

- 11:45-12:15** **Coffee break**
- 12:15-12:45** Unilog's approach to GDP guidelines implementation
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
Apostolos Pontas
Lawyer
- 12:45-13:45** **WORKSHOP C**

Using a Risk-Based Approach in GDP Compliance
Robert J. Hayes, Coordinator
Mechanical Engineer, Trainer & Consultant
SeerPharma (UK)
- 12:45-13:45** **WORKSHOP D**

The last mile – how to ensure quality
Dr Umit Kartoglu, Coordinator
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
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

SPEAKERS

- Apostolos Pontas** Lawyer
- Christopher Wallace** Distribution Director Genzyme
- Dimitrios Dimas** Dep. Head of Production Control Dept. (GMP Inspections), Division of Production & Distribution Control, National Organization for Medicines
- George Chaliotis** Commercial Manager Mediline
- George Tzoumbas** Mechanical Engineer, R&D Officer Mediline - GDP Certified
- James Vesper** BS, MPH, President, LearningPlus
- Konstantinos A. Dontis** C.C.O. President / Biomedical Engineer
- Nigel Cryer** Vice President, Quality and Regulatory, NextPharma, Göttingen, Germany
- Pantelia Goura** Head of Division of Production & Distribution Control, National Organization for Medicines
- Pavlos D. Seisopoulos** QA Manager - GDP Certified
- Raffik H. Bishara** PhD, Technical Advisor and Leader PDA
- Riekert Bruinink** Group Chairman of the PIC/S, GDP Working Group, EMA GDP Drafting Group Member, Dutch Health Care Inspectorate
- Robert J. Hayes** Mechanical Engineer, Trainer & Consultant, SeerPharma (UK)
- Stella Stamati** Head of Distribution Control Dept. (GDP Inspections), Division of Production & Distribution Control National Organization for Medicines
- The Smile of the Child** Nonprofit Voluntary Organization
- Dr. Umit Kartoglu** Scientist, Quality, Safety and Standards Department of Essential Medicines and Health Products World Health Organization
- Vassilis Theodoridis** QA Manager UNILOG /QP - RP

[FEBRUARY²⁰]
25 & 26¹⁵
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[Wednesday]
[25 February]
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PROGRAM

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 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 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 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 Dr Umit Kartoglu Scientist, Quality, Safety and Standards Department of Essential Medicines and Health Products World Health Organization
12:55-15:20	Session 3 - CORPORATE PERSPECTIVES
12:55-13:35	End-to-End Supply Chain Management and Visibility Christopher Wallace Distribution Director Genzyme
13:35-14:15	Light lunch
14:15-14:55	Good distribution practice for pharmaceuticals - Chapter 9: Transportation 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 George Tzoumbas Mechanical Engineer R&D Officer Mediline - GDP Certified
14:15-15:15	WORKSHOP A Expert analysis of your hot topics in cold chain Nigel Cryer , Coordinator Vice President, Quality and Regulatory NextPharma, Göttingen, Germany
15:35-16:35	WORKSHOP B Compliance in the distribution chain in the transportation specifications of the temperature sensitive drugs George Tzoumbas , Coordinator Mechanical Engineer R&D Officer Mediline - GDP Certified

15:35-15:55	Global perspectives in regulatory oversight on pharmaceutical time and temperature products Raffik H. Bishara , Video - Speech
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 James Vesper BS MPH, US
	[Thursday] [26 February]
09:00-09:30	Registration
09:30-10:10	Results of GDP inspections based on the new EU GDP Guidelines <ul style="list-style-type: none"> • The focus of the GDP inspectors • Inspection case • Review of 35 GDP inspections 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) Robert J. Hayes Mechanical Engineer, Trainer & Consultant SeerPharma (UK)
10:50-11:30	Cold Chain Management on wheels 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 George Chaliotis Commercial Manager Mediline