Heinrich Klech

Smart Systems – Can They Enhance Clinical Operations?
Greg Koski, ACRES, United States (USA)

What is Smart Monitoring – Can New Approaches Make a Difference?
Randy Ramin-Wright, ii4sm, Switzerland

| | | |
|---|---|---|
| 10.30 Uhr | Coffee Break | Coffee Break |
| | **The role of health care professionals in the future of drug development**<br>Chair: Gustavo Kesselring, Brasil | Otmar Kloiber, France | SYMPOSIUM 5A | **Impact of health care systems on the quality of care**<br>Chair: Kurt Bestehorn, Germany | Anselm K. Gitt, Germany | SYMPOSIUM 5B |
| 11:00 Uhr | How MDs could contribute to the innovation on medicine products<br>Otmar Kloiber, World Medical Association, France | Introduction into the topic<br>Hans-Dieter Nolting, IGES Institut GmbH, Germany |
| 11:30 Uhr | How pharmaceutical companies could improve the clinical research enterprise through their own R&D departments<br>Michael Devoy, Bayer HealthCare Pharmaceuticals, Germany | Impact of a budget restrictive vs. an incentive driven reimbursement system in clinical practice<br>Anselm K. Gitt, Cardiac Center Ludwigshafen, Germany |
| 12.00 Uhr | Lunch Break | Hotel restaurant and dining area | Lunch Break | Hotel restaurant and dining area |

## Hot regulatory topics: Focus on audits and inspections

SYMPOSIUM 6A

Chair: Gabriele Schwarz, Germany | Sabine Brunschön-Harti, Germany

**13.00 Uhr** Computerized systems in clinical trials – Opportunities and challenges from a regulator's perspective
Andy Fisher, Medicines and Healthcare Products Regulatory Agency, United Kingdom

**13.30 Uhr** Ethical considerations in clinical trials performed in developing countries
Cristina Torres, FERCAP Coordinator, Philippines

**14.00 Uhr** To be or not to be – Key issues identified during site regulatory Inspections
Sabine Brunschön-Harti, Parexel Quality, Germany

**14.30 Uhr** Sponsor Site Inspections – Key Findings on study setup & organization
Gabriele Schwarz, Federal Institute for Drugs and Medical Devices, Germany

## Ongoing issues in drug development: The international experience

SYMPOSIUM 6B

Chair: Luis Francisco Collia, Argentina | J.P. Deslypere, Singapore

Perspectives from India
Kiran Marthak, India

Perspective on Drug Development in North East Asia
Kihito Takahashi, GlaxoSmithKline, Japan

Enhancing clinical research in Mexico
Marlene Llopiz, AMEIFAC, Mexico

Building an infrastructure for research in Korea
Min Soo Park, Clinical Trials Center, Severance Hospital, South Korea

15.00 Uhr Coffee Break

## Data protection in drug development: Patient rights in a changing regulatory landscape

ROUND TABLE

Chair: Axel Mescheder, Germay | Yil-Seob Lee, South Korea

15.30 Uhr Invited faculty:
Otmar Kloiber, World Medical Association, France
Kenneth I. Kaitin, Tufts Center for the Study of Drug Development, United States (USA)
Greg Koski, ACRES, United States (USA)
Michael Devoy, Bayer HealthCare Pharmaceuticals, Germany
Michael Rosenblatt, Merck & Co., Inc., United States (USA)
Ignaz Wessler, Medical Association Rheinland-Pfalz, Germany

16.30 Uhr Concluding remarks
Axel Mescheder, President of DGPharMed, Germany

This program was prepared by the DGPharMed and IFAPP committees:

Scientific Committee: Axel Mescheder, Medpace, Germany · Thomas Bethke, Boehringer Ingelheim, Germany · Domenico Criscuolo, Genovax, Italy · Christoph Gleiter, CenTrial GmbH, Germany · Gustavo Kesselring, ViS Research Institute, Brasil · Greg Koski, ACRES, United States (USA) · Yil-Seob Lee, GlaxoSmithKline, South Korea · Shinichi Nishiuma, GPS-J Medical, Japan · Honorio Silva, Inter American Foundation for Clinical Research, United States (USA) · Peter Stonier, Faculty of Pharmaceutical Medicine, United Kingdom

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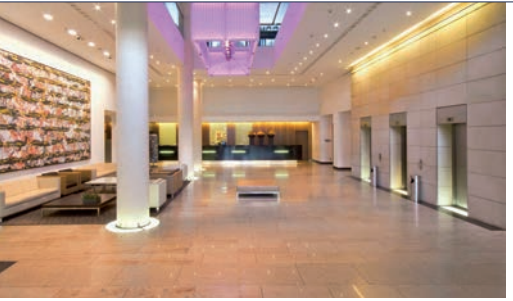

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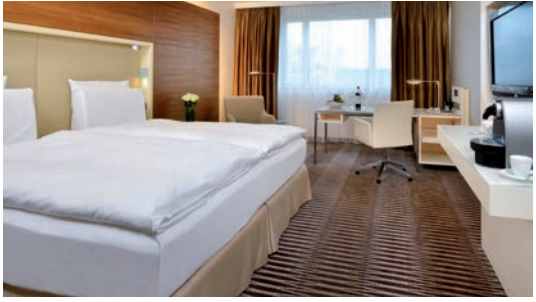
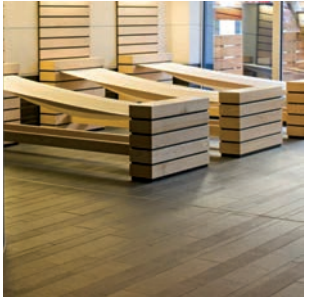
The hotel has a quota of rooms available.
Please mention the password "DGPharMed" when booking.



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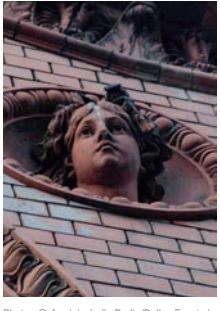


## Thursday, March 20, 2014, from 20.00 h

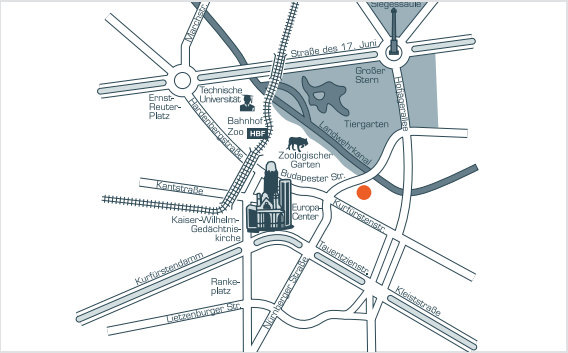
**We invite you to an outstanding scientific event, and also to share with us some relaxing moments in Berlin. During our evening event in the Arminiushalle, you will experience an exciting location with typical Berlin spirit!**

Arminiushalle
Arminiusstrasse 2-4, 10551 Berlin-Tiergarten/Moabit
www.zunfthalle-berlin.de
Please arrange individual transfer to the venue

## Your way to the congress

**Distances from the hotel:**

Train Station "Zoologischer Garten" ..... 1 km ..... 5 min walk
Motorway Exit "Hohenzollerdamm" ..... 5 km ..... 11 min by car
Airport "Berlin-Tegel" ..... 10 km..... 20 min by taxi
Airport "Berlin-Schönefeld" ..... 24 km ..... 26 min by taxi




## Congress fees

**Early-Bird-Rates until 20 January 2014**
IFAPP/DGPharMed Members: ..... 590,– €*
Non-Members: ..... 740,– €*

**Booking from 21 January 2014**
IFAPP/DGPharMed Members: ..... 690,– €*
Non-Members: ..... 840,– €*

Dinner at the Congress Hotel on 19 March 2014 ..... 30,– €*
Evening event at Arminiushalle on 20 March 2014 ..... included

Includes lecture documentation in digital form (USB flash drive). A printed documentation will be charged with 25,– €. Please note your choice on the the registration form. Choice in advance is binding as the documentation can not be printed at the event.

## Event Organization

PRIMECON

**PRIMECON GmbH**
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Phone: +49 211 49767-20
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**Attendees & speakers service**
Mr. Dennis Rennen
Phone: +49-211 49767-28
rennen@prime-con.eu

Please note:
In the case of cancellation without an exchange participant four weeks prior to the congress begin, an administrative charge of 100,– € will be raised. A cancellation 8 days prior to the congress will be charged with half the congress fee, any later cancellation with the full congress fee. Cancellation is only possible in written form to the address mentioned above. The date of arrival at the recipient („Event Organization") applies for the applicability of rates and cancellation conditions. The congress fee includes congress documentation, catering and coffee in the congress breaks and is due on receipt. In case of cancellation through the organizer, the congress fee will be refunded in full, further claims are excluded.

Please send your filled registration to

DGPharMed e.V.
c/o PRIMECON GmbH
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40237 Düsseldorf
GERMANY

Fax: +49 211 49767-29
E-Mail: info@dgpharmed.de

# 17th ICPM 2014 International Conference on Pharmaceutical Medicine
# 30th DGPharMed Annual meeting

I herewith register for the above named congress from 20–21 March 2014 in Berlin, Germany.

Surname/First Name

E-Mail | Institution/Company

Department/Occupation | Member of DGPharMed/IFAPP: ❑ yes ❑ no

Postal address

❑ I wish to take part at the dinner at the event hotel on 19 March 2014 — 30,– € (incl. dinner buffet). Binding registration.

❑ I wish to take part at the evening event on 20 March 2014 — Included in congress fee. Binding registration.

Congress documentation ❑ digital (USB Flash Drive) ❑ printed (25,– €/binder) — Binding choice necessary.

Your name and address will be published on a list available to other participants at the congress. If you disagree, please tick here ❑ — Please note!

Date | Signature ✗


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