



Μια πολύτιμη αλυσίδα ζωής

Final Program

2nd Panhellenic Conference for “Good Distribution Practice for Pharmaceuticals”

25-26/02/2015

Wednesday, 25 February

08:30 – 09:15 Registration

09:15 – 09:30 Opening ceremony

C.C.O. President Konstantinos A. Dontis – Welcome Speech

Representative from Ministry of Health – Welcome Speech

09:30 – 09:45 The Smile of the Child

Video Presentation and Actions of the nonprofit voluntary Organization

The Smile of the Child

09:45 – 11:45 **Session 1 NATIONAL ORGANIZATION FOR MEDICINES**

Medicines Wholesale Licensing

Speaker: **Stella Stamati**

Head of Distribution Control Dept. (GDP Inspections)

Division of Production & Distribution Control

National Organization for Medicines

Practical application issues of the requirements of the new

Good Distribution Practice of Medicinal Products for Human Use, part 1

Speaker: **Dimitrios Dimas**

Dep. Head of Production Control Dept. (GMP Inspections)

Division of Production & Distribution Control

National Organization for Medicines

Practical application issues of the requirements of the new Good Distribution Practice of Medicinal Products for Human Use, part 2

Speaker: **Pantelia Goura**
*Head of Division of Production & Distribution Control
National Organization for Medicines*

11:45 – 12:15 Coffee Break

12:15 – 12:55 **Session 2 - WORLD HEALTH ORGANIZATION**

Tools and approaches to ensure quality of vaccines throughout the cold chain.

Speaker: **Dr Umit Kartoglu**
Scientist, Quality, Safety and Standards Department of
Essential Medicines and Health Products
World Health Organization

12:55 – 15:35 **Session 3 CORPORATE PERSPECTIVES**

12:55 – 13:35 End-to-End Supply Chain Management and Visibility.

Speaker: **Christopher Wallace**
*Distribution Director
Genzyme*

13:35 – 14:15 Light Lunch

14:15 – 14:55 Good distribution practice for pharmaceuticals – Chapter 9: Transportation

Speaker: **Pavlos D. Seisopoulos**
QA Manager - GDP Certified

14:55 – 15:35 Compliance in the distribution chain in the transportation specifications of the temperature sensitive drugs

Speaker: **George Tzoumbas**
Mechanical Engineer
R&D Officer Mediline - GDP Certified

WORKSHOP A

14:15 – 15:15 Expert analysis of your hot topics in cold chain

Coordinator: **Nigel Cryer**
Vice President, Quality and Regulatory
NextPharma, Göttingen, Germany

WORKSHOP B

15:35 – 16:35 Compliance in the distribution chain in the transportation specifications of the temperature sensitive drugs

Coordinator: **George Tzoumbas**
Mechanical Engineer
R&D Officer Mediline - GDP Certified

15:35 – 15:55 Global perspectives in regulatory oversight on pharmaceutical time and temperature products

*Video – Speech of **Raffik H. Bishara***
PhD, Technical Advisor and Leader PDA

15:55 – 16:15 Sled dogs, serum run and saved lives

Video – Speech of a diphtheria outbreak in an Alaskan town in 1925 and how it was dealt with a heroic and team effort, while at the same time, risks were identified and controlled.

Speaker: **James Vesper**
BS, MPH, President LearningPlus

Thursday, 26 February

09:00 – 09:30 Registration

09:30 – 10:10 Results of GDP inspections based on the new EU GDP Guidelines

- The focus of the GDP inspectors
- Inspection case
- Review of 35 GDP inspections

Speaker: **Riekert Bruinink**
*Group Chairman of the PIC/S
GDP Working Group, EMA GDP Drafting Group
Member, Dutch Health Care Inspectorate*

10:10 – 10:50 Developing and Managing a Compliant GDP Supply Chain (Storage and Distribution)

Speaker: **Robert J. Hayes**
*Mechanical Engineer, Trainer & Consultant
SeerPharma (UK)*

10:50 – 11:30 Cold Chain Management on wheels

Speaker: **Dr Umit Kartoglu**
*Scientist, Quality, Safety and Standards Department of
Essential Medicines and Health Products
World Health Organization*

11:30 – 11:45 Mediline's approach to new GDP challenges

Speaker: **George Chaliotis**
Commercial Manager Mediline

11:45– 12:15 Coffee Break

12:15 – 12:45 Unilog's approach to GDP guidelines implementation

Speaker: **Vassilis Theodoridis**
QA Manager/QP - RP

12:45 – 13:30 Legal responsibilities that arise, for everyone involved, from the failures in good distribution practice of medical products

Speaker: **Apostolos Pontas**
Lawyer

WORKSHOP C

12:45 – 13:45 Using a Risk-Based Approach in GDP Compliance

Coordinator: **Robert J. Hayes**

*Mechanical Engineer, Trainer & Consultant
SeerPharma (UK)*

WORKSHOP D

12:45 – 13:45 The last mile – how to ensure quality

Coordinator: **Dr Umit Kartoglu**

*Scientist, Quality, Safety and Standards Department of
Essential Medicines and Health Products
World Health Organization*

13:30 – 14:10 A risk based approach to managing your whole supply chain

Speaker: **Nigel Cryer**

*Vice President, Quality and Regulatory
NextPharma, Göttingen, Germany*

14:10 – 14:20 Closing Ceremony C.C.O. President Konstantinos A. Dontis – Closing Speech