

## **New FDA and EMA Initiative Allows Mutual Recognition of Inspections**

The latest step in the increased collaboration between European authorities (represented by the European Medicines Agency - EMA) and the FDA is about to pave the way for a new relationship leading to a better use of inspection resources and some relief to EU and US manufacturers.

The new initiative, starting in January 2012, should enable the authorities in the European Economic Area (EEA) and the US to rely on the results of inspections performed in each other's territories. This should allow at least some inspections to be deferred or waived completely.

As defined in EMA's press release, the goals are to:

- "Enable better use of the two authorities' inspection resources"
- "Reduce the burden of inspections for medicines manufacturers"
- "Shift the authorities' inspection capacity to other regions"

However, and, of course, a few considerations need to be taken into account:

- Mainly post-authorisation/surveillance inspections will be considered
- The manufacturing sites are already known to the respective authorities
- The sites have an inspection history showing good GMP-compliance
- Sites in the US have already been inspected by an EEA inspectorate with satisfactory outcome and vice versa
- The nature of the product (and its assorted risk)
- No quality defects are associated with the site
- Variations or significant changes since the last inspection
- Any outstanding inspection follow-up

After three years, this new initiative and the results will be reviewed.