EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency and U.S. Food and Drug Administration announce pilot program for parallel assessment of Quality by Design applications

Pilot to start as of 1 April 2011

The European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) are launching a three-year pilot program that will allow parallel evaluation of relevant quality data components, known as Quality by Design (QbD), of selected applications that are submitted to both agencies at the same time. The pilot will be starting on 1 April 2011.

QbD in pharmaceuticals involves an enhanced systematic and science-based approach to development and manufacturing, to better ensure product quality. Several guidelines and question-and-answer documents have been developed by the International Conference on Harmonisation (ICH) in order to facilitate the implementation of QbD. Taking into account the global perspective of pharmaceutical manufacturing, and to facilitate the harmonised implementation of the ICH concepts, the EMA and FDA agreed that experts from both agencies should exchange their views using real applications.

Under this program, both agencies will assess the parts of the applications relevant to QbD, such as development, design space and real-time release testing. The evaluation will be performed separately by each agency, with regular communication and consultation throughout the review, with the aim of having a common list of questions to the applicants and a harmonised evaluation of their responses.

In Europe this pilot applies to new marketing authorisation applications and quality-related scientific advice requests. Type II variations may be included on a case-by-case basis. In the US the programme will cover new drug marketing applications (NDA), prior-approval supplements (sNDA) and chemistry manufacturing control meeting requests. The pilot program will only include chemical entities. However, ongoing consideration will be given to other areas of collaboration.

Participation in the pilot is voluntary, and interested applicants/sponsors are asked to notify both agencies three months prior to submission of an application. The notification should include a brief description of the QbD elements in the application and expected submission dates. This pilot will conclude on 31 March 2014. Both agencies will jointly assess and publish the outcome of this pilot programme.

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Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More detailed information about the objectives of the pilot program, the criteria that will be used to select candidate products, and the procedure that will be followed can be found in the background document 'EMA-FDA pilot program for parallel assessment of quality by design applications medicines', available on the Agency's website.
3. The pilot program will operate under the EU-US confidentiality arrangements and within the framework of the EU-US Bilateral Technical Working Group on Medicines Quality and Manufacturing.
4. More information on the interaction between the EMA and FDA is available on the Agency's website.
5. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) quality guidelines are available on the Agency's website.
6. More information on ICH can be found on its website: http://www.ich.org/home.html
7. More information on the work of the U.S. Food and Drug Administration (FDA) can be found on the FDA website at: http://www.fda.gov/
8. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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