Nanomedicine

Design of Nanodrugs

Personalized Nanomedicine

Nanomaterials for drug delivery

Nanomedicine and Nanotechnology

Synthesis of Nanoparticles for Drug Delivery

Drug Delivery Research

Novel Drug Delivery Systems

Smart Drug Delivery Technology

Regenerative Medicine and Tissue Engineering

Biopharmaceutics and Biologic Drugs

Nano Pharmaceutical Industry and Market

Regulatory Aspects Towards Approval of Nanomedicine

**Academic Partners** 



2<sup>nd</sup> International Conference and Exhibition on

## **Nanomedicine and Drug Delivery Nanodelivery 2018**

@DrugDeliveryCon

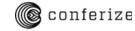
May 21-23, 2018 Tokyo, Japan





**Participation** 

(70 Industry: 30 Academia)



Interactive

Sessions



Keynote

Lectures



Plenary

Lectures







**Exhibitors** 



Meetings







Workshops

### @DrugDeliveryCon

# **nyitation**

### **Conference Highlights:**

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Possessing the right formulation and drug delivery strategy is the foundation of successful drug development. But how do you achieve this? There are on-going innovations in technology, processes and partnership types being trialed across the industry. It's vital to stay abreast of these developments and look to incorporate selected elements into your existing practice to buoy strengths further and overcome weaknesses.

Nanodelivery 2018 provides the perfect platform for just this as an interactive and engaging 3-day event: unique in format, content, networking and engagement. The event brings together truly innovative thinkers who are leading the way through trialing new disruptive solutions and rethinking the conventional formulation and delivery mind-set.

Nanodelivery 2018 will help you to better understand how to develop the right formulation and delivery strategy with a strong scientific, clinical and commercial mind set and how innovative scientific techniques, emerging technologies and innovative devices can transform formulation and drug delivery.

#### Regards, Nanodelivery 2018 Organizing Committee



Hiroshi Maeda Osaka University Medical School, Japan



Teikyo University



University of Illinois



University of Wisconsin-Madison, USA



Hebrew University of Jerusalem, Israel



Illinois Institute of Technology, USA



Catholic University of Louvain, Belguim







#### **Summary of Nano Delivery 2018 Conference:**

Nano Delivery 2018 is an emerging field of engineering and life sciences that promises to revolutionize medicine and medical technology. There are numerous applications of nanomedicine and nanotechnology in medicinal diagnostics. These include improved imagining of the human (or any) body and detecting tumors that are only a few cells in size.

The idea that pharmaceutical agents should be delivered specifically to diseased cells holds the promise of a variety of benefits. The promise of individualized medicine is that it is efficient. Targeted drug-delivery allows doctors and patients to benefit from small dosages at just the right place and thus from fewer side effects.

Nanomedicine has therapeutic uses as well. Nanotechnology is capable of delivering medication to the exact location where they are needed, hence lesser side effects. It can also be used to destroy harmful organisms or cancer cells by interrupting their division process. Nanoprobes can be made to generate radiation that could kill bacteria, viruses and cancer cells. Nanotechnology also theoretically allows the mimicking of natural biological processes, e.g. repair of damaged tissues or acting as artificial red blood cells to transport oxygen.

The global market for healthcare nanotechnology is expected to reach USD 196.02 billion by 2020 growing at a CAGR of 12.1%, according to a new study by Grand View Research, Inc. Increasing susceptibility of patients towards chronic diseases such as cardiovascular, neurological, oncology and respiratory diseases coupled with increasing R&D spending opening new application avenues is expected to drive market growth over the next six years. Other drivers of this market include increasing government and private sector R&D aid and new players entering the market to bridge the gap between supply and demand.

#### Importance & Scope of Nano Delivery:

Researchers are developing a nanoparticle that can be taken orally and pass through the lining of the intestines into the bloodsteam. This should allow drugs that must now be delivered with a shot to be taken in pill form. The researchers have demonstrated the technique with lab mice so far.

Researchers are also developing a nanoparticle to defeat viruses. The nanoparticle does not actually destroy viruses molecules, but delivers an enzyme that prevents the reproduction of viruses molecules in the patients bloodstream. The effectiveness of the technique has been demonstrated in lab tests.

#### Nanomedicine Market in Japan: Why Japan?

Nanomedicine is a promising sub-segment in medicine that took off in the 1980s with the first generation of developed nanopharmaceuticals. With the use of nanotechnology, drugs can be delivered in ways not experienced so far.U.S. is a strong actor in this field with many patents having commercialized several nanopharmaceuticals.



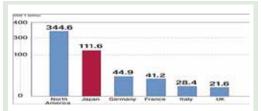




The global nanomedicine market was valued at US\$50.1 billion in 2011 and is projected to grow to US\$96.9 billion in 2016. The share of nanomedicine to the total global pharmaceutical market is estimated at 5.3 percent in 2011 indicating its niche character presently.

In Japan, for various reasons, the nanomedicine market size in terms of the total market is much smaller. A rough estimate shows that the share is between 1 to 2 percent corresponding to approximately US\$1 to 2 billion. A limited number of approved Japanese nanodrugs together with a long time until approved foreign products entered the Japanese market have seemingly slowed the market expansion.

- Japan = World's 2nd largest pharmaceutical market!
- Japan is the 2nd largest pharmaceutical market in the world, marking JPY 10 trillion (USD 84.4 billion) in ethical drug in 2016.
- Nikkei Stock Average has been continuously increasing since mid October, 2016.
- The government is to ease the regulations to develop new medicines for intractable diseases by shortening 5 years of drug development time.



Japan hugely depends on imported pharmaceutical products. The annual import value in Japan was JPY 1.94 trillion (USD 16 billion) in 2015 compared to the export value of JPY 0.32 trillion (USD 2.7 billion).

Japan's pharmaceutical industry is the world's second largest market, after U.S., valued at US\$112.1 billion in 2012 or 11.6 percent of the world market. Historically, the market has been protected from foreign competition. These days, however, deregulation has prompted investment from abroad and increased the presence of foreign companies. The pharmaceutical industry is one of the few industrial sectors in which Japan has a trade deficit. Japan imports more than two times what it exports. The rapid aging of the population and the weak global competitiveness of domestic companies are contributing factors to the trade deficit.

#### Japan Nanomedicine Market Size:

There is no market information available on the size of Japan's nanomedicine market published by any of the large Japanese market research companies. Table 2 below tries to estimate the market size. The global nanomedicine market was estimated to be about 5 percent of the global pharmaceutical market in 2010 and 2011. In case of Japan, this ratio is much lower compared to the global nanomedicine market. A rough estimate indicates that the market size was approximately 1-2 percent of the Japanese pharmaceutical market in 2011-2012, or roughly between US\$1 billion – US\$2 billion. The drug lag of imported nanopharmaceuticals (explained in section 3.5.) is one cause of this. Nanomedicines have not been defined in Japan and are regulated within the general framework of the Pharmaceutical Affairs Law (PAL) on a product-by-product basis (20).





#### Approved Nanopharmaceutical Products by Application:

As there is no specific definition for drug and device (nanocarrier) combinations, they are regulated as drugs or medical devices according to their main function or purpose (20).

Pharmaceuticals are classified as nanomedicine by their sizes, i.e. materials in the submicron range. Information on marketed nanopharmaceuticals in Japan comes from various sources (21) including "Current Initiatives in Japan for Nanomedicines", Kumiko Sakai-Kato, Toru Kawanishi, 2011, National Institute of Health Sciences (NIHS) and Ministry of Health, Labour and Welfare (MHLW) (22).

Trade name	Technology	Compound	Company
Ropion	Lipid emulsion	Flurbiprofen	Kaken (JPN)
Visudyne	Liposome	Verteporfin	Novartis
Zevalin	Antibody Conjugates	Zevalin	Bayer
Somavert	PEGylated protein	Pegvisomant	Pfizer
Emend	Nanocrystal	Aprepitant	Merck
Abraxane	Polymeric Nanoparticles	Paclitaxel	Abraxis

#### **Government Pushing for Change:**

In order to reduce the time span from discovery and innovation to commercialization, the importance to establish open user facility networks to promote the integration of dissimilar fields and academic-industry collaboration is emphasized.

It is apparent that the government is aiming at more concrete and speedy results for R&D. Issue-driven innovation based on "exit-oriented" R&D is targeted to impact the competitive power of related industries.

A report by the Japan Science & Technology Agency titled "Japan's New Science and Innovation Policy - Beyond the Boundaries for Innovation", published in 2016 (50) lists up the time span for selected target applications of nanomedicine, such as:

- Molecular imaging (2015-2020)
- Integrated system of drug delivery, diagnosis and treatment (2015-2020)
- Implant devices for diagnosis and treatment (2020-2030)
- Nano-cell surgery (2020-2030)
- 3D-imaging in cells (2020-2030)

These are quite ambitious targets showing the directions where R&D will be focused.

In addition to the latest basic plan, there are other signals that the government is increasingly prioritizing innovative medicine. For instance, The Ministry of Health, Labour and Welfare will jointly with the European Union (EU) promote the development of nano-based block copolymer micelles. Together with European Medicines Agency (EMA) the ministry has released a reflection paper (February 2013) emphasizing that such micelles are able to preferentially accumulate in solid tumors (51).

#### Nanomedicine - Research and Development in Japan:

- University of Tokyo
- Hokkaido University

- Tokyo Prefecture University
- Tokyo University

- Tohoku University
- National Institute for Materials Science

#### The Japanese Nanomedicine Industry:

Nanomedicine start-ups and small-medium enterprises have driven the innovation process, not only in US and Europe but also in Japan. The commercialization of nanopharmaceuticals have basically followed three types of business models (67), such as:

- Development of a nanotechnology platform used to add value to second-party products
- Development and manufacturing of high-value materials for the pharmaceutical industry
- Development of nanotechnology-improved pharmaceuticals or medical devices

The majority of start-ups has adopted the third business model utilizing nanotechnology to develop own proprietary product pipelines. Often such companies introduce new or standard drugs that are delivered with a drug delivery system. Then they try to team up with pharmaceutical companies that take the products through the clinical trials.

- NanoCarrier Co., Ltd.
- LTT Bio-Pharma Co., Ltd.
- Mebiopharm Co., Ltd.

#### **Target Audience:**

- Pharmaceutical Scientists
- Drug Delivery Researchers
- Nanomedicine Scientists

- Nippon Kayaku Co., Ltd
- Kowa Company Ltd.
- Mitsubishi Tanabe Pharma Corporation
- Medicine clinicians
- Pharmacists
- Molecular Scientists

- Taisho Pharmaceutical Co., Ltd.
- Astellas Pharma Inc
- Kaken Pharmaceutical Co., Ltd.
- Pharmaceutical Associations and Societies
- Pharmaceutical Faculty
- Medical Colleges

### **Market Analysis**

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- Data Management Companies
- Training Institutes

- Software developing companies
- Business Entrepreneurs and Many More....

#### Global Nanotechnology Drug Delivery Market, by Technology:

- Nanocrystals
- Nanoparticles
- Dendrimers
- Gold Nanopartilces

- Dendrimers
- Fullerens
- Others
- Liposomes

- Micelles
- Nanotubes
- Others

#### Pharmaceutical Regulations in Japan:

Manufacturing, importation, and sales of drugs and medical devices are regulated by the Pharmaceutical Affairs Law (PAL) of Japan.

All manufacturing and marketing applications in Japan for drugs and devices are reviewed by the Pharmaceutical and Medical Devices Agency (PMDA) (83). All applications are thoroughly reviewed before PMDA submits an approval recommendation to the Ministry of Health, Labour and Welfare (MHLW).

Under PAL, when importing to Japan and selling pharmaceutical products manufactured in other countries, a license for marketing authorization is required. The Marketing Authorization Holder (MAH) will be the owner of the license for marketing authorization.

The MAH must be based in Japan and can be the foreign company's Japan office, the foreign company's distributor, or an independent third party acting as the Designated Marketing Authorization Holder (DMAH).

To import and market a new drug in Japan, an approval (marketing approval) will be necessary. And the approval must be held by the Marketing Authorization Holder.

A foreign manufacturer intending to manufacture drugs in foreign countries and export them to Japan, is required to be accredited by MHLW as an "Accredited Foreign Manufacturer" (84). And it is necessary to obtain accreditation for each foreign factory location at which pharmaceuticals for export are manufactured.

The appointed MAH will be responsible for the labelling and advertising of the pharmaceuticals in Japan. As stipulated in PAL, the manufacturers/seller's address, name of product, production indication, name of ingredients, expiration, etc., must be printed on the container of drugs.







#### Overall research in various disciplines:

The North American nanomedicine market held the majority of global market share in 2012 because of the rapidly growing nanomedicine market in the Asia-Pacific, Latin American and African region, presence of large number of patented nanomedicine products and favorable regulatory framework in the region. In addition, the presence of sophisticated healthcare infrastructure supports development of advanced products such as nano probes, nanorobots, monoclonal antibody based immunoassays and nanoparticle based imaging agents for early detection of diseases.



However, the Asia-Pacific region is expected to grow at a faster CAGR owing to presence of high unmet healthcare needs, research collaborations and increase in nanomedicine research funding in emerging economies such as China, India and other economies in the region. China is expected to surpass the United States in terms of nanotechnology funding in the near future, which indicates the growth offered by this region.

#### Major Nano Delivery Associations around the Globe:

- American Nano Society
- European Biotechnology Thematic Network Association
- Society for Biomaterials
- Nano Canadian Society
- American Academy of NanoMedicine
- American Association for the Advancement of Science
- Nanometer-Scale Science and Technology Division of the American Vaccum Society
- NanoScience and Technology Institute
- ASME NanoTechnology Institute
- Foresight Nanotech Institute
- International Association of NanoTechnology

- The Institute of NanoTechnology
- Microscopy Society of America
- Nano Business Alliance
- European NanoTechnology Gateway
- Scottish Center for NanoTechnology in Construction Materials
- Royal Society-NanoTechnology and NanoScience
- Czech NanoTechnology Industries Association
- Erwin Schrodinger Society for NanoSciences
- Innovationsallianz Carbon NanoTubes
- NanoTechnologies for Tommorow's Society
- American Association for the Advancement of Science







#### Companies involved in Nano Delivery:

**USA** 

Oncolytics Biotech

Bristol-Myers Squibb

GlaxoSmithKline

Bend Research

Pfizer

**BioDelivery Sciences** 

GE Healthcare

Mallinckrodt plc

Nanosphere Inc., USA

Pfizer Inc., USA

Merck & Co Inc., USA

Celgene Corporation, USA

CombiMatrix Corporation, USA

**Abbott Laboratories** 

Many Major companies in the Nano Delivery

market.

Global

PolyActivaUnilife

Mati Therapeutics

Formac Pharmaceuticals

Battelle

Toxikon

**Novartis** 

Johnson & Johnson

Merck & Co

Novartis International AG

Pfizer

Roche

Bayer AG

AbbVie

Amgen

Celgene Corporation





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### **Tentative Agenda**

#### May 21, 2018 Monday

Time	Session	
08:30-09:30	Registrations	
09:30-11:30	Keynote Forum	
Group Photo		
11:30-11:45	Network & Refreshments Break*	
11:45-13:00	Track 1: Nanomedicine	
	Track 2: Design of Nanodrugs	
13:00-13:45	Lunch Break**	
13:45-16:00	Track 3: Personalized Nanomedicine	
16:00-16:15	Network & Refreshments Break*	
16:15-18:00	Track 4: Nanomaterials for drug delivery	
Day Concludes		

#### May 23, 2018 Wednesday

Time	Session	
09:30-11:30	Track 9: Regenerative Medicine and Tissue	
	Engineering	
11:30-11:45	Network & Refreshments Break*	
11:45-13:00	Track 10: Nano Pharmaceuticals	
13:00-13:45	Lunch Break**	
13:45-16:00	Track 11: Nano Pharmaceutical Industry and	
	Market	
16:00-16:15	Network & Refreshments Break*	
16:15-18:00	Track 12: Regulatory Aspects Towards	
	Approval of Nanomedicine	
	Award Ceremony	
Conference Concludes		

#### May 22, 2018 Tuesday

Time	Session	
08:30-09:30	Registrations	
09:30-10:30	Keynote Forum	
10:30-11:30	Track 5: Nanomedicine and	
	Nanotechnology	
11:30-11:45	Network & Refreshments Break*	
11 45 12 00	Track 6: Synthesis of Nanoparticles	
11:45-13:00	for Drug Delivery	
13:00-13:45	Lunch Break**	
13:45-16:00	Track 7: Drug Delivery Research	
16:00-16:15	Network & Refreshments Break*	
16:15-18:00	Track 8: Novel Drug Delivery	
	Systems	
16:00-18:00	Poster Presentations	
	Day Concludes	

<sup>\*</sup> Exclusive Exhibitor Event

Note: Conference schedule is subject to change.

Note: Workshops and Symposia slots are available. To book slot for

Workshop and Symposium send us the proposal.

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<sup>\*\*</sup> Networking Event

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### **Keynote Speakers**



Challenges and Innovations in Nanomedicine and Drug Delivery Research

**Hiroshi Maeda**Osaka University Medical School
Japan



PED4 inhibitor-loaded phosphatiosomes for attenuating neutrophilic inflammation in acute lung injury

Jia-You Fang Chang Gung University Taiwan



**Unimolecular Nanoparticles for Targeted Drug Delivery** 

Shaoqin Sarah Gong University of Wisconsin-Madison USA



Nanomedicines for Glioblastoma Treatment

Veronique Preat Catholic University of Louvain Belguim



Nanocellulose alginate composite for 3D cell growth

**Julian Brass** University Grenoble Alpes, France



New biocompatible oxide nanoparticles as carriers of bioactive compounds through the blood-brain barrier

Michał M WULS-SGGW, Poland



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- Will be published in our conference proceedings and also the conference book.
- Publication of entire article at 50% rebate in the respective subject journals.
- Posters will be evaluated by our Jury and the best poster will be awarded a certificate.

#### **Poster Specifications:**

 Present numerical data in the form of graphs, rather than tables (graphs make trends in the data much more evident). If data must be presented in table-form, keep it Simple.

- Visuals should be simple and bold.
- Organize your poster into subdivisions, e.g., Introduction, Methods, Results; Discussion, Conclusions, and Literature Cited (avoid using too many citations).
- Use bright colours to enhance the detail.
- Text should be readable from five feet distance.
- Besides your project, the text could also include future research plans or questions.
- Each poster should be approximately 1x1 M long.
- The title, contents and the author's information should be clearly visible from a distance of 1-2 feet.
- Benefits: Each abstract will be labelled with a Digital Object Identification Number (DOI) provided by Cross Ref
- Abstract pages created in Google on your name would get worldwide acknowledgment to your research.

For more info, PS: https://nanomedicine.pharmaceuticalconferences.com/poster-presentation.php

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### **Young Researchers Forum**

Come Let's Bring a Transformation in the Scientific Society: The Young Researchers Forum offers young researchers the possibility to meet and discuss research topics and methodologies, share and develop ideas, learn from each other and gain knowledge from senior researchers.

#### **Benefits:**

- Showcase your research through oral presentations.
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- This forum will give pertinent and timely information to those who conduct research and those who use and benefit from research.

- Develop a foundation for collaboration among young researchers.
- The forum will provide an opportunity for collegial interaction with other young investigators and established senior investigators across the globe.
- Interact and share ideas with both peers and mentors.
- Opportunity for young researchers to learn about the research areas of their peers to increase their capacity as multidisciplinary researchers.
- Actively distribute information and promote the benefits of education and career matters.

**For more info, PS:** https://nanomedicine.pharmaceuticalconferences.com/young-researchers-forum.php

#### **Important Dates**







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