



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 February 2010  
EMA/607891/2009  
Human Medicines Development and Evaluation

26-27 APRIL 2010  
EUROPEAN MEDICINES AGENCY  
1<sup>ST</sup> INTERNATIONAL WORKSHOP ON  
NANOMEDICINES

**AGENDA**

**Program Chairperson**

Patrick Le Courtois

**Program Committee**

European Medicines Agency: Tomas Salmonson, Jean-Louis Robert, Beatriz Silva Lima, Ruth Duncan, Rogério Gaspar, Marisa Papaluca Amati  
MHLW/PMDA: Yoshikazu Hayashi  
United States Food and Drug Administration (FDA): Nakissa Sadrieh, Carlos Peña

**Scope:**

The proposed workshop will focus on key features of nanomedicines<sup>1</sup> and the emerging scientific knowledge in the field.

**Objective:**

Explore scientific aspects specific to nanomedicines and share experience at an international level, to anticipate future needs.

**Outcome:**

Report on identified issues and emerging science aspects, which may assist future developments in the field and may be relevant to future regulatory considerations.

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<sup>1</sup> To ensure a comprehensive approach, the workshop will address products containing materials in the submicron range.





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**1<sup>ST</sup> INTERNATIONAL WORKSHOP ON  
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**EUROPEAN MEDICINES AGENCY  
CONFERENCE ROOM 2A  
AGENDA**

**DAY 1**

**Starts on the 26<sup>th</sup> of April at 9:00 am**

**09:00 – 09:30**

**INTRODUCTION**

Chairperson: Patrick Le Courtois, Head of Unit, Human Medicines Development and Evaluation, European Medicines Agency

- Welcome address and objectives of the workshop  
Speaker: Thomas Lönngren, Executive Director of the European Medicines Agency
- European Commission perspective  
Speaker: Philippe Martin, Directorate-General for Health and Consumers Risk Assessment - R&D - Nanotechnologies Policy Development & Coordination, European Commission

**09:30 – 10:30**

**Keynote lecture + Q&A session:**

- Current perspective on how nanosciences apply to pharmaceuticals  
Speaker: Kazunori Kataoka, Professor at the Department of Materials Engineering, Graduate School of Engineering Division of Clinical Biotechnology, Center for Disease Biology and Integrative Medicine, Graduate School of Medicine, University of Tokyo



**10:30 – 12:00**

**SESSION 1: Nanomedicines on the market and in clinical development**

*The speakers will highlight scientific issues specifically relevant to the unique properties of each type of nanomedicine considered.*

Chairperson: Eric Abadie (European Medicines Agency CHMP Chair)

European Medicines Agency: Mayeul Boucaumont (Scientific Support & Projects Section)

- Liposomal nanomedicines and innovative formulations  
Speaker: Daan Crommelin, Professor of Pharmaceutics, Utrecht University, and Scientific Director, Dutch Top Institute Pharma, Leiden
- Polymer conjugates  
Speaker: Ruth Duncan, Professor of Cell Biology and Drug Delivery, Welsh School of Pharmacy, Cardiff University and Director of the Centre for Polymer Therapeutics
- Nanoparticles  
Speaker: Rogério Gaspar, Professor of Pharmaceutics, University of Lisbon

Q&A panel and conclusion by the Chair

**12:00 – 13:00 Lunch break**

**13:00 – 15:00**

**SESSION 2: Special aspects of nanomedicines**

*Nanosize does not necessarily imply novelty and experience has been gathered as nanomedicines have already been authorised under the existing regulatory frameworks. New methods have been developed to manufacture and characterise nanomedicines. The purpose of the session is to identify the most relevant characterisation methods indicative for safety and efficacy, the factors affecting the stability in vitro / in vivo of nanomedicines.*

**Development, Manufacturing & Characterisation**

Chairperson: Jean-Louis Robert (European Medicines Agency Quality Working Party Chair)

European Medicines Agency: Evdokia Korakianiti (Quality of Medicines, Chemicals)

- Viewpoint by Mamoun Muhammed, Head of Functional Materials Division, and Nano Characterization Centre, Royal Institute of Technology, Stockholm
- Viewpoint by Simon Holland, GlaxoSmithKline, Director, Process Understanding & Control within GSK Pharmaceutical Development, Ware
- Viewpoint by Jan Möschwitzer, Solvay Pharmaceuticals, Head of Early Pharmaceutical Development, Weesp, The Netherlands

Q&A panel and conclusion by the Chair

**15:00 – 15:30 Coffee break**

**15:30 – 17:30**

**SESSION 3: Special aspects of nanomedicines**

*The speakers will address new scientific knowledge on biological interactions of nanomedicines and existing and emerging toxicology approaches. Limits and possibility to extrapolate safety results from in vitro to in vivo will also be discussed.*

**Non-Clinical Assessment**

Chairperson: Beatriz Silva Lima (European Medicines Agency Safety Working Party chair)  
European Medicines Agency: Jean-Marc Vidal (Scientific Support & Projects Section)

- Nanomedicines interaction with biological systems  
Speaker: Kenneth Dawson, Professor of Physical Chemistry, University College of Dublin, School of Chemistry and Chemical Biology, Dublin
- Key elements in non-clinical assessment: new approaches  
(*dose/exposure/response characterisation, pharmacokinetics, tissue distribution and release, toxicology evaluation and design*)  
Speaker: Wim de Jong, Toxicological pathologist at the Laboratory for Health Protection Research, National Institute for Public Health and the Environment, Bilthoven
- Immunology and immuno-toxicity of nanomedicines  
Speaker: Bengt Fadeel, Assoc. Prof., Institute of Environmental Medicine, Karolinska Institutet, Stockholm

Q&A panel and conclusion by the Chair

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**DAY 2**

**Starts on 27<sup>th</sup> of April at 9:00 am**

**09:00 – 10:30**

**SESSION 4: Emerging nanomedicines**

*The speakers will provide an overview of the challenges raised by the development of emerging nanomedicines in the light of existing frameworks and clinical development guidelines.*

Chairperson: Bruno Flamion (European Medicines Agency Scientific Advice Working Party chair)  
European Medicines Agency: Spiros Vamvakas (Head of Scientific Advice Section)

- Novel and innovative nanotechnology-based delivery system  
Speaker: Vladimir Torchilin, Professor of Pharmaceutical Sciences, Chair, Department of Pharmaceutical Sciences Director, Center for Pharmaceutical Biotechnology and Nanomedicine Northeastern University
- Nanosystems in regenerative medicine  
Speaker: Jöns Hilborn, Professor of Polymer Chemistry and Research Coordinator on Polymer Chemistry, Uppsala University
- Theranostics nanoparticles (therapeutic and diagnostic)  
Speaker: Peter Dobson, Academic Director, Oxford University Begbroke Science Park

Q&A panel and conclusion by the Chair

**10:30 – 11:00 Coffee break**

**11:00 – 12:00**

**SESSION 5: Nanomedicines and the application of Risk Management Principles**

*Benefit/Risk and Environmental risk assessment in the life cycle of medicinal products: What additional requirements for nanomedicines may be needed? How do we reconcile the risks from the interactions between medicines and "activating devices"? Risk Minimization: why and when? Risk communication?*

Chairperson: Peter Arlett (European Medicines Agency Pharmacovigilance and Risk Assessment Sector)  
European Medicines Agency: Jan Petracek (Head of Risk Management Section)

**Benefit/Risk Assessment**

- Safety Specifications Identification and Methodology (Quality, Safety, Clinical)  
Speaker: Thomas Goedecke (Risk Management Section)
- Pharmacovigilance and Risk Minimization Programme  
Speaker: Jan Petracek (Head of Risk Management Section)

Q&A panel

**12:00 – 13:00 Lunch break**

**13:00 – 14:00**

**SESSION 5 (continued): Nanomedicines and the application of Risk Management Principles**

Chairperson: Peter Arlett (European Medicines Agency Pharmacovigilance and Risk Assessment Sector)  
European Medicines Agency: Jan Petracek (Head of Risk Management Section)

**Environmental Risk Assessment**

- Specific Methodological Issues and Implications for Risk Assessment  
Speaker: Willie Peijnenburg, Project Manager/Scientific co-ordinator at the Laboratory for Ecological Risk Assessment, National Institute for Public Health and the Environment, Bilthoven

Q&A panel and conclusion by the Chair

**14:00 – 15:45**

**SESSION 6: International outlook for Nanomedicines**

*An overview of the regulatory approaches and perspectives from different regulatory agencies viewpoint will be presented and discussed in this session.*

Chairperson: (invited)

European Medicines Agency: Emer Cooke (International liaison officer)

- Current initiatives in the US  
Nakissa Sadrieh, FDA
- Current initiatives in Japan  
Kumiko Sakai-Kato and Toru Kawanishi, National Institute of Health Sciences/MHLW
- Current initiatives in Canada  
Jim Galliver, Health Canada

Q&A panel and conclusion by the Chair

**15:45 – 16:00**

**Way forward:**

- Marisa Papaluca, Head of Scientific Support and Projects, European Medicines Agency

**16:00 – 16:30 Coffee**

**Closure of the meeting**