



US Food and Drug Administration

**EMA-EU MSs-FDA initiative on inspections for Generic Applications
Terms of engagements and procedures for participating authorities**

Pilot phase (18 months): Start date 02 January 2014

1. Background

The Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in light of the successful implementation of the initiative on GCP inspections which started in 2009, discussed the possibility to expand the scope of such initiative to include inspections for generic marketing applications. Since in EU, an important number of the generic marketing authorizations are obtained through the Mutual Recognition/Decentralized/National procedures, the involvement of the EU Member States is considered essential for the success of this expansion.

Taking on board these considerations, the EMA, interested EU Member States (EU MSs) including France, Germany (BfArM), Italy, The Netherlands, and United Kingdom, and the US FDA have agreed to launch a parallel initiative in the area of inspections of facilities involved in the conduct of bioequivalence studies submitted in generic marketing applications submitted to the FDA and EMA and/or EU MSs. This initiative will be carried out in the framework of the confidentiality arrangements established between the European Commission, the EMA, interested EU Members States and the US FDA and will be run separately from the main initiative, although handled in a similar way. It will also commence with an 18-month pilot phase.

This document sets out these terms of engagement specific for this EMA-EU MSs-FDA initiative on inspections of bioequivalence studies submitted in generic marketing applications. The principles and procedures of the "Terms of engagement" of the main EMA-FDA GCP initiative still apply but in the context of bioequivalence studies and whenever they are in line with the objectives described in this document.

2. Objectives

This initiative should be focused on the following objectives:

- 2.1 Conduct periodic information exchanges on inspections.
 - a. Streamline information sharing on inspections of bioequivalence studies conducted and planned for generic drug applications (clinical facilities, analytical facilities or both).
 - b. Communicate effectively and in a timely manner on negative inspection outcomes that reveal system problems of the facilities involved in the conduct of those trials and with potential impact on the acceptability/reliability of the data obtained from other studies conducted in the same facility.
- 2.2 Conduct joint inspections involving not only sites within EU and/or US but other sites all over the world. It should be noted that since the reference product is not expected to be the same in US and EU, the trials to be inspected for these particular joint inspections will be different as well.
- 2.3 Conduct observed inspections, when possible, as described in the "Terms of engagement" of the EMA-FDA GCP initiative. When an observed inspection is conducted and the inspection itself reveals critical findings, the inspection can switch from observed to joint and the observer should have the opportunity to act as an inspector.
- 2.4 Provide training opportunities to improve bioequivalence inspections.

3. Next Steps

- 3.1 A pilot phase will commence on 02 January 2014.
- 3.2 EMA and FDA will monitor the progress of the pilot phase and a joint assessment will be made to report on its outcome.
- 3.3 According to the outcome of the pilot phase, the process may need to be amended and the scope of the terms of engagement modified as needed.