

EFGCP Annual Conference 2011

Certified GCP Training Needs & Solutions

1 & 2 February 2011 - Budapest, Hungary

organised by the

European Forum for Good Clinical Practice



'where science & ethics meet'

conferences@efgcp.eu – www.efgcp.eu

Conference Rationale

Safe and efficient new treatment options for patients are constantly being developed. These require clinical trials that are both ethical and of high-quality so as to ensure that study participants are protected and that the generated data are reliable. Good Clinical Practice (GCP) is the world-wide accepted standard for clinical research to ensure this goal. Yet although the European Commission has established a comprehensive regulatory package to ensure that GCP principles apply to the conduct of clinical trials within Europe, it is very apparent that the practical implementation of this regulatory package differs between Member States. Nevertheless, the principles of GCP must be upheld and training in these principles is essential. Such training should be appropriate for the needs of all stakeholders taking part in clinical trials, be they sponsors in industry and academia, ethics committees, competent authorities or investigators. However, this training in, for example, one Member State and for one discipline, may be inadequate and inconsistent with that provided elsewhere. Indeed, it is often theoretical and not practical. This needs to be addressed, as does the recognised desirability of ensuring that patients and the public are made better aware of the benefits and risks of taking part in clinical trials conducted to GCP standards.

There is a multitude of options to achieve more efficient GCP training that would suit all those needing it. These include establishing a common curriculum using various methods and techniques and providing certification and accreditation. The EFGCP Annual Conference 2011 will be devoted to bringing highly experienced representatives from all relevant clinical trial disciplines together to discuss the needs for GCP training, to exchange their national and organisational experiences and to devise constructive proposals for a quantum leap in training towards an improved GCP environment.

Programme Committee

Michael Bone	AREC, AAPEC, EFGCP, United Kingdom
JanHasker Jonkman	University of Groningen, EFGCP, The Netherlands
Jean-Marc Husson	Eudipharm, EFGCP, France
Ingrid Klingmann	Pharmaplex, EFGCP, Belgium
Tamas Paál	Hungary
Susan Trainor	Trainor and Partners, EFGCP, Belgium
Frank O. Wells	NRES, EFGCP, United Kingdom

Conference Language

The language of the Conference will be English.

Social Event

On the evening of February 1st all delegates are invited to take part in the Annual Conference social event. Details will be communicated at a later stage.

Agenda

Tuesday, 1 February 2011

- 08:00 Registration and Welcome Coffee
08:45 Welcome and Introduction to the Conference

Plenary Session 1

*Certified GCP Training for All Involved Disciplines
- A Necessity or Another Administrative Burden? -*

- 09:00 **Key Note Introduction** on: Why Do We Need Harmonised Training Standards?
09:30 Update on Modern Teaching and Learning Methodology
10:00 Will Accreditation Solve Current Issues?
10:30 Coffee Break

Plenary Session 2

Investigators Training in Europe

- 10:50 Business Teaching Improves Investigators' Training
11:15 Experience with Obligatory Investigator Training in Hungary
11:40 **Panel and Open Forum Discussion: Investigators Training and Certification in Europe – How?**
12:30 Lunch

Workshops

- 13:30 Workshop 1: Experiences with e-GCP Training
Workshop 2: How to Teach Clinical Research to Medical Students – Need for Undergraduate Curricula
Workshop 3: Training of Experienced Investigators & Subsequent Responsibilities in
15:00 Coffee Break
15:20 **Panel and Open Forum Discussion: Optimised Training of Pharma Industry – Is it Fit for Purpose?**

Plenary Session 3

The Joseph Hoet Lecture on Ethics in Clinical Research

16:45 Education & Expectations for Future Research: Going Beyond the Training Challenges of Future Treatments' Developments (ethical, scientific & GCP aspects)

17:30 EFGCP Annual General Meeting

18:30 EFGCP Annual Conference Social Event

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Wednesday, 2 February 2011

08:00 Welcome Coffee

Plenary Session 4

Needs & Tools for Training of Patients Representatives

08:30 Results from the PatientPartner Project

09:00 Diplom-Patienten – Breast-cancer organisation experience in Germany

09:30 A Plan for a Virtual Patients Academy

10:00 Coffee Break

10:20 **Open Forum Discussion on: Training of the Public: Information & Communication (in prevision of all being patients)**

Workshops

11:00 Workshop 4: Suitability of SOPs as Training Tools?

Workshop 5: How to Train Risk-Benefit Assessment in Rare Diseases?

Workshop 6: The Contribution of Patients in Research Ethics Committees

12:30 Lunch

Plenary Session 5

Reports from the Workshops

13:30 Reports from the Workshops

15:00 Coffee Break

Plenary Session 6

Training for Research Ethics Committees (RECs)

15:20 Basic Knowledge Requirements for REC Members

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(*Preliminary Programme, 4 August 2010 – v5PP*)

- 15:50 E-Learning Capacity Building for RECs
- 16:20 Training Needs versus Accreditation
- 16:50 **Open Forum Discussion on: Would a “European Approach” to Training of REC Members Bring Us Closer to Harmonised Ethical Review in Multi-national Trials?**
- 17:20 Closing Remarks
- End of the Conference