1st BIORIMA Training School

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BOOK OF ABSTRACTS

Lecturer

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Short CV

Professor at Heriot Watt University.
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Participant in H2020 GRACIOUS and PATROLS.

Title of the lecture

Introduction to the BIORIMA project

Abstract

BIORIMA stands for Biomaterial Risk Management. BIORIMA aims to develop an integrated risk management (IRM) framework for nano-biomaterials (NBM) used in Advanced Therapeutic Medicinal Products (ATMP) and Medical Devices (MD). The BIORIMA RM framework is a structure upon which the validated tools and methods for materials, exposure, hazard and risk identification/assessment and management are allocated plus a rationale for selecting and using them to manage and reduce the risk for specific NBM used in ATMP and MD. Specifically, the IRM framework will consist of: (i) Risk Management strategies and systems, based on validated methodologies, tools, and guidance, for monitoring and reducing the risks together with methods for evaluating them; (ii) Validated methodologies and tools to identify the potential Exposure and Hazard posed by NBM to humans and the environment; (iii) A strategy for Intelligent Testing (ITS) and Tiered Risk Assessment for NBM used in ATMP and MD. BIORIMA workplan consists of 7 workpackages covering the major themes: Materials, Exposure, Hazard and Risk. BIORIMA will generate methods and tools for these themes for use in risk evaluation and reduction. The BIORIMA toolbox will consist of validated methods/tools for materials synthesis; reference materials bank; methods for human/environment exposure assessment and monitoring; (eco)-toxicology testing protocols; methods for prevention of accidental risks – massive release or explosion – A tiered risk assessment method for humans/ environment; An intelligent testing strategy for NBM and risk reduction measures, including the safer-by-design approach. BIORIMA will deliver a web-based Decision Support System to help users, especially SME, evaluate the risk/benefit profile of their NBM products and help to shorten the time to market for NBM products.

Lecturer

Name: **Professor Terry Wilkins**

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Short CV

Terry Wilkins is Europe's first professor of Nanomanufacturing. He has 35 years industrial and 13 years academic experience at Director level (GE Healthcare, Nobel Laureate Christian de Duve's Institute Université Catholic de Louvain, ICI Plc and University of Leeds), as an innovator in high-value manufacturing for the medical device, biotechnology, nanotechnology, advanced materials and environmental engineering industries, yielding substantial economic and societal impact. Examples of his teams' innovations include: ~ 140 (nano) immunoassays for a wide range of diseases, finding the Cystic Fibrosis gene, the world's first DNA fingerprinting business and the world's first HFC manufacturing business. Note: the latter has led to healing the hole in the ozone layer (UN, EC & NSF joint report, 2016). He is an active member and chair of EC NMBP advisory groups from FP6 to H2020, leading R&I policy development and funding of nanotechnology, including championing nano EHS research. Uniquely, within Europe he has led EU projects in all framework programmes from FP1 to H2020. His innovations have been recognised by 10 prizes/medals including 2 Prince of Wales awards.

Title of the lecture

Nanotechnology: its journey from "Hype" to "Success" and the importance of Europe's nanosafety research

Abstract

Large strategic investments in research and innovation by the EU, US, JP and CN governments, coinciding with a revolution in the way industry does innovation, has led to an unprecedented explosion in commercial nanotechnology applications and markets worldwide with high economic impact. What was a near zero market in 2000 became a $1 trillion global market in 2013 and is on schedule to be $4.4 trillion global market in 2018. This phenomenon has been fuelled by an "arms race", in publicly funded nanotechnology research, between the world's 4 largest economies and delivered by organisational change amongst large industries stimulating new models innovation involving other actors. This lecture introduces the Gartner "hype to reality" cycle to describe the rise of global nanotechnology and where on the curve nanotechnology is located today. The economic and organisational changes amongst innovation actors during the cycle has led to 3 new models of interacting **Open Innovation Ecosystems,** described by Wilkins et al, 2010, further accelerating market growth. Today, nanotechnology is increasingly providing solutions to global challenges such as health, energy, climate change, water etc.

The rapid pace of nanotechnology innovation has stimulated a parallel demand amongst responsible scientists, citizens, policy makers, industry, regulators and standards bodies for new knowledge and

tools to understand the environment, health and safety (EHS) risks of these new nanomaterials. From a low research base, an exponential increase in nano-EHS research skills and knowledge has been created. Europe has played a leading role in this process. Europe has deployed >€400 million in funds in >50 EU research projects since 2002. Similarly, the US has spent ~$800 million in the same period. Recently, a series of EU nano EHS projects have distilled the essential knowledge from the 50+ projects into tools, guidelines and embryonic standards. The totality and quality of this work is revolutionary. It provides a basis for investigating the EHS risks of future emergent technologies.

Some questions for discussion are:

1. Can the Gartner Hype to Reality cycle also be applied to nano-EHS research?
2. Is the European Nano EHS research community a new 4th model of an innovation ecosystem.
3. Can nano-EHS innovation and nano-product innovation be more closely integrated?

Lecturer

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Short CV

Dr. Magda Blosi (female), PhD is a researcher at ISTEC-CNR, she took her PhD in Industrial Chemistry (University of Bologna, 2009). She holds expertise in synthesis and characterization of metal and oxide NPs for application as catalysts, photocatalysts and surface multifunctional coatings (antibacterial, self-cleaning, hydrophobic-oleophobic coatings). She developed and patented several green synthesis methods (5 international patents) to achieve metal and oxide NPs. She is involved in different kinds of research projects (national, EU and with companies). She has collaborated in FP7 EU-funded projects (Sanowork and SUN) and she is collaborating in H2020 projects (BIORIMA, PATROLS, PROTECT) as WP leader or as key staff. Bibliography: 40 scientific publications, 15 lectures at international conferences, 3 as invited speaker (H-index = 15)

Title of the lecture

Antibacterial function: preparation, characterization and engineering of silver NPs

Abstract

Ag NPs are well-known for their antimicrobial effect. Their use in commercial products is increasing and this raised the attention of the European Community on the nano-safety research on such materials [1]. In fact, dealing with antimicrobials always implies a basic cost-benefit evaluation of the balancing between toxicity for human and microorganisms. Ag NPs are found as antibacterial additives in several every-day products and their application for producing auto-sanitizing textiles for healthcare is an interesting goal that could have a remarkable impact, especially if we think that they could be widely used in hospitals, where the higher-than-usual amount of bacteria meets an increased resistance to antibiotics [2].

In this work we present examples of coated Ag NPs as safe alternatives enabling the preservation of their antibacterial activity, but with a reduced toxicity with respect to their uncoated counterpart.
Ag-HEC is an innovative antibacterial hydrogel achieved by means of a green synthesis performed at room temperature and based on spherical Ag NPs (15-20 nm) capped with hydroxyethylcellulose (HEC). The outstanding potentialities of this patented process [3] stem from its low environmental impact combined with the absence of any kind of heating treatment. An excellent antimicrobial activity, revealed after testing Ag-HEC both against E. coli and against a pathogenic isolate of E. coli (strain CFT073), is coupled with a low cytotoxicity (strongly reduced with respect to the commercial AgNPs) assessed in presence of cell lines representative of human skin models.

References:

- *Regulatory Challenges in the Risk Assessment of Nanomaterials, Helsinki, ECHA: Helsinki, 2014.*
- *H2020-NMBP-PILOTS-2016 – Grant Agreement number: 720851 "Pre-commercial lines for production of surface nanostructured antimicrobial and antibiofilm textiles, medical devices and water treatment membranes"*
- *A.L. Costa, M Blosi, Process for the preparation of nanoparticles of noble metals in hydrogel and nanoparticles thus obtained WO2016IB50501 20160201 (2016)*

Lecturer

Name: **Paolo Gasco**

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Short CV

Paolo Gasco (male, 1961) graduated in Aeronautical Engineering at the Polytechnic of Turin (110 cum laude), and holds a Master Degree in Artificial Intelligence. After professional experience in different fields, such as information technology, building design, logistics and advertising, and teaching of technical subjects in high school, both public and private schools, he has actively contributed in creation and growth of Nanovector, fascinated by innovation coming up by Nanomedicine, arising science at that time. CEO of Nanovector since 2002, he coordinated all researches performed by Nanovector along the lines set out in projects, whether they have been financed by public or private entities. He's inventor of 3 patents relevant to formulations of Solid Lipid Nanoparticles and therapeutic use, and co-author in several scientific publications. Since 2006 he has been Principal Investigator on behalf of Nanovector of projects granted by EC (BONSAI (FP6) , NAD (FP7), MAGNIFYCO (FP7), UNION (FP7), DNA-TRAP (FP7)), and of several projects funded by Regione Piemonte (NANO-IGT, IMMONC, BANP, MAG-CHIP, ACTA, and others), and by the Italian Ministry of Industry (RESV). Nanovector is partner in BIORIMA project.

Title of the lecture

Lipid based approach in nanobiomaterials

Abstract

Solid Lipid Nanoparticles (SLN) are colloidal drug carriers invented in early 90ties, first patents have been filed in 1991. Since then many different production methods have been described and huge amount of papers have been published, making SLN one of more studied Drug Delivery System. After short introduction about the history of SLN and available methods to produce them, we will focus on SLN obtained by warm microemulsion process, analyzing different compositions and physico-chemical characterization. Some details will be then given on biological behaviour of SLN, as by their testing in ophthalmic administration in Retinitis Pigmentosa animal model, and by other in-vivo experiments for membrane overcoming. Finally, recent development toward food supplement implementation will be shortly described.

References:

- *Strettoi E et al. Inhibition of ceramide biosynthesis preserves photoreceptor structure and function in a mouse model of retinitis pigmentosa. Proc Natl Acad Sci U S A. 2010 Oct 26;107(43):18706-11*
- *Piano I, et al Cone survival and preservation of visual acuity in an animal model of retinal degeneration Eur J Neurosci. 2013 Jun;37(11):1853-62*
- *Dal Magro R. et Al. - ApoE-modified solid lipid nanoparticles: A feasible strategy to cross the blood-brain barrier - J Control Release. 2017 Mar 10;249:103-110*

Lecturer

Name: **Elena Gazzano**

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Short CV

Elena Gazzano was born in Torino, Italy in 1978. She obtained the degree in Biotechnology in 2002 and her Ph.D. in Bio-chemical Sciences in 2006, at the University of Torino. She is actually a postdoctoral researcher at the Department of Oncology in Torino. She is involved in research on: particles and nanoparticles mechanisms of toxicity, including oxidative-nitrosative stress and epithelial-mesenchymal transition; molecular basis of mesothelioma; new formulations of chemotherapeutic drugs to overcome chemoresistance in cancer cells. Her scientific production includes 51 papers in international peer reviewed journals.

Title of the lecture

Epithelial-mesenchymal transition: insights into the role of nanoparticles

Abstract

Fibrosis has been described to occur following inhalation of nanomaterials: inhaled particles can significantly increase the release of pro-inflammatory cytokines, including TGF-beta, whose signalling pathway is associated to the induction of inflammation and fibrosis. Fibrosis depends on the ability of epithelial cells to transform into mesenchymal cell through the process of epithelial-mesenchymal transition. This presentation will provide insights into the mechanisms of epithelial-mesenchymal transition following exposure to inhaled particles. Case studies of different materials, e.g. chrysotile asbestos fibres and carbon nanotubes, will be presented.

Lecturer

Name: **Dania Movia**

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Short CV

Dr. Dania Movia is a Senior Research Fellow at the Laboratory for Biological Characterization of Advanced Materials (LBCAM), part of the Trinity Translational Medicine Institute (TTMI) of Trinity College Dublin. She is also a part-time lecturer at the School of Medicine of Trinity College Dublin, where she teaches on the MSc in Molecular Medicine, and mentors/supervises students from various undergraduate and postgraduate degrees.
Dania was awarded an MSc in Chemistry and Pharmaceutical Technologies at the School of Pharmacy of the University of Trieste (Italy) (2007), the national accreditation to the Italian pharmacists' registers (2008) and a PhD in Chemistry at Trinity College Dublin (Ireland) (2012).
She is an EU Expert and PI in the recently funded Johns Hopkins University CAAT project (2018-2020). She was awarded the IRC Government of Ireland Postdoctoral Fellowship (2015-2017); AMBER Director's Fund (2015), CRANN Pathfinder Fellowship (2012-2013), IRCSET Postgraduate Research Scholarship (2008-2011) and TCD Postgraduate Research Studentships (2007). She received a research award in recognition of the publication of an internationally peer-reviewed article of the highest quality (CRANN Institute, 2012). In 2017, she was shortlisted for the Lush Prize (Young Researchers category), a major initiative aiming to bring forward the day when safety testing takes place without the use of animals.

Title of the lecture

Alternative 3D in vitro models for hazard assessment of inhaled nanomedicine products

Abstract

Nanomedicine products have found application in many biomedical fields, raising enthusiasm but also concerns associated with the fact that such products could show toxic effects. Inhaled nanomedicine products, with applications ranging from lung diseases treatment to pulmonary administration carriers, can, in fact, pose potential health risks to the human respiratory system by inducing local and systemic pathological responses. Animal studies are widely used for inhalation toxicology studies. The use of animal models is however constantly raising ethical concerns and research costs. In addition, animal models do not comprehensively mimic the human body, and this entirely holds true in relation to the histology of the human respiratory system.
Alternative models such as three-dimensional (3D) cell cultures represent a distinct milestone towards capturing the realities of biology in vitro and reduce animal experimentation at the preclinical stage of nanomedicine products assessment. This lecture aims at describing the parameters that should be taken into account when selecting the most appropriate 3D in vitro testing model for inhaled nanomedicine products, for efficacy and/or safety assessment purposes.

Lecturer

Name: **Joanna Adamczak**

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Short CV

2015 – now	Senior Scientist at HEALTH – Institute for Biomedicine and Health Sciences, JOANNEUM RESEARCH Forschungsgesellschaft mbH (Graz, Austria)
2013 – 2015	Post Doc at Max Planck Institute for Neurological Research (Cologne, Germany) and Percuros B.V. (Enschede, The Netherlands)
2009 – 2013	PhD thesis at Max Planck Institute for Neurological Research in Cologne (Cologne, Germany)

Title of the lecture

Open Flow Microperfusion offers high temporal and spatial resolution to investigate the penetration of nanoparticles into the skin

Abstract

This talk gives an introduction to a novel sampling technology - open flow microperfusion (OFM). The OFM sampling technology is based on membrane-free probes that are inserted directly into the biological tissue. OFM probes are perfused with physiological fluid which is in direct contact with the interstitial fluid of the surrounding tissue. OFM collects unfiltered, merely diluted interstitial fluid with no substance exclusion criteria regarding molecular size or lipophilicity. This talk will present current OFM applications in clinical and preclinical skin research, including pharmacokinetic and pharmacodynamic studies of topical drugs as well as recent applications including nanoparticle penetration of the skin and the blood brain barrier. The talk will conclude with an overview of the planned OFM studies in the BIORIMA project.

Lecturer

Name: **Dr. Marco Monopoli**

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Short CV

Dr Marco Monopoli is StAR Research Lecturer in the Department of Pharmaceutical and Medical Chemistry in the RCSI where he has establishing the BioNano research laboratory, a multi-disciplinary centre focused to obtain a complete understanding of the mechanisms of interaction between nanomaterials and living systems essential for Nanomedicine, Nanotoxicology applications and to evaluate their Environmental Impact. Dr Monopoli's studies have been focused on revealing the forces that govern bio-nano interactions and in understanding the biological implications of the protein corona and has developed a variety of methods to isolate and characterise these nanoparticle-protein corona complexes combining physicochemical and proteomic techniques. Dr Monopoli is the author of several high impact publications related to breakthroughs in the understanding and implications of the protein corona, and further to this, his work has been featured on the cover of Nature Nanotechnology (December 2012 Volume 7 No 12). In 2016 he was awarded the SFI Industry fellowship that allowed him to carryout a research project in a biopharma company in Oxford, UK. As a Principal Research Scientist in the CBNI, UCD he was directly involved in several European FP7 collaborative projects, which were either coordinated or supported as work package leader by the centre. He also overseen the Transational Access of Qualitynano research infrastructure.

Title of the lecture

Biological identity of Nanoparticles in biological fluids, the biomolecular corona

Abstract

Nanoparticles (NP) are believed to radically change the way we treat diseases. Because of their small size, they can directly interact with biomolecules in a completely different way, and their behaviour in biology is still not fully understood. Once in biological fluids, NPs rapidly interact with biomolecules from the environment that strongly and rapidly adsorb to the NP surface forming the long-lived biomolecular corona.
The biomolecular corona gives a new identity to NP in the biological milieu as it has been shown to interact with cellular receptors and biological barrier directly.
Understanding and controlling the corona is of utmost importance to predict the potential nanotoxicity of a nanomaterial in biological milieu but also to help develop more effective products for applications in nanomedicine.

Lecturer

Name: **Maria Moros**

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Short CV

Dr. Maria Moros graduated as a pharmacist in 2003 at the University of Navarra and earned her PhD in 2012 at the 'Instituto de Nanociencia de Aragón' (INA-University of Zaragoza, Spain). She performed postdoctoral research at the INA (2013–2015) and the Institute of Applied and Intelligent Systems–CNR (Naples, Italy) (2015-2017) after being awarded with a Marie Sklodowska-Curie Fellowship. Currently she is a Juan de la Cierva researcher (Spanish Government grant, 2018-2020) at the Aragon Materials Science Institute (Zaragoza, Spain). Her research interests include synthesis of nanoparticles, magnetic and optical hyperthermia, and biofunctionalization of nanoparticles for biomedical applications using in vitro, in vivo and invertebrate model systems.

Title of the lecture

Biodistribution of Nanoparticles in biological systems

Abstract

Once a nanoparticle (NP) is administered *in vivo*, it interacts with components of the physiological environment what results in the formation of a biomolecule corona. The NP corona is mostly composed of proteins (hence the protein corona (PC) definition) and it can dramatically change the nanomaterial size, aggregation state and interfacial properties. As a result the NP acquires a new biological identity that would dominate the *in vivo* behaviour. Therefore, investigation of the PC is of the upmost importance for understanding and controlling NPs performance *in vivo*. Moreover, long term studies encompassing the whole NP lifecycle are necessary to clarify the fears concerning NPs safety. Thoroughly, unravelling of the interactions of commonly known nanomaterials with living organisms could diminish the huge discrepancy between the produced numerous nanoscale size therapeutics and scarce clinical outcomes.

Lecturer

Name: **Janeck J Scott-Fordsmand**

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Short CV

Dr. Janeck J. Scott-Fordsmand has been working for more than 20 years on the ecotoxicology of various chemicals and nanoparticles in terrestrial ecosystems. His emphasis has been linking effects from the molecular level (biomarkers) to the population and community level. He is also an expert in risk assessment of chemicals and nanoparticles, advisor on the international test guidelines, guidance document and risk assessment of chemicals for various national EPAs, Nordic Council, EU (TCNES, ECHA and REACH) and OECD/OECD Work Programme on Manufactured Nanomaterials and in subgroups. Leader of International Nanosafety Risk working groups. Co-author of the scientific part of REACH regarding terrestrial ecotoxicology. He is an experienced project leader and advisor of both national and international nano-related projects. He is continuously supervising Post Doc, PhD and Master students.

Title of the lecture

Environmental issues for NBMs

Abstract

While environmental risk information is to some extend available for biomaterials and nanomaterials, there is virtually no available information on nanobiomaterials. The present lecture highlight some of the key issues and uncertainties that are present when trying to evaluate the environmental risk of nanobiomaterials.

Lecturer

Name: **Bernd Nowack**

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Short CV

Prof. Dr. Bernd Nowack holds a MSc. (1992) and a PhD (1995) in environmental sciences from ETH Zürich. He is leading the "Environmental Risk Assessment and Management" group at Empa, the Swiss Federal Laboratories for Materials Science and Technology, and is adjunct professor at ETH Zurich. His current research deals with the chances and risks of engineered nanomaterials, nanobiomaterials and microplastics, comprising a wide spectrum of different approaches: development and application of methods for material flow modeling, exposure modeling, environmental risk assessment and life cycle assessment; experimental studies about release of materials from products and investigations about their behaviour in the environment. With the combinations of these investigations he aims to gain a comprehensive understanding of the chances and risks of novel materials for the environment. Bernd Nowack has published more than 150 peer-reviewed publications and has an h-factor of 53. He acted as co-advisor of 18 PhD projects, is founding co-Editor-in-Chief of the journal NanoImpact and is Associate Editor of the journal Environmental Pollution. He is listed as “Highly Cited Researcher” from Clarivate Analytics (Web of Science) in the category “Environmental Sciences/Ecology”.

Title of the lecture

Life-cycle perspectives as basis for exposure assessment

Abstract

The current and future usage of nanobiomaterials (NBM) in medical applications will cause emissions of NBM to the environment and thus result in environmental exposure. As a starting point for an exposure and risk assessment, exploring sources and pathways of release helps to identify relevant applications and release scenarios. By tracking the life cycle of specific products and applications, it is possible to quantitatively predict the flows of NBM to the environment.
Within the environmental exposure assessment two very critical points with limited data are the knowledge about production amounts of NBM and the distribution of the NBM to different product categories and their specific use patterns. Also limited information on the characterization of the released NBM is available.
This presentation shows how approaches developed for engineered nanomaterials can be used to quantify the exposure of NBM. The existing modeling approaches – material flow modeling and environmental fate modeling – are presented and selected examples for engineered nanomaterials are shown. The example of nano-gold used in medical applications is presented in detail and the potential of a prospective exposure assessment is shown. Finally, it is shown how exposure assessment can be coupled with hazard assessment in a full environmental risk assessment.

Lecturer

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Short CV

MSc Degree in Biology and Master Degree in Environmental Health. Carlos Fito is ITENE' head of nanosafety department, coordinator of nanosafety related projects and senior consultant in chemical risk assessment and risk management. Since 2008, Carlos Fito has been involved in the scientific and technical management of European and national projects focussed on the environmental, health and safety assessment of nanomaterials, particularly in exposure monitoring and modelling.

Title of the lecture

Modelling approaches to predict the flows, transformations, concentrations and ultimate fate of nanobiomaterials (NBM) in the environment.

Abstract

Predictive modelling techniques are considered to be among the highest priority issues for characterizing if a potential risk exist, however, the current lack of understanding of the specific processes governing the fate and behaviour of NBMs in the environmental makes current estimations highly uncertain.
Environmental exposure assessment for NBMs are mainly based on probabilistic approaches or make use of different scenarios to provide estimates. Uncertainty depends greatly on the amount of affecting parameters that are taken into account. For instance most of the models available do not take into account processes that could be critical for the fate of the NBMs within the different environmental compartments. Processes like dissolution, adsorption, biological uptake, photolysis, hydrolysis, biodegradation are processes that are very likely to occur in aquatic environments and therefore their consideration in a model would increase dramatically the general uncertainty.
BIORIMA propose an ambitious work plan in both scheduled activities and expected results. The progress is mainly related with the increase of the accuracy of current probabilistic modelling approaches, a better understanding of the transformation and transport process of NBMs in the environment, as well as the generation of predictions at high spatial and temporal resolution in different compartments.

Lecturer

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Short CV

Bryan Hellack is working as senior scientist at the Institute of Energy and Environmental Technology (IUTA), Duisburg (Germany). After working at the Leibniz Institute of Environmental Medicine, Duesseldorf he changed to the IUTA. Up to now he is working at the IUTA mainly on the field of particle generated reactive oxygen species using Electron Spin Resonance Spectroscopy as well as on (nano-)particle characterization, (nano-)particle exposure and health, source apportionment of particles in the environment and assessment of ambient air quality. He is involved in several FP7 research projects and national funded projects dealing with nanomaterial (NM) characterisation, NM fate and behaviour as well as effects on the environment and human health of NM.

Title of the lecture I

Existing approaches for exposure assessment - Tiered approaches for assessing exposure and risks (at workplaces) for nanomaterials.

Abstract

Nanomaterials are frequently used in several applications and everyday life products with the consequence of a potential release and finally exposure for humans and the environment during their lifecycle. Due to that an exposure assessment is important for risk assessment as it is used as a proxy for the potential dose an organism could receive. However, uncertainties concern on which parameter and which method should be used to describe the dose of nanomaterials. The presentation will focus on existing exposure approaches and their application (at workplaces).

Title of the lecture II

Monitoring of emissions/release of NBMs in occupational and environmental settings - NMBs in dentistry

Abstract

Nanotechnology is already frequently used in dentistry e.g. for therapeutic (Biomineralization, Peridontology,...), reinforcement (Bioceramic implantation, Fillers,...), antimicrobial reasons. A short overview on personal monitoring of particle exposure as well as on applications of NMBs in dentistry will be given before the presentation will focus on dental composites that are typically containing high amounts of nanosized filler particles. Here the question will be determined if dental personnel and patients may inhale nanosized dust particles during abrasive procedures to shape, finish or remove restorations based on literature case studies.

Lecturer

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Short CV

Dr. Cécile Philippot received her Ph.D. in chemistry at University of Grenoble in 2010 on the development of core-shell hybrid nanoparticles for biophotonics. After working as a postdoctoral fellow from 2010 to 2012 at CEA Grenoble on the chemistry of quantum dots, she joined as a project leader from 2012 to 2014 at Genes'Ink Company. She was in charge of the news inks development, based on nanoparticles for different uses (printed electronic, energy harvesting, safety). She joined in 2014 the Nanosafety Platform of CEA Grenoble in charge of the assessment of the potential exposure of workers to nanoparticles at workplaces. Since then, she performed numbers of measurement campaigns in research laboratories or industry. Dr. Cécile Philippot is (co-)author of 1 patent, 1 book chapter and 14 publications.

Title of the lecture

Measurements and exposure to particles in air

Abstract

This lecture will focus on three main axes concerning the thematic of the “Measurements and exposure to particles in air”. After a short introduction on the nature of nanoparticles (NPs) that we can find in the air, we will interested in the behaviours and the forces which impact the rules of transport of NPs in suspension in the air. Then, we will provide some tools to know how to measure the NPs in the air and which methodology use to done worker exposure assessment.

Lecturer

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Short CV

Enrico Bergamaschi, MD, PhD, is full professor of Occupational Medicine at the University of Torino, Italy. The research activity has been carried out in the field of Industrial and Environmental Toxicology and has been characterized by the development of biomarkers of exposure, internal dose and early effects on critical organs (namely, central nervous system, lung and kidney) and by their application on specific groups of workers occupationally exposed to xenobiotics (heavy metals and organic solvents) and in groups of the general population. National coordinator of MIUR Project 2006-2007: "Interaction of novel nanoparticulate materials with biological systems: testing models for human health risk assessment", funded by Italian Ministry of University & Scientific Research; Partner in "Reference Methods for Managing the Risk of Engineered Nanoparticles" - MaRiNa (FP7-Call NMP.2010.1.3-1)-WP 9 "Human Toxicology; Partner in "Safe Nano Worker Exposure Scenarios" - SANOWORK. - (FP7-280716) 2012-2015 - WP5 "Toxicological Hazard Assessment"; Partner in BIORIMA (WP2, 3 and 4). Active member of the EU initiative "EU Nanosafety Cluster", Member of the International Commission on Occupational Health (Scientific Committee on 'Nanomaterial Workers' Health); Member of the National Committee for the Occupational Safety of Nanomaterials (Italian Ministry of Health). Expert evaluator for the EC. Author or co-author of >120 peer-reviewed full papers in international journals and 15 book chapters. Google Scholar: h-index = 35 (ISI: 31); n. total citations = > 3500.

Title of the lecture

The role of biological monitoring in nano-safety

Abstract

Although no overt health effects in humans caused by nanomaterials (NM) have been reported yet, ensuring the safety of workers is mandatory for the responsible development and the long-term sustainability of nanotechnology-enabled industry. To improve the safety assessment of NM, many pragmatic approaches have been proposed, including non-testing strategies (reading-across and categorization), whereas our current testing strategy is actualized by using simplified models, different dosing regimens and exposure routes which represent a compromise to understand what could happen in humans. These settings are not truly representative of nano-bio-interactions occurring in a real-life scenario, which requires more caution in the interpretation of findings with consideration of the weight of evidence. As a result, insufficiency and ambiguity of the existing in vitro and in vivo toxicological data on NM hamper a consistent risk assessment (RA) required for scientifically sound regulatory and policy decision-making.

Research of biomarkers and their validation in biomonitoring (BM) programs have been considered a complementary approach to decrease the uncertainty in estimating exposures by biologically relevant measures and to determine whether individuals or a population are at increased risk of adverse health effects. Within the hierarchy of biomarker development, a pragmatic approach is to draw exploratory and candidate biomarkers from other fields of particle and metal toxicology, to find similarities and differences in molecular pathways of toxicity. Comparative proteomic studies have shown strong similarities in the pulmonary response to different NM with known hazardous particles and fibres. Achievements in this field may make more consistent also the regulatory approach to hazard based on dynamic adverse outcome pathway (AOP) models.

Since BM has different meanings in the research and practice, candidate biomarkers, which are potentially useful for occupational health surveillance, epidemiology and environmental sustainability should meet validity criteria, and thus undergo field validation and assessment of their predictive value towards relevant health outcomes and, ultimately, potential risks.

BM represents a valuable component of an integrated strategy and a pro-active approach to RA and management, an opportunity for companies committed with the responsible development of nanotechnology, and also an ethical obligation towards all working population.

Lecturer

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Short CV

Caroline Marie-Desvergne is a researcher at the Medical Biology Laboratory (LBM) of CEA Grenoble in France. She is specialized in occupational and environmental toxicology with the development of innovative biomarkers in humans. Since 2010, she has focused her expertise in the development of human biomonitoring for nanoparticles.

Title of the lecture

Nanoparticle exposure biomonitoring: experimental approaches for the development of biomarkers of exposure and effect

Abstract

The use of engineered nanoparticles (NP) is more and more widespread in various industrial sectors. The inhalation route of exposure is a matter of concern. Although available epidemiological studies have led to the identification of a panel of candidate biomarkers, no validated biomonitoring recommendations are available so far for NP. The LBM of CEA Grenoble is currently conducting several experimental approaches to develop and evaluate different biomarkers of exposure and early effects for occupational health applications. These approaches will be presented in the lecture.

Lecturer

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Short CV

Dr Alexis Vignes (M) holds a MSc and PhD in Chemical Engineering. Since 2005, he has been actively involved in several EU projects dedicated to nanosafety (NANOSAFE 2, SAPHIR, MARINA, NANOREG II…) and process safety (e.g. FP7 DEMCAMER, ALFABIRD, ASCENT…) as task or WP leader. He is a technical expert in fire and explosion hazards at INERIS and is actively involved in European Committees for standardization (e.g. CEN TC 352 Nanotechnologies, CEN TC 305 Explosion Protection and Prevention).

Title of the lecture

Accident Risk management of nanobiomaterials: Overview of the current knowledge and challenges

Abstract

Nanobiomaterials are sometimes considered as a key to the next medical revolution. Over the past years, many applications have already been developed. Research in the field is growing very rapidly, and all the developed countries see potential for expansion and applications in numerous fields as well as great potential economic spin-offs. As nanobiomaterial production and use are going to increase, there can be more and more associated hazards. A potential hazard of nanobiomaterials that appears to have received little attention to date is their accident risks that can lead to fire, explosion and potentially massive dispersion to environment. In fact, as well as (non)combustible micromaterials are considered in accident risks assessments, nanobiomaterials have also to be assessed along the value chain. In that context, this lecture will give an overview of the current knowledge and future challenges posed by bionanomaterials from an accident point of view.

Lecturer

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Short CV

Dr. Georgios Drakakis received his Diploma in Computer Science from the Aristotle University of Thessaloniki in 2007. He then proceeded to obtain two MSc degrees in Computer Science and Advanced Biological Sciences/Bioinformatics from Trinity College Dublin and the University of Liverpool respectively. In January of 2015 he completed his PhD at the University of Cambridge in the area of Computational Chemistry/Cheminformatics and joined the National Technical University of Athens as a research associate. He then completed a year of research at the University of Cambridge in 2017 before returning to the National Technical University of Athens, where he is currently a Post-Doctoral Research Associate at the Unit of Process Control and Informatics working on algorithm design and nano-QSAR modelling. His research interests are in the areas of machine learning, data mining, cheminformatics, computational chemistry and computer vision. Over the past 4 years he has co-authored 11 original research publications in these fields and contributed to 2 book chapters.

Title of the lecture

In silico modelling to support risk assessment and Safety by Design of NBMs

Abstract

Nanobiomaterials are increasingly infiltrating our lives due to their applications in multiple fields. Their usage however may result in the modulation of pathways and mechanisms that endanger human health and the environment. Alternative testing methods such as in silico approaches are becoming highly popular for assessing their safety as they are cost- and time- effective.

To this end, this lecture will comprise an overview of state-of-the-art nano-QSAR approaches, as well as future directions tailored to the BIORIMA project. Several challenges will be discussed, such as the evident need for harmonisation in terms of databases, ontology and modelling infrastructures, as well as the lack of concrete nanomaterial characterisation and public data availability. We will conclude the session with a hands-on workshop using Jaqpot Quattro, an open source web application for nanomaterial modelling with emphasis on predicting adverse effects.

Lecturer

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Short CV

I am working at ISTEC, from 2008 with permanent position. I acquired knowledge, skills and competence in different fields: powder process for the sintering and characterisation of piezoelectric ceramics; structure- properties correlation applied to ceramic engineering; sol-gel synthesis, functionalisation and characterisation of ceramic micro/nanophases and their colloidal properties; technology transfer of ceramic nanostructured coatings and their functional characterisation (photoactive membranes, antibacterial surfaces, multi-functional textile). I am recently investigating properties and mechanisms of nano-world in biological environment, clinging to the idea that nano-phases can help our understanding of the mode of action and perturbation of biological pathways leading to toxicity. I am co-author of more than 80 papers on ISI journals; H-index: 23; Citations: 1544 (Google Scholar). I am co-author of 2 international patents, 5 chapters of books and more than 80 communication in international conferences (more than 20 oral invitation). OrcID: 0000-0003-1407-6498.

Title of the lecture

Case studies for NMB surface modification & related characterization of relevance for a safety by design approach.

Abstract

Nanomaterials (NMs) may exhibit additional complexity when compared to simple molecular systems. This creates some concerns about potential human and environment risk that exposure to NMs can generate. Under this prospective, a “Safe by Design” approach (SbD) that aims to control and reduce hazard and exposure potency whilst preserving nanoscale reactivity, is highly recommended. Nevertheless what appears very complex and far to be validated is the process of selection and justification of design solutions that necessary pass through an accurate characterisation of intrinsic, extrinsic and hazard concern properties that directly affect hazard and exposure mechanisms. Approaches and case studies developed under FP7 collaborative projects Sanowork and SUN will be presented.

Lecturer

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Short CV

Dr. Badetti holds a Ph.D. in organic chemistry, with European Mention, at Universidad Autónoma de Barcelona, Spain (2008). From 2008 to 2010 she had a postdoctoral research contract at the Department of Molecular Nanoscience and Organic Materials of ICMAB-CSIC of Barcelona and from 2012 to 2016 she was postdoctoral researcher at the University of Padova (Italy), at the Department of Chemical Sciences. She acquired experience in organic synthesis, catalysis, coordination and supramolecular chemistry as well as in synthesis, functionalization and characterization of nanomaterials. Since 2016 she is a senior research scientist at the Department of Environmental Sciences, Informatics and Statistics (DAIS) at Ca' Foscari University of Venice. Her research activity is currently focused on the functionalization (in the frame of a Safe by Design approach) and characterization of engineered nanomaterials. She has been involved in several European Projects such as EU-FP7 (SUN) and Horizon2020 (NANORESTART, NanoFASE, BIORIMA). She is co-author of 32 scientific publications in international peer reviewed journals.

Title of the lecture

Case studies for NBM surface modification & related characterization of relevance for a safety by design approach

Abstract

The development and application of new nano-enabled products, especially in the medical field, requires special attention to adverse effects on human health and post consumption fate. Safe by Design (SbD) strategies can be used as preventing tool and can support formulators in the early steps of product development, with the aim to provide safer nano-formulations, while retaining their functionality. In this context, a SbD approach developed in H2020 projects will be presented, focusing the attention to the ecotoxicological implications associated with pre- and post-application stages.

Lecturer

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Short CV

Alex Zabeo, Senior Researcher, Ph.D. in Informatics. His research activities focus on Decision analysis and Probabilistic Risk Assessment. He has proven expertise in project and development of standard and Geographical Decision Support Systems (DSS) and in Multi-Criteria Decision Analysis (MCDA) - Fuzzy Logic (FL) - Value of Information (VoI) based assessment methodologies as well as in design and realization of studies and software related to Life Cycle Assessment (LCA). He's been guiding the Decision Support area of several European and National projects.

Title of the lecture

PRACTICAL EXCERCISE: Risk assessment and management of NBMs by means of the SUNDS tool

Abstract

During this exercise the SUNDS web application for Risk assessment and management of Nano Bio Materials (https://sunds.gd) will be demonstrated through the application to a fictitious case study. The tool is able to perform probabilistic Human Health and Environmental risk assessment, social impact assessment, economic assessment and Life Cycle Impact Assessment. Multiple exposure scenarios will be generated and compared by means of the previously mentioned assessment aspects during the exercise.

Lecturer

Name: **Simone Sprio**

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Short CV

M.Sc Degree in Physics and Ph.D in Chemistry at University of Bologna, since 1997 is researcher at ISTEC-CNR, and leads the research group on Bioceramics for bone regeneration. Particular focus is on biomimetic multi-doped nanocrystalline apatites in the form of powders, injectable pastes and 3-D porous scaffolds, indicated for regeneration of different bony compartments (e.g. cranio-maxillofacial, spinal, extremities). Development of new fabrication processes based on direct foaming and on biomorphic transformations under controlled temperature and atmospheric conditions. Author of more than 100 papers and inventor of 9 international patents. Editor of a monograph on advanced materials for tissue regeneration.

Title of the lecture

Biomimetic ceramics and hybrid composites for regenerative medicine and theranostics

Abstract

The role of bioactive materials and devices is pivotal to achieve tissue regeneration and recovery of the original functionality which, particularly for hard connective tissue (i.e. bone, cartilage and teeth) has a great societal relevance, even though in most cases these are still unmet clinical needs. The present talk describes the recent advances in the development of bioactive 3-D devices based on biomimetic apatite phases, with excellent regenerative ability given by their close mimicry with native tissues that enable cell instruction and sustain of the physiological metabolic process.
Also, in the form of superparamagnetic biocompatible and bioresorbable nanoparticles these highly bioactive materials demonstrate great potential in advanced diagnosis and therapies, and can be exploited in advanced applications in nanomedicine, with much enhanced safety in comparison with cytotoxic nanoparticles.

Lecturer

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Short CV

I've got my PhD in Environmental Sciences at the University Ca' Foscari of Venice in 2005, with a research subject on the risk assessment of persistent pollutants in the lagoon of Venice. I started to work on nanosafety issues in the same year, in the FP6 project Particle_Risk, and never stopped since. After 3-year postdoc experience at the JRC (from 2008 to 2011), tackling issues at the frontier of science and policy, I worked in a research lab in Italy, as risk assessor, project manager, and regulatory affair specialist, and lately also as consultant for companies. From 2018, I work in TEMAS AG in Zürich as a project manager, providing support to companies in the MD industry and nanotechnology in general, and also working in EU research projects.

Title of the lecture

Safe-by-Design Implementation Platform

Abstract

Responsible Research and Innovation is one of the main themes (and program) of the European Commission when talking about sustainability of innovation, which is declined in different ways (see the recent focus on circular economy). This theme is even more important for nanotechnology, since a good public perception is essential to be able to transfer the benefits of nanotech to the society. We cannot afford to make mistakes; therefore, a proactive approach is necessary, also in relation to the regulations. In the EU projects NANoREG, ProSafe, and now NANOREG^2, TEMAS AG, together with RIVM and other partners, developed the Safe-by-Design (SbD) concept. In short, SbD aims at including safety concerns in the innovation process as soon as possible, starting from the idea stage. Among the different actors, industry is at the core of innovation process: industry takes the research and transfer the novel properties to products placed into the market. Therefore, to have a successful implementation of RR&I industry needs to be involved from the start.
TEMAS AG developed a web-based platform to translate and implement practically the SbD concept. The SbD platform allows to design an innovation process including all participants in an open approach, collecting the regulatory and innovation-relevant data and information, and assessing at specific decision points the functionality and safety properties against self-defined and/or regulatory benchmarks. The platform, together with other tools developed in NANOREG^2 project, aims to support a safe innovation and dialogue with regulators and all relevant stakeholders. During the lecture, the NANoREG SbD concepts will be presented and the SbD platform will be demonstrated.

Lecturer

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Short CV

Susan Dekkers is a senior researcher in the Centre for Safety of Substances and Products at the National Institute for Public Health and the Environment in The Netherland (RIVM). She holds a M.Sc. in Environmental Health Sciences at Maastricht University. Her main focus is addressing the challenges of human risk assessment of chemicals and nanomaterials in food, consumer products and for workplace exposure. She has acted as co-WP-leader in NANoREG and contributed to several other projects on the risk assessment of nanomaterials, including NanoMILE, NanoReg2, Gracious and caLIBRAte. Previously, she has worked as risk assessor and project leader at TNO within the Department of Toxicological Risk Assessment and the Department of Food and Chemical Risk Analysis.

Title of the lecture

Moving towards a Safe Innovation Approach

Abstract

Susan Dekkers, Lya G. Soeteman Hernandez and Cornelle Noorlander
Centre for Safety of Substances and Products, National Institute for Public Health and the Environment (RIVM), P.O. Box 1, 3720 BA, Bilthoven, The Netherlands

Technological innovations are developing at such a dynamic pace that they pose a challenge to governance of public and environmental safety due to the large difference in the pace between innovation and the development of suited governance. Nanotechnology innovation is an example where the pace by which innovative materials and products is developed exceeds the generation of knowledge required to sufficiently address the safety of these materials and their products. With the Safe Innovation Approach (SIA), under development within the EU project NanoReg2 (www.nanoreg2.eu), we look for ways to enhance the ability of all stakeholders to create robust, yet flexible processes of integrating the safety evaluation in the innovation. SIA is an approach that combines the Safe by Design (SbD) concept and the Regulatory Preparedness (RP) concept. The Safe by Design (SbD) concept aims at reducing uncertainties and risks of human and environmental safety, starting at an early phase of the innovation process and covering the whole innovation value chain. The Regulatory Preparedness (RP) concept aims for regulators to be prepared for innovations. The basis of SIA is that innovators and regulators are more aware of safety from the early stage of innovation onwards, that there is better interaction between industry and regulators and regulators are better prepared for innovations. SIA promotes a safe and responsible approach for companies working on the development of innovative products and materials and stimulates a proactive attitude amongst policymakers or regulators to ensure that regulations keep up with the pace of innovations. SIA should lead to a resilient process which has the ability to anticipate, learn about and adapt to technological innovations.

Lecturer

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Short CV

Dr. Nina Jeliazkova is founder and coowner of Ideaconsult Ltd and is technical manager of the company since 2009. Ideaconsult (https://www.ideaconsult.net/) is a SME providing consultancy, technical services, chemical safety data hosting and software development in the areas of chemoinformatics, QSAR, and data mining since 2004. Nina received PhD in Computer Science with research subject on the molecular modelling methods, and was a PostDoc at the Central Product Safety department, Procter & Gamble, Brussels, Belgium in 2002-2003. She participated in a number of international and national R&D projects, leading the database workpackages in FP7 ToxBank and eNanoMapper project as well as the framework implementation in the earlier FP7 OpenTox project. Currently she leads the Data Solution team of the NANoREG2 H2020 project and is involved in big data modelling in High Performance Computing and predictive chemogenomics context in the framework of the ExCAPE H2020 project. Nina received the Blue Obelisk Award in 2010 for achievements in promoting Open Data, Open Source and Open Standards.

Title of the lecture

Making project data available through eNanoMapper database

Abstract

We present experience with integrating large sets of nanosafety data generated from past NanoSafety Cluster projects with the help of a substance data model, implemented in the eNanoMapper database. Data generated by multiple nanosafety projects is compiled, annotated and imported into separate eNanoMapper database instances. The eNanoMapper ontology is used for harmonisation of the terminology. While multiple structured import formats are supported (IUCLID, RDF, JSON), the nanosafety data from past and ongoing projects use custom spreadsheet templates, currently encompassing over 1000 Excel files.

Import of Excel files is enabled by a configurable parser that maps the spreadsheet data via external configuration files. Multiple export formats are supported, including tab delimited files, RDF and ISA-JSON. Free text and faceted search applications, with public and restricted access for different subsets of data, are available at https://search.data.enanomapper.net. The NanoReg2 integrated database view is online at https://search.data.enanomapper.net/nanoreg2 and allows project partners to access data from past EU FP7 funded projects (NANoREG http://www.nanoreg.eu/, MARINA, NanoGenoTox, Nanotest) through a common view and faceted search. The database is actively used by project partners, helping to identify and, where possible, resolve a range of data quality and completeness issues.

BIO RIMA

BIOmaterial RIsk MAnagement

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