VAMAS

Synthetic Biomaterials
Technical Work Area 40

Covid-19 Response - 2
Physicochemical profiling of virus-like particles as reference materials for vaccine development and virus particle diagnosis

Objectives

Physicochemical validation of synthetic virus-like particles (VLPs) as dimensional standards to:

a) assess physicochemical attributes of vaccines during development, manufacturing and batch release
b) detect virus particles in cells and tissues

Background

There is currently an international effort for the development of a COVID19 vaccine, with over 150 candidates in clinical trials. Vaccine can show variability in their physical and biological properties, whilst manufacturers must take a particular care to ensure performance consistency for vaccine products from development to batch release. To succeed in this, reference materials based on prototype vaccine platforms are needed, but lacking. Similarly, effective management and tracing of viral pandemics relies on the accurate and reliable detection of infectious viruses.
Electron microscopy provides nanoscale resolution required for identification and differential diagnosis of unknown viral agents in cells and tissues at various stages of infection, e.g. from entry to release.

Standardization needs

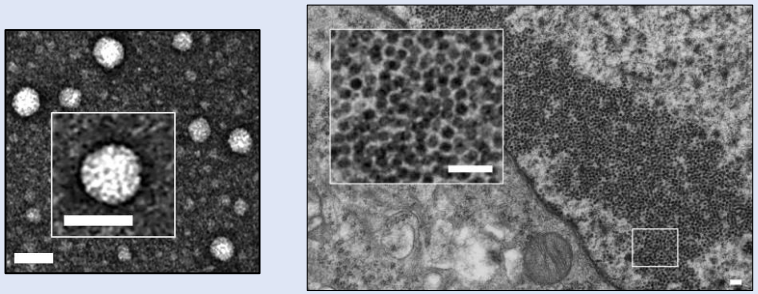
A key need is to formulate and validate suitable standards that would exhibit the physical and biological properties of viruses and virus-like structures to benchmark the physicochemical and biological attributes of vaccines and as internal standards for virus detection in cells and tissues.

Specific needs are the development of:

- VLP reference materials
- assigned values for these materials consistent between laboratories for different measurement techniques (e.g. TEM, AFM, DLS)
- reference procedures for quantitative and reproducible analysis of the assigned values
- performance assessment datasets of commercial vaccines
- protocols for accurate and quantitative detection of viruses in cells and tissues

Relevant Committees
ISO/TC 276 - Biotechnology
ISO/TC 202 - Microbeam analysis
ISO/TC 229 - Nanotechnologies
ISO/TC 194 - Medical devices
ISO/TC 212 - Clinical Laboratory testing

Call for participants



Representative electron micrographs of synthetic virus-like particles (left) and BK viruses of similar size and morphology in kidney tubular epithelial cells (right, courtesy of EM Unit, Charing Cross Hospital, London). Scale bars are 50 nm (left) and 200 nm (right).

Relevant guidelines and standards

ISO Guide 35 Reference materials
ISO 29301: 2017 and ISO 13022: 2012

Work Programme

Two types of EM grids will be provided for the round robin:

- synthetic virus-like particles fixed on the EM grids
- microtomes of VLP infected cells
- the grids are distributed to individual participants with instructions for imaging and analysis.
- analysis of the results with full uncertainty evaluation is performed by each participant
- repeatability and reproducibility of the measurement results is then tested by a smaller group of participants.

Funding

Participants will fund their own involvement in the project.

Deliverables and Dissemination

International round-robin tests and reports, publications, measurement good practice guidelines supporting development of vaccines and new drugs, contribution to the development of new standards under ISO/TC.

International participation

The project is active from July 2020. Expressions of interest from global participants welcome.

For more information on participation, please contact:

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