



Nanomedicines ALLIANCE NanoMed Digest

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Legislative and Regulatory Highlights

US FDA Draft Guidance on Nanomaterials

The US Food and Drug Administration released in December 2017 draft guidance for industry on “[Drug Products, Including Biological Products, that Contain Nanomaterials](#).” The draft guidance covers potential risk factors for nanomaterials, quality considerations, nonclinical studies, and clinical development.

European Commission Draft Regulation to Amend REACH Annexes

In October 2017 the European Commission [published draft regulation](#) to amend the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) annexes for registration of nanomaterials. The European Commission has also published comments from 36 organizations, including research institutions and business associations.

United Kingdom and China Coordinate on Graphene

The UK and China have established a [Graphene Standardization Cooperative Working Group Conference](#). Experts from the Working Group Conference plan to submit a co-authored International Organization for Standardization (ISO) proposal by February 2018.

Swedish Chemicals Agency on Nanomaterials

The Swedish Chemicals Agency is introducing a [new reporting requirement for nanomaterials](#), to take effect in January 2018. Companies registering the contents of chemical products will now need to declare whether the products contain intentionally added nanomaterials.

Business News

[Nanobiotix](#) has completed enrollment of patients into a Phase II/III trial of NBTXR3 in soft tissue sarcoma. The trial is aimed at expanding the potential of NBTXR3 to recurrent and metastatic disease. Nanobiotix plans to start the trial with combining the drug with any approved checkpoint inhibitors in head and neck squamous cell carcinoma or non-small cell lung cancer.

[Vigilant Diagnostics](#), a University of Michigan spin-off, is developing technology to heat the gold nanoparticle-biomarker complex in many lateral flow assays.

[Immix Biopharma, Inc.](#) has announced the closing of financing to bring Imx-110 through completion of a Phase 1B clinical trial. In preclinical trials the drug has demonstrated efficacy against glioblastoma, triple negative breast, colorectal, and ovarian cancer models.

[Arrowhead Pharmaceuticals Inc.](#) has filed for regulatory clearance to begin first-in-human trials of ARO-AAT, second-generation investigational medicine for the treatment of alpha-1 liver disease.

Conferences and Workshops

[International Conference on Nanoscience and Nanotechnology](#), 29 January - 2 February 2018, NSW, Australia.

[Drug Delivery & Formulation Summit](#), 12 - 14 March 2018, Berlin, Germany.

[Nanoparticle Concentration – Critical Needs and State-of-the-Art Measurement](#), 24 April 2018, London, UK.

[BioNanoMed 2018](#), 25 – 27 April 2018, Graz, Austria.

[Nanomedicine and Drug Delivery](#), 21 – 23 May 2018, Tokyo, Japan.

[NanoTox 2018](#), 18 – 21 September, Neuss, Germany.

[ACS National Meeting: Nanoscience, Nanotechnology, and Beyond](#), 19 – 23 August 2018, Boston, MA, USA.

Reference Section

Nano Organizations

[National Center for Toxicological Research \(NCTR\)](#)

[National Nanotechnology Initiative \(NNI\)](#)

[Nano Science and Technology Consortium \(NSTC\)](#)

[Nano Science and Technology Institute \(NSTI\)](#)

[The Nanotechnology Institute \(NTI\)](#)

Nano Journals

[American Chemical Society -- Nano Letters](#)

[Institute of Physics – Nanotechnology](#)

[NanoTrends - A Journal of Nanotechnology and its Applications](#)

[BCC Research -- Nanotechnology Reports](#)

[Nanomedicine: Nanotechnology, Biology, and Medicine](#)

[Nature Nanotechnology](#)

Contact

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

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