

JULY  
2014

## TRAINING OF MEDICINES DEVELOPMENT AND REGULATION IN EMERGING COUNTRIES



Magyar Kísérletes és Klinikai  
Farmakológiai Társaság

Hungarian Society for Experimental and  
Clinical Pharmacology

### SPEAKERS:

- **Elizabeth Allen** - BSc(hons) Pharmacy, MPH, South African Faculty, Global Health Network, University of Cape Town, South Africa
- **Rolf Bass** – Visiting Professor for Pharmaceutical Medicine, University of Basel, Switzerland
- **Dominique Dubois**, Patient Value Solutions (PVS) Consultancy, Huldenberg, Belgium. Managing Director and Principal Consultant Health-Economics and Patient-Reported Outcomes Research
- **Alex Dodoo**, MSc, PhD, Centre for Tropical Clinical Pharmacology and Therapeutics, University of Ghana Medical School, Accra, Ghana
- **Steven E. Kern**, PhD, Deputy Director, Quantative Sciences, Global Health-Integrated Development, Bill & Melinda Gates Foundation
- **Sandor Kerpel-Fronius**, MD, DSc, Professor of Clinical Pharmacology, Dept. of Pharmacology and Pharmacotherapy, Semmelweis University, Faculty of Medicine, Budapest, Hungary
- **João Massud Filho**, MD, FFPM (Honorary), Professor of Pharmaceutical Medicine, Federal University of São Paulo, Snr. Consultant in Drug Development, Trials Consulting, President of Brazilian Society of Pharmaceutical Medicine, São Paulo, Brazil
- **Mandisa Hela**, Registrar of Medicines, Medicines Control Council (MCC), Pretoria, South Africa
- **Jacques Demotes Mainard** – Director, European Clinical Research Infrastructure Network (ECRIN), Paris, France
- **Bernd Rosenkranz**, MD PhD (Germany), FFPM, Head of Division of Clinical Pharmacology, Faculty of Medicine and Health Sciences, Stellenbosch University and Fundisa African Academy of Medicines Development, Cape Town, South Africa
- **Honorio Silva**, MD, Inter American Foundation for Clinical Research, New York, USA; International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine
- **Jeremy Whitty**, Director, School of Health Sciences, Hibernia College, Dublin, Ireland and Professor of Operations and Quality in Health Sciences, I.E. Business School, Madrid, Spain

A WCP 2014 Satellite Workshop under the joint auspices of the International Federation of Associations of Pharmaceutical Physicians (IFAPP) and of the European Innovative Medicines Initiative (IMI), PharmaTrain.

The aim of the workshop is to initiate discussion about the optimal methods and practical approaches for teaching of medicines development and regulation in countries with emerging economies.

**WHERE:** *The Westin Cape Town,  
Convention Square, Lower  
Long Street, Cape Town,  
South Africa*

**WHEN:** *Sunday, 13 JULY 2014*

**TIME:** *9h00 - 15h00*

**RSVP date:** *8 June 2014*

**Contact:** *Colene Collins*

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**Tel.:** *+27(0)21 9579400*

**Registration Fee:**

**R400 (includes lunch)**

**Students Free**

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# TRAINING OF MEDICINES DEVELOPMENT AND REGULATION IN EMERGING COUNTRIES PROGRAM

TIME	SPEAKER	TITLE
<b>Chairpersons: Massud Filho J. &amp; Rosenkranz B.</b>		
9:00	Sandor Kerpel-Fronius	Welcome and Introduction. The modular PharmaTrain educational concept. The role of university network for joint teaching.
9:20	Alex Dodoo	The need for training specialists in medicines development, clinical investigation and drug regulation in emerging economies
9:40	Honorio Silva	The alignment of various competencies in medicines research and development. The need for globalizing and harmonizing training
10:00	Bernd Rosenkranz	Regional experience and needs for teaching medicines development in Africa
10:15	Mandisa Hela	Training regulatory specialists in Africa
10:30	<b>Discussion</b>	
<b>10:45 - 11:15 TEA BREAK</b>		
<b>Chairpersons: Silva H. &amp; Kerpel-Fronius S.</b>		
11:15	João Massud Filho	Regional experience and needs for teaching medicines development and regulation in South America
11:30	Rolf Bass	The needs and experience for global training in regulatory affairs
11:45	Steven Kern	Integrated Medicines Development for problems in emerging economies: opportunities to put training into practice
12:05	Jeremy Whitty	Teaching medicines development and regulation by blended learning in emerging economies
12:25	<b>Discussion</b>	
<b>12:40 - 13:30 LUNCH</b>		
<b>Chairpersons: Dodoo A. &amp; Kern S.</b>		
13:30	Elizabeth Allen	Affordable training and career development for clinical trial staff around the globe
13:45	Jacques Demotes Mainard	Training of clinical investigators. The significance of organizing clinical investigator networks
14:00	Dominique Dubois	The benefits of teaching quality management at courses on medicine development and regulation in emerging economies
14:30	<b>Discussion</b>	
14:55	Bernd Rosenkranz	Concluding remarks. Adjourn of the meeting

## ORGANISERS

**Prof Sandor Kerpel-Fronius**, Dept of Pharmacology and Pharmacotherapy, Semmelweis University, Budapest, Hungary and Cooperative European Medicines Development Course (CEMDC).

**Prof Bernd Rosenkranz**, Division of Clinical Pharmacology, Faculty of Medicine and Health Science, Stellenbosch University, Cape Town and Fundisa African Academy for Medicines Development.

## SPONSORS

