Foreword

A guidance document on Good *In Vitro* Method Practices (GIVIMP) for the development and implementation of *in vitro* methods for regulatory use in human safety assessment was identified as a high priority requirement by the OECD. The aim of this guidance document is to reduce the uncertainties in cell and tissue-based *in vitro* method derived predictions by applying all necessary good scientific, technical and quality practices from *in vitro* method development to *in vitro* method implementation for regulatory use. This guidance document also applies to *in vitro* methods already accepted by the OECD.

Development of GIVIMP began in 2013 when the OECD Working Group on Good Laboratory Practice (WG GLP) and the Working Group of the National Coordinators of the Test Guidelines Programme (WNT) agreed that there was merit in having guidance for OECD countries on these important issues. The draft guidance was coordinated by the validation body European Union Reference Laboratory for Alternatives to Animal Testing (EURL ECVAM) and was accepted on the work plan of the OECD test guideline programme in April 2015 as a joint activity between the WG GLP and the WNT.

The guidance is targeted primarily at users that implement *in vitro* methods, but also provides guidance for *in vitro* method developers. The document satisfies the following objectives;

1. A detailed update on good practices for state-of-the-art *in vitro* methods applied to regulatory human safety assessment of a variety of compounds.
2. Guidance to users and implementers of *in vitro* methods to help to ensure that Standard Operating Procedures (SOPs) of such methods are well-designed, robust, well-defined and described and can be carried out in a GLP environment, which is essential for use in a regulatory context.
3. Description of the key aspects that may impact the reliability and relevance of the *in vitro* data for quantitative human safety assessment purposes.
4. Description of the importance of reporting criteria, applying good experimental design, establishing acceptance criteria, and performance standards based on scientific evidence from the generated *in vitro* datasets.

The development and revision of GIVIMP has occurred with input from a large group of experts, including experts from both the WG GLP and the WNT. Additionally, an OECD GIVIMP expert group (established specifically for GIVIMP) provided input through teleconferences, a face-to-face meeting and two rounds of written comments.

In January 2017 the first round of comments of the OECD WG GLP and nominated experts of the OECD WNT were forwarded to EURL ECVAM who incorporated these comments, where applicable, and prepared an updated version. The OECD GIVIMP expert group addressed specific outstanding issues on the 23 and 24 March 2017 (Annex D OECD GIVIMP meeting 23-24 March, 2017) and agreed on content, structure, and wording of the GIVIMP so as to provide the OECD with an updated version ready to

enter the second OECD commenting round. After this round, during summer 2017, EURL ECVAM prepared the final GIVIMP version, which was submitted to OECD for adoption.