



CCQM workshop "Metrology for Viral systems as molecular tools"

24th to 27th January 2023



Workshop aim

The workshop aims to explore established and emergent measurement technologies, reference materials and methods development, regulatory landscape and standardization needs and gaps for a diverse set of stakeholder-driven applications utilising these systems. The workshop will aim to cover applications covering the principle viral entities in use and develop a strategy to foster links and provide metrology support between public and private stakeholders and NMI/Dis, prioritizing and developing measurement solutions and calibration services.

Register at ccqm/ccqm-ws/2023-01-24 - BIPM

CCQM workshop “Metrology for viral systems as molecular tools”.

Jan 24th 13:00 to 15:30 UTC+1

Welcome

Sang-Ryoul Park. President, CCQM

Background and further instructions.

Jonathan Campbell NML@LGC

Session 1. Background Challenges and Opportunities

Chair, Neil Almond, MHRA UK

Viral Vectors: Challenges of Measurement	Isobel Searing, Oxford Biomedica (UK) Limited
Regulatory perspectives on medicines that use viral systems	Francis Galaway Medicines and Healthcare products Regulatory Agency, UK
AAV Characterisation - Challenges and Opportunities	Wilson Li Cell and Gene Therapy Catapult. UK
The New Bioassay Challenge. Gene therapy Products	Ulrike Herbrand Charles River Gene Therapy Solutions, Erkrath, Germany
Chair led Q&A	

Jan 25th 13:00 to 15:30 UTC+1

Welcome Day 2

Jonathan Campbell

Chair Feedback Session 1. 15mins

Neil Almond

Session 2. Entity characterisation 1. Physical Titre Measurement.

Molecular methods.

Chair, Jim Huggett NML@LGC

Review of physical titer methods for viral vector reference materials	Ed Kwee National Institute of Standards and Technology, USA
Using digital PCR to measure nucleic acids from viral vectors	Alexandra Whale National Measurement Laboratory hosted at LGC Ltd. UK
NGS for detection of viral impurities	Arifa Khan Center for Biologics Evaluation and Research, FDA. USA
Can biological standardisation provide assurance to NGS analyses	Ravneet Bhuller. Medicines and Healthcare products Regulatory Agency, UK
Chair led Q&A	

Jan 26th 13:00 to 16:00 UTC+1

Welcome Day 3.

Jonathan Campbell

Session 3. Entity characterisation 2. Towards Functional Measurement. Mass, Particle and Microscopy methods.	
Chair, Caterina Minelli NPL	
Title TBC	Ian Anderson. Lonza, UK
Viral vector characterisation by mass spectrometry	Luise Luckau. National Measurement Laboratory hosted at LGC Ltd. UK
DNA content analysis of AAVs by cryogenic electron microscopy (CryoEM)	Thomas Cleveland National Institute of Standards and Technology, USA
Nano-Metrology for Biological (including Viral) Systems using Scanning Probe Microscopy	Sang-Joon Cho Park Systems, South Korea
Characterization of Nanometer-Sized Gene Delivery Systems by Flow Cytometry	Lili Wang National Institute of Standards and Technology, USA
Chair led Q&A	

Jan 27th 13:00 to 16:00 UTC+1

Welcome day 4.

Jonathan Campbell

Feedback Session 3.

Caterina Minelli

Session 4. Standardisation and Control	
Chair, Sheng Lin-Gibson NIST	
Documentary Standards Considerations for Viral Vectors. Title TBC	Julian Braybrook National Measurement Laboratory hosted at LGC Ltd. UK
Virus-like particles as reference materials: mass-spectrometry and quantitation of cellular uptake.	Andrea Briones Higher Research Scientist, NPL
NIST test material for integrated lentiviral vector copy number (VCN) measurements: results from an interlaboratory study	Hua-Jun He National Institute of Standards and Technology, USA
Reference materials for EM and differential diagnostics including viruses.	Ibolya Kepiro Higher Research Scientist, NPL
Establishing critical quality attributes for AAV vector preparations: characterisation of a candidate Reference Material	Sarah Kempster Medicines and Healthcare products Regulatory Agency, UK
Chair led Q&A	

Final remarks and Close

Jonathan Campbell