Coordination of data systems in SEURAT-1 and alternative testing regulatory frameworks to provide smooth and efficient translation of research developments to qualified toxicity assays

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Introduction

The SEURAT-1 cluster is intended to operate with a dedicated central data-warehouse called ToxBank. It is vital that this consortium coordinates with the pre-existing and developing data-systems operating as part of the SEURAT-1 project in addition ToxBank is expected to establish a role beyond the lifetime of SEURAT-1 whereby its operation inter-digitates with, and supports, established regulatory and industrial organisations. This will be essential to support the effective and efficient development of stem cell-based tox assays for the future. Here we describe a forward view on how the data systems in SEURAT-1 are intended to become coordinated with clear and complementary roles. In particular ToxBank’s remit is to gather developing research data and protocols to enable regulators and industry to identify strong candidates for development of assays that can be taken up for formal comparative studies, qualification and approval developed. As the SEURAT-1 project concludes, Toxbank will establish a platform to provide training and support for academics with interests in development of assays for the replacement of animals, provide one source of information on access to qualified biomaterials and provide new coordinated information and data sets, to inform regulators and industry.

Overview

A ToxBank-based process, which includes data collation opportunities for development of protocols and biomaterials, will enable researchers to progress their research protocols towards regulatory compliance through provision of data, best practice, standardisation and training. A process involving Toxbank working with the JRCs could help to make the process of translational research and development to industrial application, smoother and more efficient.

The Challenge

A key issue is making procedures and materials fit-for-purpose. There is a difference between R&D and regulatory requirements. A vital element is not just making early data and protocols available from a central resource in SEURAT-1 i.e. Toxbank, but requires the data to be managed and processed in a way that adds value for users and enables them to begin the journey from candidate research protocol to industry qualified SOPs with appropriate controls, standards and acceptability from regulatory bodies.

Academic Protocols to Industrial and Regulatory Best Practice

Establishing the resource, coordination of key bodies on pathway to qualified methods and ongoing service provision

Acknowledgements

Coordination between Toxbank and eNanoMapper will apply OpenTox/ToxBank in a nanotech cluster, thus filling a current unmet need in SEURAT-1. ToxBank will be able to cover the early stage R&D and protocol evolution to a validation/regulatory candidate, such as JRC. Toxbank will also be in a good position to transfer to our commercial service in a complementary service alongside resources such as the JRCs.

We would like to thank the members of the SEURAT-1 cluster for their help and input in helping us to establish, populate and update the content of the database. We would also like to thank the European Commission and Cosmetics Europe for providing financial support for the project.

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