



Nanomedicines Alliance Symposium Review

Remember to look to **Page 5** of this issue for a short summary of the Nanomedicines Alliance's industry symposium that was held 6-7 March 2013 in Rockville, MD, USA, entitled

"Nanomedicines: Charting a Roadmap to Commercialization."

A brief report on the Symposium will be coming out soon.

REGULATORY AND LEGISLATIVE DEVELOPMENTS

Human and Ecotoxicity of Synthetic Nanomaterials by BAFU

A report evaluates the long term safety of synthetic nanomaterials for humans and for the environment. It emphasizes the importance of identifying risks promptly so that preventative measures may be taken. The study concludes that the safety regulations in place for chemicals are currently adequate for synthetic nanomaterials. Nevertheless, further research is necessary to properly evaluate the risks associated with these products. The report combines analysis and guidelines from several international sources.

The report can be found here:

<http://www.bafu.admin.ch/publikationen/publikation/01697/index.html?lang=en>

Nanotechnology Faces FDA Hurdles

MDDI has published an article on the interaction of nanotechnology with FDA regulations, expressing the views that follow.

Nanotechnology developers must take caution with FDA regulations concerning raw materials in their products. Many developers neglect the extra regulation process for raw materials used to compose nanomedicines. Even as nanotechnology evolves, it is unclear how the FDA will regulate these products and how companies will utilize them, leading to regulatory and classification challenges.

The article can be found here:

<http://www.mddionline.com/blog/devicetalk/nanotechnology-faces-fda-hurdles>

ETP Nanomedicine Newsletter

The European Technology Platform launched a new Nanomedicines newsletter, highlighting research developments and European news in

nanotechnology. The January 2013 issue includes a Final Draft White Paper addressing nuclear nanomedicine and radiotherapy using nanoparticles. The newsletter also highlights the upcoming Strategic Research and Innovation Agenda, a new Chair of ETPN, upcoming nanotechnology events in Europe, and other news for those involved in the nanomedicine industry.

The newsletter can be found here: <http://www.etp-nanomedicine.eu/public/news-events/newsletter/etpn-newsletter/etp-nanomedicine-newsletter-nr-1-2013>

NCI Office of Cancer Nanotechnology Research Public Discussion Forum

The NCI Office of Cancer Nanotechnology Research launches a public discussion forum for input on focus and research questions. Ideas must be posted by **May 1, 2013**, after which the forum will be open for votes on suggestions from the community.

The forum can be found here:

<https://nanocancer.ideascale.com/>

EMA Drafts Reflection Paper on Block Copolymer Micelles

The European Medicines Agency provides a draft reflection paper focused on the development of nanomedicines composed of block copolymer micelles (BCMs). The paper aims to provide principles and general information on these nanomedicines for pharmaceutical development, as well as early clinical and non-clinical studies. Comments on the paper are due by July 1.

The reflection paper can be found here:

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/02/WC500138390.pdf

For further information, or if you have any questions about the Nanomedicines Alliance, please contact the Nanomedicines Alliance Secretariat at 1-202-230-5607.

REVIEWS AND OTHER PUBLICATIONS OF INTEREST

Nanotechnology: Carrying Drugs. Nature, November 2012, Vol. 491, pp. S58–S60. Katherine Bourzac. Corrected online [21 December 2012](#); Table 1 shows "Nanomedicine in clinical trials - Several nanoscale drug carriers are currently in clinical trials."

http://www.nature.com/nature/journal/v491/n7425_supp/full/491S58a.html?goback=%2Egde_3355295_member_213206451#auth-1

Radioluminescent Gold Nanocages with Controlled Radioactivity for Real-Time in Vivo Imaging. Nano Letters, February 2013, Vol. 13 (2), pp. 581-585. Yucai Wang, Yongjian Liu, Hannah Luehmann, Xiaohu Xia, Dehui Wan, Cathy Cutler, and Younan Xia.

<http://pubs.acs.org/doi/abs/10.1021/nl304111v>

On-substrate fabrication of a bio-conjugated Au nanoring solution for photothermal therapy application. Nanotechnology, February 2013, Vol. 24, No. 6. Hung-Yu Tseng, Wei-Fang Chen, Che-Kuan Chu, Wen-Yen Chang, Yang Kuo, Yean-Woei Kiang and C C Yang.

<http://iopscience.iop.org/0957-4484/24/6/065102>

In vivo toxicity, biodistribution, and clearance of glutathione-coated gold nanoparticles. Nanomedicine: Nanotechnology, Biology and Medicine, February 2013, Vol. 9, Issue 2, pp. 257-263. Carrie A. Simpson, Kenneth J. Salleng, David E. Cliffler, Daniel L. Feldheim.

[http://www.nanomedjournal.com/article/S1549-9634\(12\)00398-X/abstract](http://www.nanomedjournal.com/article/S1549-9634(12)00398-X/abstract)

Development, characterization and efficacy of niosomal diallyl disulfide in treatment of disseminated murine candidiasis.

Nanomedicine: Nanotechnology, Biology and Medicine, February 2013, Vol. 9, Issue 2, pp. 247-256. Maroof Alam, Swaleha Zubair, Mohammad Farazuddin, Ejaj Ahmad, Arbab Khan, Qamar Zia, Abida Malik, Owais Mohammad.

[http://www.nanomedjournal.com/article/S1549-9634\(12\)00405-4/abstract](http://www.nanomedjournal.com/article/S1549-9634(12)00405-4/abstract)

Graphene-Based Photothermal Agent for Rapid and Effective Killing of Bacteria. ACS Nano, 2013, Vol. 7, No. 2, pp. 1281–1290. Meng-Chin Wu, Archana R. Deokar, Jhan-Hong Liao, Po-Yuan Shih, and Yong-Chien Ling.

<http://pubs.acs.org/doi/abs/10.1021/nn304782d>

Synthesis, characterization and target protein binding of drug-conjugated quantum

dots *in vitro* and in living cells.

Nanotechnology, February 2013, Vol. 24, No. 7. Youngseon Choi, Minjung Kim, Yoojin Cho, Eunsuk Yun and Rita Song.

<http://iopscience.iop.org/0957-4484/24/7/075101>

Cytotoxicity and expression of genes involved in the cellular stress response and apoptosis in mammalian fibroblast exposed to cotton cellulose nanofibers.

Nanotechnology, Vol. 27, No. 7. M M Pereira, N R B Raposo, R Brayner, E M Teixeira, V Oliveira, C C R Quintão, L S A Camargo, L H C Mattoso and H M Brandão.

<http://iopscience.iop.org/0957-4484/24/7/075103>

Comparison of the viscoelastic properties of cells from different kidney cancer phenotypes measured with atomic force.

microscopy Nanotechnology, Vol. 27, No. 5. L M Rebelo, J S de Sousa, J Mendes Filho and M Radmacher.

<http://iopscience.iop.org/0957-4484/24/5/055102>

REVIEW: Multiplexed detection of molecular biomarkers with phase-change

nanoparticles. Nanomedicine, February 2013, Vol. 8, No. 2, pp. 253-263. Ming Su.

<http://www.futuremedicine.com/doi/abs/10.2217/nnm.12.212>

Nanoparticles: Pushed off target with proteins. Nature, February 2013, Vol. 8, No. 2, pp.79 – 80. Rogério Gaspar.

<http://www.nature.com/nnano/journal/v8/n2/pdf/nnano.2013.11.pdf>

Minimal "Self" Peptides That Inhibit Phagocytic Clearance and Enhance Delivery of Nanoparticles.

Science, February 2013, Vol. 339, No. 6122, pp. 971-975. Pia L. Rodriguez, Takamasa Harada, David A. Christian, Diego A. Pantano, Richard K. Tsai, and Dennis E. Discher.

<http://www.sciencemag.org/content/339/6122/971>

Mechanism of transport of saquinavir-loaded nanostructured lipid carriers across the intestinal barrier.

Journal of Controlled Release, Volume 166, Issue 2, 10 March 2013, Pages 115-123. Ana Beloquia, María Ángeles Solinisa, Alicia R. Gascóna, Ana del Pozo-Rodrígueza, Anne des Rieux, Véronique Prétat.

<http://www.sciencedirect.com/science/article/pii/S0168365912008632>

CONFERENCES AND WORKSHOPS

BioNanoMed 2013, March 13-15, 2013, Krems, Austria.

Novel nanomedical solutions—advances in nanomedicine
 Regenerative nanomedicine
 Nano-bio-technology based diagnostics
 Nano-bio-technology based therapy
 Aspects of nano safety
 Nano-imaging technologies in medicine

<http://www.bionanomed.at/>

2013 International Conference of RNA Nanotechnology and Therapeutics, April 3-5, 2013, Lexington, KY

RNA Nanoparticle Assembly
 RNA Nanoparticles in Therapeutics
 RNA Systems Biology and Engineering

<http://nanobio.uky.edu/RNA2013/index.html#topics>

19th Congress of the International Society for Aerosols in Medicine, April 6-10, 2013, Chapel Hill, North Carolina

Inhaling nanoparticles by accident on purpose—challenges and opportunities for toxicology and therapeutics

<http://www.med.unc.edu/isam2013/scientific-program>

Nano 2013, April 22, 2013, Troy, NY

Nanotoxicity
 Commercialization for nanotechnology

<http://alumni.rpi.edu/s/1225/2col.aspx?sid=1225&gid=1&pgid=1213>

Symposium: Nanotechnology Platform-based Biomarker Assays at 2013 AAPS, National Biotechnology Conference, May 21, 2013, San Diego, CA

Nanotechnology in Cancer
 Biomarkers

http://www.nxtbook.com/nxtbooks/aaps/nbc2013_preprogram/#/0

The Accelerating Development of Difficult-to-Deliver Drugs, June 4-6, Philadelphia, PA

Nanomaterial for Drug Delivery
 Drug Reformulation
 Imaging
 Advanced Characterization
 Delivery Technology

<http://www.worldpharmacongress.com/Formulation-Drug-Delivery/>

Sydney International Nanomedicine Conference, July 1-3, 2013, Sydney, Australia

Target Delivery
 Sensing
 Diagnostics
 Regenerative Medicine
 Imaging
 Translational Medicine
 NanoSafety

<http://www.oznanomed.org/>

Cancer Nanotechnology, July 14-19, 2013, West Dover, VT

Materials synthesis
 Characterization
 Biocompatibility

<http://www.grc.org/programs.aspx?year=2013&program=cncnano>

6th International Symposium on Nanotechnology, Occupational and Environmental Health, October 28-31, 2013, Nagoya, Japan

Nanomaterial processing and characterization
 Health effects and toxicity
 ADME
 Environmental toxicity
 Risk assessment and management

<http://square.umin.ac.jp/nanoeh6/index.html>

Carbon-Based Nano-Materials and Devices, November 3-8, 2013, Hualien, Taiwan

Synthesis of carbon-based nanomaterials
 Characterization and processing of carbon-based nanomaterials
 Devices and Applications of carbon-based nanomaterials
 Multiscale modeling and computation

<http://www.engconfintl.org/13ap.html>

REFERENCE SECTION

Nanobio- and Nanomedicine Companies

Listed alphabetically:

http://www.nanowerk.com/nanotechnology/nanomaterial/nanobiomedicine_a.php

Nano Organizations

National Center for Toxicological Research (NCTR):

<http://www.fda.gov/AboutFDA/CentersOffices/NCTR/default.htm>

National Nanotechnology Initiative (NNI):

<http://www.nano.gov/>

Nano Science and Technology Consortium (NSTC): <http://www.nstc.in/>

Nano Science and Technology Institute (NSTI):

<http://www.nsti.org/>

The Nanotechnology Institute (NTI):

<http://nanotechinstitute.org/>

Nano Journals

American Chemical Society -- Nano Letters:

<http://pubs.acs.org/journal/nalefd>

Institute of Physics – Nanotechnology:

<http://iopscience.iop.org/0957-4484/>

Journal of Nanoscience and Nanotechnology:

<http://www.aspbs.com/jnn/>

NanoTrends - A Journal of Nanotechnology and its Applications: <http://www.nstc.in/journal/default.aspx>

BCC Research -- Nanotechnology Reports:

<http://www.bccresearch.com/index/category/code/nanotechnology>

Nanomedicine: Nanotechnology, Biology, and Medicine: <http://www.nanomedjournal.com/home0>

Nanomedicine:

<http://www.futuremedicine.com/page/about.jsp>

Nature Nanotechnology:

http://www.nature.com/nnano/focus/highlights/index.html?WT.mc_id=NM1110CT01

CONTACT

For further information, or if you have any questions about the Nanomedicines Alliance, please contact the Nanomedicines Alliance Secretariat at 1-202-230-5607 or info@nanomedicines-alliance.org.

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Nanomedicines:

Charting a Roadmap to Commercialization

Short Summary of Nanomedicines Symposium

The inaugural Nanomedicines Alliance Industry Symposium, *Nanomedicines: Charting a Roadmap to Commercialization* was held on March 6-7, 2013 at the Hilton Washington DC/Rockville Hotel. Seventy attendees representing government, academia and the pharmaceutical industry participated in the symposium, which featured plenary presentations from nanomedicine leaders and addressed five distinct sections:

- **Designing Nanomedicines**, which addressed recent developments in the area of design, highlighting the need for collaboration in various fields ranging from biology, chemistry, physics, and engineering.
- **Preclinical Pharmacology**, featuring a review of nonclinical animal studies and considerations into translating these into safe and effective human medicines.
- **Chemistry, Manufacturing and Controls (CMC)**, which focused on case studies illustrating CMC challenges specific to nanomedicines, and potential solutions to these challenges.
- **Toxicology/Absorption, Distribution, Metabolism and Excretion (ADME)** addressed the evaluation of toxicological properties and ADME patterns, with focus on the immune system, stability and deposition, and in-vitro/in-vivo correlation.
- **Clinical Studies** focused on unique tools, adaptive trial designs, and other innovations that may facilitate clinical development for nanomedicines.

Importantly, representatives from government agencies and labs such as the FDA, NCL, NIH, EPA, GAO actively participated. The symposium included extensive breakout sessions in each of the focus areas with dialogue among regulators from the FDA, NCL, NIH, academia and the pharmaceutical industry. These sessions addressed practical challenges in getting nanomedicines into the market as well as possible solutions. One attendee stated, "For the first time, we had an opportunity to discuss concerns about the development of nanomedicines with big pharma." The symposium also featured a poster session that included 11 posters representing case studies and research in the five focus areas.

Feedback from symposium participants was overwhelmingly positive regarding the content and structure, but the overall networking opportunity and the solicitation for input on the topics were particularly well received.

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