Objectives

The aim of this work is to characterise the morphological and physical characteristics of synthetic filamentous structures at a single filament level (a few nanometres) using electron microscopy (both low and high resolution). These filaments are being proposed as internal calibrants for high-resolution electron microscopy (HR-EM).

Background

There exists commercialisation barriers for healthcare and biotechnology products, prompting the need for the parameterised specification of biomaterial properties. This need is reinforced by existing regulatory policies limiting the wide use of advanced therapies (EC/1394/2007; EC/2001/83).

Physico-chemical and bio-chemical measurements that advance the pre-standardisation of synthetic materials as defined by interdependencies between physical and biological parameters of the materials is a prerequisite for the commercialisation of these products.

Standardization Needs

There is a pre-standardisation need to focus on:

- ability to produce and characterise materials to a common physical specification.
- Assigned values consistent between laboratories and with the laws of biological assembly.
- procedures for quantitative analysis of the values by measurements of the highest resolution and highest metrological order
- material validation in biologically native and near-native environments in real time

Work Programme

- Materials will be assembled and deposited on a required substrate for distribution.
- Material characterisation by microscopy will be undertaken by the participating laboratories
- Analysis of the results including statistical evaluation

Second stage analysis

- Procedures adopted by different participants will be repeated by a smaller group of participants to determine the effect of test parameters on the repeatability and reproducibility of the measurement.

Participation and Funding

Participants fund their own involvement in the project.

Deliverables and Dissemination

International round-robin tests, good practice guidelines, peer-review publications and presentations as KT components of existing projects.

Status

In progress since Feb 2017.

For more information on participation, please contact:

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