27 September 2010
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EMA / FDA joint GMP inspection pilot programme. General principles

1. Purpose

The purpose of this document is to provide advice to applicants and describe the policies and procedures to be used by the European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) on the coordination and performance of joint EMA/FDA GMP inspections.

2. Definition

"Applicant" refers to: (a) the "applicant" that submits drug applications (NDA/ANDA) in the United States of America coming under the authority of FDA's Center for Drug Evaluation and Research (CDER) or (b) a potential marketing authorisation applicant (MAA) under the centralised marketing authorisation process in the European Union.

3. Background

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

The majority of national regulatory authorities are obliged by law to have systems in place to verify the GMP status of medicinal product (finished drug product) manufacturers whose products are marketed in their territory. Most "developed" regulatory authorities ensure that these manufacturers in their territory are subject to routine GMP inspections. However, different approaches are taken to supervision of the manufacture of medicinal products outside a national territory. The international industry associations have raised the issue of international duplication of inspection and the potential for more efficient use of resources on a number of occasions.

The objective of the paper is to outline a proposal for joint inspections between FDA and EU National Regulatory Authorities. The basic idea is that companies planning comparable submissions to both Agencies which are expected to trigger a pre-authorisation/pre-approval inspection, or those simply seeking to lessen the burden of 2 individual post-authorization/post-approval inspections may contact the FDA and/or EMA to express interest in a joint inspection. Based on the information received and the common areas of interest, both authorities may agree to organise a joint inspection in accordance with the principles and procedure outlined below.

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The expected advantages from such interactions are:

- Increased dialogue between the two agencies and the applicants from the beginning of the evaluation of a new product,
- A deeper understanding of the approaches to GMP inspections by either agency,
- Extending mutual confidence,
- Enhanced understanding of GMP interpretations made by the respective agencies, and
- The opportunity to optimize resources and avoid unnecessary duplication of inspections.

4. Policy

Joint inspections are voluntary and usually occur at the request of the applicant. A joint inspection may also be initiated by either the EMA or FDA. The scope of this pilot covers pre-authorisation/pre-approval inspections and post-authorization/post-approval of finished drug products.

4.1. Both agencies remain committed to meeting domestic process and review goals and timeframes. The joint inspection should not adversely affect either agency's ability to meet its formal domestic performance expectations. Both agencies commit to be cognizant of the other's formal domestic performance expectations and to exhibit as much flexibility as possible in scheduling meetings and accommodating the different timeframes for the inspection.

4.2. Both EMA and FDA will make these "General Principles" public on the websites of both agencies in order to make the pilot programme procedures and goals more transparent and to help answer many questions about the pilot that my exist in the general public.

4.3. Requests for participation in the pilot should be sent by the requesting applicant through designated central points of contact at EMA and FDA so that the evaluation of the request can be efficiently performed by both agencies and any required documentation provided.

4.4. Applicants that wish to nominate a manufacturer for joint inspection should address one single "Request for joint inspection" letter to both the EMA contact person and FDA contact person. In this letter, the applicant should provide details of the product, manufacturing site, drug application number(s), submission date(s), manufacturing process, inspection history of the manufacturer and all other information considered relevant. In addition, the applicant should explicitly authorise in the request permission for the comprehensive exchange between the two agencies of all information relevant to the subject, specifically including trade secret information (as defined by US statute).

4.5. Both agencies will maintain the confidentiality of all such information.

4.6. A request for a joint inspection is no guarantee that a joint inspection will be performed. For a variety of reasons, including scheduling conflicts and available resources at any specific time, one or both of the agencies may decline to participate.

4.7. If an applicant's request for a joint inspection under this pilot is not granted, this will in no way affect the processing of any submission which will proceed with each agency individually, following each agency's normal procedures.

4.8. If both agencies agree to conduct a joint inspection, the applicant should receive an electronic mail message acknowledging such agreement. The message should state the primary contact person at each agency for the specific inspection.

4.9. Each agency will follow the principles described in the "Terms of reference and procedures for participating authorities".

4.10. The agencies will assure that records are maintained to facilitate an assessment of the benefits and detriments of this pilot.

5. References

Terms of Reference and procedures for participating authorities (EMA/INS/GMP/770330/2009)

Appendices

EMA/FDA joint GMP inspection pilot programme

Request for joint inspection.
Manufacturing sites based in an EEA member state or in the USA.

Please fill in the questionnaire and send it to :

Point of contact for EMA for joint inspections: GMP@ema.europa.eu
Point of contact for FDA for joint inspections: CDERInternationalGMP@fda.hhs.gov

Subject: EMA/FDA inspection pilot

Name of the site:

Address:

Post Code:

City:

Country:

Name of the product (s) subject to the inspection:

EMA product number (s): EMA / / C / 00

FDA product registration number:

Date of submission in EU:

Date of submission in USA:

Inspection history of the site:

Manufacturing processes carried out on the site:

Name of the contact person for the inspection:

E-mail address of the contact:

I ……authorise the comprehensive exchange between the two agencies of all information relevant to the subject, specifically including trade secret information (as defined by US statute).

Name, position in the site, date and signature.