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Workshop: Meet the Biobank Experts

23 OCT 2018

Rue Royale 2-4,
1000 Brussels

If you use human samples or human cell lines for your research, you'll need to register your organisation as an official BIOBANK with FAMHP. What are the different steps? Who should be involved and how?

During this workshop, several experts will give you an update on the legislation (we expect additional changes to the legislation before the workshop) and on the practical steps to be taken for registration based a.o. on the compendium. After the informative part of the workshop, you will have the opportunity to meet in one-on-one sessions with:

- operational biobank experts
- legal and regulatory experts
- representatives of FAMHP
- representatives of Ethics Committees

Agenda of the Session:

10h30-11h00	Registration	
11h00 - 12h30	Plenary Session	Kathleen Devos - Ablynx Gwendolyn Goedbloed - Janssen Diane Kleinermans - Kabinet Minister De Block Nick Van Gelder - FAMHP Christel Vansteenkiste - UZ Brussel
12h30 - 13h30	Lunch	
13h30 - 14h45	Case Studies	René Custers - VIB Marcin Jurga - The Cell Factory Nathalie Van Bruaene - Anacura
14h45 - 15h00	Break	
15h00 - 16h45	B2B meetings	Kathleen Devos - Ablynx Laurent Dollé - Biothèque Wallonie Bruxelles Sandrine Fontaine - GSK Biologicals S.A. Gwendolyn Goedbloed - Janssen Marcin Jurga - The Cell Factory André Lhoir - FAMHP Marc Martens - Two Birds Pieter Moons - UZA/UAntwerpen Biobank Nick Van Gelder - FAMHP Pascale Van Rooij - Perseus Bvba Christel Vansteenkiste - UZ Brussel
16h45 - 17h00	Closure Session	

Practical Details:

Location: BIP - 2 Rue Royale, 1000 Brussels, Belgium
Date: 23 OCT 2018 from 11:00 to 17:00 (Doors open at 10:30)
Fees:

- Academic Fee:€ 120 (for all students, hospital staff, academics, public and non-profit organisations)
- Industry Fee: € 250

The Speakers:

René Custers

Regulatory & responsible research manager at VIB

René Custers is trained in molecular biology and joined VIB – a life sciences research institute based in Flanders – in 1997. He has more than 20 years of experience in regulatory affairs, biosafety, and societal aspects of modern biotechnology. He is an expert in the legislation and safety of GMOs and genome edited organisms. At VIB he coordinates the institutes' policies on regulatory compliance, (bio) safety, ethics and integrity. He is also involved in science communication activities to a wider audience. He is a member of the Belgian Biosafety Advisory Council, and secretary of the European Biosafety Association.

Kathleen Devos

Section Head Technical Expert team "Discovery-Lead Characterization-Cell Based Solutions" at Ablynx

1982: Master in Biology (Physiology-Biochemistry)
1986: PhD in Science (UGent Lab. Molecular Biology, Prof. Fiers)
1986-1989: post doc (UGent Lab. Molecular Biology, Prof. Fiers)
1990-2011: Innogenetics in several functions: Research Scientist, Line Manager different units (Molecular Biology/Protein expression ; R&D general services team), Project Leader Product & Platform Lifecycle Projects
2012-2018: Ablynx as Section Head Technical Expert team "Discovery-Lead Characterization-Cell Based Solutions"

Laurent Dollé

Managing Director at Biothèque Wallonie Bruxelles

Laurent Dollé is a scientist in Biomedical Sciences with 16 years of experience in Cell Biology and Molecular Biology with interests on healthcare systems and innovative technologies/devises. Laurent has a deep knowledge in the field of breast cancer research (growth, migration, invasion and metastasis), in hepatology (fibrosis, cirrhosis, and hepatocarcinoma), and liver regeneration (stem cells, liver repair and therapies, mouse models).

In 2012, Laurent became Assistant Professor at the Free University of Brussels VUB, and from 2016, he became the operating manager of the biobanks network from Wallonia-Brussels regions (BWB) allowing him to accumulate a profound awareness on the vast ecosystem of Biobanking (collection, harvesting, storage, distribution compliant with international quality standards (GLP/GMP and ISO standards) and regulations (law and royal decree). Since September 2017, Laurent is the managing director at BWB.

Sandrine Fontaine

Head Medical Governance for Human Subject Research at GSK Biologicals S.A.

Bioengineer by training, I am working in the Pharmaceutical industry since more than 15 years. Over my carrier I had various role in GCP/ GLP auditing, ISO implementation, clinical operations and Risk management. I am currently working for GSK Biologicals S.A. in the Medical Governance and Bioethics group. I am supporting the deployment of the Biobank legislation. I am part of the Compendium deployment among other stakeholders of the industries, academic, regulator and Ethical Committee.

Gwendolyn Goedbloed

Director at Janssen, Pharmaceutical Companies of Johnson and Johnson

Gwendolyn graduated as Industrial Engineer in Chemistry and Automation and joined Tibotec in 1999 setting up the Compound Logistics department. Few years later she became operational head of the Virco Diagnostics Lab.

In 2011 Gwendolyn led the implementation of the Biobank in Beerse, the first Biobank in Janssen. She built the department and designed a process to ensure compliance to local Belgian Biobank legislation. More recently, Gwendolyn took additional managerial responsibilities for the Spring House Biobank team in US.

In 2013, Gwendolyn took the global lead to initiate the Janssen Global Biobank Community of Practice. Under her leadership, the team implemented 1 global process and 1 global centralized database covering all Janssen Biobank sites: Spring House, La Jolla, Raritan, Beerse, Leiden and Shanghai.

In 2017, Gwendolyn took an additional global responsibility on Quality & Compliance and Environment, Health and Safety activities. Supporting the scientific community by building connectivity with business partners to create a culture of safe and compliant practices.

Marcin Jurga PhD

General Manager, R&D Director at The Cell Factory

Marcin Jurga specializes in drug development, bioproduction and advanced regenerative medicine. Marcin Jurga graduated at Warsaw University in Poland (2002) in the field of molecular biology. In 2007 Marcin Jurga got a Ph.D. in Medical Sciences at Medical Research Institute of Polish Academy of Sciences in Warsaw, Poland with specialty in human stem cell biology and tissue engineering.

Marcin Jurga continued his career at The Newcastle University, UK and at The Institute of Cell Research Therapy Lyon, France as a team leader (2007-2011). In this period Marcin Jurga coordinated international research projects focused on neural, pancreatic and bone tissue engineering and was involved in preparation of clinical trial in stem cell application in pediatric neurology. Since 2011 Marcin Jurga is the head of R&D at The Cell Factory biotech company in Niel, Belgium. Marcin Jurga is responsible for drug products development, quality assurance, bioproduction process (GMP) and clinical translation of the IMPs in accordance with the international regulations.

Currently he is responsible for clinical translation of EVs drug candidates for treatment of Crohn's disease, epilepsy and stroke. Marcin Jurga is also experienced in management of intellectual property, business development and fundraising. Marcin Jurga received multiple non-dilutive research grants including H2020 project recently funded by the European Commission (2018). In 2016 Marcin Jurga participated in securing EUR 13 million major investment by Esperite Group.

Diane Kleinermans

Conseiller - Adviseur at Minister van Sociale Zaken en Volksgezondheid / Ministre des Affaires sociales et de la Santé publique, Maggie De Block

Diane Kleinermans works as advisor to the Minister of Public Health and Social Affairs since 2015. Her main responsibilities include clinical trials, human body material but also the BeNeLuxA initiative.

Diane has a medical background and a broad experience in various fields. She started her career as GP in Brussels but rapidly collaborated with the pharmaceutical industry.

Her first employer was Pfizer where she stayed for more than 15 years, working in early development and creating their Phase I Unit at the Erasme hospital (Brussels). She managed the unit for 10 years, She then left Belgium and worked as medical director of CRO's in France and the UK, before joining Novartis Ophthalmics as head of the scientists group in Zurich.

She then came back to Belgium where, after a short experience in the regulatory department of GSK Biologicals, she joined the NIHDI as internal expert to the Commission of Drugs reimbursement, being amongst others in charge of orphan drugs assessments.

Pieter Moons

Manager UZA/UAntwerpen Biobank

Pieter Moons obtained a PhD in Bioscience engineering from the University of Leuven in 2009. He remained in KULeuven as a post doc with research lines focusing on genetic pathways related to bacterial communication systems. Pieter joined Sanico NV, a pharmaceutical company in 2010 where he worked as a Scientist in the QC department, co-leading a team of about 20 lab technicians.

He then moved to University of Antwerp in 2011 where he joined the internationally renowned lab of medical microbiology of Prof. Herman Goossens. There he managed and was scientifically involved in multi-partner academia-industry consortia focused on the development of rapid diagnostics for infectious diseases, participated in a clinical trial network aimed at combatting antimicrobial resistance and the rapid spread of emerging pandemics and established research projects focusing on infectious disease diagnostics, from early stage biomarker discovery to technology integration and spin-off creation. Although still partly connected to the UA lab, Pieter is now the manager of the UZA/UAntwerpen Biobank where he focuses on the integration of the UAntwerpen biobank facilities and bringing the biobank in line with the 2018 Belgian legislation.

Nathalie Van Bruaene

Business Innovation Manager at Anacura

Nathalie Van Bruaene was trained as a doctor in Applied Biological Engineering and has 20 years of experience in the field of Cell Biology. Starting with fundamental research for her PhD at the university, she switched to the industry as operational responsible of an in vitro fertilization lab. She then worked in a clinical lab as head of the flowcytometry department, conducting analyses for clinical trials in different domains (leukemia, multiple myeloma, arthritis, …).

Since 2014 she works at business innovation manager at Anacura, where she initiated the cell-based division of Anacura Life sciences. Now she is the lead of Sportana, a new business group within the incubator of Anacura that develops algorithms based on blood tests for measuring health and performance of athletes.

Nick Van Gelder

Jurist at FAMHP

Nick is one of the FAMHP's legal advisors. His field of expertise pertains to the legislation regarding the use of human material, both for therapeutic and scientific purposes. In 2013, he presented his PhD research, entitled "Naar een commercialisering van menselijk lichaamsmateriaal?" (Towards a commercialisation of human bodily material), and he has been active at the University of Antwerp as a visiting professor at the Antwerp Health Law and Ethics Center (AHLEC).

Pascale Van Rooij

Biosafety and Regulatory Specialist at Perseus Bvba

Pascale Van Rooij is trained in Biology and holds a PhD in Veterinary Sciences. She has 15 years of experience in medical microbiology. She started her career at Sciensano as a scientific attaché and subsequently as curator of the BCCM/IHEM culture collection of biomedical yeasts and fungi. As research assistant at UGent she focused on amphibian in vitro-modelling.

In 2017 she joined Perseus BVBA, a service provider for biosafety and regulatory requirements in biotechnology. Perseus aims at helping clients to find their way through the European & international regulatory obligations for biological material, including the biobank legislation. Last year Pascale has been working out a practical guide to the biobank legislation and a step-by-step plan guiding clients through the registration process.

Christel Vansteenkiste

Commissie Medische Ethiek at UZ Brussel

Christel Vansteenkiste is scientific secretary of the Ethics Committee of the UZ Brussel/VUB. As founding member and chairman of BAREC, the Belgian Association of Research Ethics Committees, she participated in multiple advisory boards on the wording and implementation of research-related legislation in Belgium. She gained expertise as visiting lecturer in ethics and clinical trials at the VUB, the Erasmushogeschool Brussel and the Odisee Hogescholen Brussel/ Aalst.