European Medicines Agency
Press office

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PRESS RELEASE
European Medicines Agency and U.S. Food and Drug Administration (FDA) launch Good Clinical Practice Initiative

The European Medicines Agency and the FDA have agreed to launch a joint initiative to collaborate on international Good Clinical Practice (GCP) inspection activities. This initiative comes under the scope of the confidentiality arrangements between the European Commission, the European Medicines Agency and the US FDA. The objectives of the initiative include the sharing of information on inspection planning, policy and outcomes and the conduct of collaborative inspections.

This initiative is an important contribution to ensuring the protection of clinical-trial subjects in the context of the increasing globalisation of clinical research. The European Medicines Agency and the FDA will start their new initiative with an 18-month pilot phase on 1 September 2009.

Announcing this pilot Thomas Lönngren, the European Medicines Agency's Executive Director said: "This important initiative demonstrates the increasing collaboration between the European Medicines Agency and the FDA. It marks an important step to the building of a global regulatory network for supervision of clinical trials. By working together in a collaborative and synergistic manner GCP inspection resources can be used more efficiently."

Key objectives of the FDA-European Medicines Agency GCP initiative will be:

- To conduct periodic information exchanges on GCP-related information in order to streamline sharing of GCP inspection planning information, and to communicate timely and effectively on inspection outcomes.
- To conduct collaborative GCP inspections by sharing information, experience and inspection procedures, cooperating in the conduct of inspections, and sharing best-practice knowledge.
- To share information on interpretation of GCP, by keeping each regulatory agency informed of GCP-related legislation, regulatory guidance and related documents, and to identify and act together to benefit the clinical research process.

Applicants interested in volunteering to participate in a collaborative inspection during the pilot phase can contact the European Medicines Agency or the FDA. Contact point for the European Medicines Agency is Dr Ana Rodriguez, Inspections Sector, at GCP@emea.europa.eu.

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Notes:

1. More detailed information about the EMEA-FDA GCP Initiative can be found here.
2. The confidentiality arrangements allow the European Commission/European Medicines Agency and the FDA to exchange information as part of their regulatory processes. The types of information covered by the arrangements include legal and regulatory issues, scientific advice, orphan-drug designation, inspection reports, marketing-authorisation procedures and post-marketing surveillance. They cover medicinal products that are subject to evaluation or are authorised under the centralised procedure. In addition, they cover medicines authorised at national level by the EU Member States that are subject to EU arbitration and referral procedures.
3. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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