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Enhancing GMP inspection cooperation between the EMA and FDA

Moving from confidence-building to reliance upon

1. Background

Many demands are placed on the resources of the EEA and FDA GMP inspectorates. With the globalisation of the manufacture of medicines, it is increasingly evident that sharing of resources by authorities is necessary and in the best interest of public health.

FDA and the European Regulatory Network, recognising the need for cooperation on inspections, have explored options to increase information sharing and ultimately rely upon that information to meet inspectional obligations. These include confidentiality arrangements and participation in joint inspection and information-sharing projects.

Authorities from both regions have recognised the potential resource efficiencies to be gained from progression beyond existing collaborative projects towards reliance on each others inspection outcomes. It has been noted that a large number of inspections are being carried out by FDA in EU and vice versa, and that in the face of the globalisation of manufacture and shift of manufacturing base away from Europe and USA, a change may be justified. Since EMA is responsible for requesting many EEA inspections in USA, it has been asked to take a lead on the EU side in exploring how this change could come about.

Both sides see this progression as an important next step, and FDA believes that using EMA as a central contact point in relation to GMP inspections for both centrally and nationally authorised products is critical.

Finally, such a change would not only enable better use of inspection resources, but also provide some relief to manufacturers, who direct substantial resources to host inspections.

2. Proposed strategy

A strategy has been developed that will allow some inspections on each others' territories to be deferred or waived completely based on a number of considerations. The strategy is applicable to GMP inspections related to manufacturing sites located in USA and EEA involving products for both human and veterinary use.

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The general approach will utilise information exchange for sites. It will primarily focus on sites which are already known to each authority and already have a history of satisfactory GMP compliance following previous inspections by EEA authorities in the case of sites in USA and by FDA in the case of sites in EEA.

The most likely impact will consequently be in the area of routine post-authorisation/surveillance inspections. Pre-authorisation/pre-approval inspections will continue largely unchanged, as by definition the sites are unknown or a specific inspection trigger has been identified. Exceptions nevertheless may be made on a case-by-case basis.

The following considerations will be taken into account:

- As mentioned above, the inspection history of the site.
- The nature of the product.
- Quality defects associated with the site.
- Variations or significant changes since the last inspection.
- Outstanding inspection follow up.
- Whether there is an urgent public health need to expedite regulatory decision-making e.g., product shortage.

Waiving inspections connected to the centrally authorised products will be proposed by EMA but the final decision will rest with the Supervisory Authority.

3. Next steps

EMA plans to start this initiative for inspections planned for adoption by CHMP/CVMP from January 2012.

FDA also plans to start to implement this initiative in January 2012.

Member States have been encouraged to develop similar approaches for inspections to be performed in USA that are not directly coordinated by EMA. In some cases, this will require the establishment of bilateral confidentiality arrangements with FDA.

The EMA/FDA joint inspection pilot project for dosage forms will continue as it remains important to maintain mutual confidence and build further mutual understanding of GMP inspection approaches.

Both parties will keep track of the number of inspections deferred or waived, and any other information that both parties agree upon. After a period of 3 years, the approach should be reviewed and further extension considered.