

Certification of Substances Division

Title:	Programme to rationalise international GMP inspections of active pharmaceutical ingredients/active substances manufacturers - Terms of reference
Reference Document:	PA/PH/CEP (12) 30

The EDQM has been involved in the international API Inspection Pilot Programme since its inception by the EMA at the end of 2007.

This programme, which now has become routine since 2011, involves inspection authorities from the US, Australia and Europe, as well as the EDQM, and is aimed at optimising inspection resources through the exchange of information and the performance of joint inspections. The terms of reference have been published by the participating organisations and are available here http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/02/news_detail_001456.jsp&mid=WC0b01ac058004d5c1&jsenabled=true