EMA and US FDA seek potential candidate companies for joint GMP inspection programme

August 11, 2010 - The European Medicines Agency (EMA) and the Food and Drug Administration of the United States of America (US FDA) continue to seek potential candidate companies for a joint GMP inspection pilot programme for manufacturers of medicinal products. Companies that have submitted in parallel two equivalent marketing authorisation applications for the same medicinal product to both the EMA and the US FDA can request to participate in the pilot programme for joint pre-approval inspection should such an inspection be considered necessary by both agencies.

The overall objective is to see whether greater international collaboration can help to distribute inspection capacity allowing more manufacturing sites to be monitored and reducing unnecessary duplication.

Companies can also participate in the pilot exercise by hosting a single join re-inspection (routine surveillance) where both the EMA and the US FDA have separately planned routine surveillance inspections (re-inspections) to take place within a similar time period at a manufacturing site of a medicinal product authorised in the USA and centrally authorised in the European Union.

Companies that wish to participate should contact either gmp@ema.europa.eu and/or CDERInternationalGMP@fda.hhs.gov.

For more information see the 'General Principles' document and the 'Terms of reference and procedures for participating authorities' document.