



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1st International Workshop on Nanomedicines

Welcome address

P Le Courtois, EMA Human Medicines Development and Evaluation – Head of Unit

An agency of the European Union





Why this workshop?

- Nanotechnologies are integrated in a large range of applications from aerospace materials to medicinal products
- Regulators from the EU, US, Canada, Japan and Australia started a platform for dialogue across frameworks including food, medical devices, cosmetics and pharmaceuticals in 2006:
 - an international observatory to share experience and understanding not to regulate
- A Regulators' conference was held at the FDA in June 2009:
 - an informal international working group on nanomedicines started in 2009
 - the organisation of a scientific workshop dedicated to nanomedicines was proposed (endorsed by the European Commissioner Sanco and the US FDA Commissioner)



Challenges of nanotechnology applications

- Materials sciences are developed and applied
- Understanding the behaviour in biological systems and living organisms under active research
- Need to further develop a multidisciplinary integrated science-based approach to address specificities of particular applications and borderline issues
- Preparedness is essential to:
 - Understand and anticipate how the emerging science may impact on the way health and diseases are defined and treated
 - Evaluate not only molecules but integrated systems
 - Evaluate additional and novel dimensions above classical immunological, pharmacological and metabolic functions
 - Explore legal/regulatory frameworks applicability



Objectives of this conference (1/2)

Bring together regulators, academics and industry scientists with healthcare professionals and patient representatives:

- To do lessons learnt exercise on nanomedicines so far on the market and in development
- To discuss quality, non-clinical and clinical aspects, and risk management
- To explore key emerging technologies that will provide medicines for the future



Objectives of this conference (2/2)

- To seek knowledge and innovation from science to inform regulatory understanding and requirements of a promising evolving field, not to regulate
- To seek benefits for patients and identify challenges





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1st International Workshop on Nanomedicines
Conference room 2A

Day 1
Starts on the 2nd of September at 9:00 am

09:00 – 09:30

Introduction

- Welcome address and objectives of the workshop
Speaker: Patrick Le Courtols, Head of Unit, Human Medicines Development and Evaluation, European Medicines Agency
- European Commission perspective
Speaker: Philippe Martin, Directorate General for Health and Consumers

09:30 – 10:30

Keynote lecture + Q&A session:

- Way to the future: key ongoing applications in nanosciences and how they apply to pharmaceuticals
Promising and innovative applications today with outstanding preliminary clinical results; where we want to go and what are the milestones?
Speaker: Rutledge Ellis-Behnke, Neuroscientist in the Brain and Cognitive Sciences Department at Massachusetts Institute of Technology and Associate Professor in the Department of Anatomy at the University of Hong Kong Faculty of Medicine

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