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Compliance and Inspection

## Enhancing Quality Assurance of API Manufacture

Regulators from Europe, North America and Australia gathered in Washington DC late last year to discuss strategies to enhance assurance of the quality of active pharmaceutical ingredient (API) manufacture and distribution.

Whilst regulatory standards for the manufacture of active ingredients have been harmonised through the adoption of *ICH Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients* (Q7), certain differences exist in pre-licensing approaches, inspections, and expectations of finished dose form manufacturers that will benefit from further exchange by the regulators. However, the approaches are largely the same, and in particular regulators acknowledge the primary responsibility of finished dose form manufacturers to qualify and audit their API suppliers to assure reliable manufacturing practices and integrity of their supply chains.

Given that much of the world's active ingredients are made in countries with less developed regulatory requirements, regulators agreed there was a need to increase cooperation and information sharing between agencies, and to incorporate capacity building measures in countries that are seeking to develop their regulatory systems for APIs. This would include encouraging more involvement by national regulatory authorities during overseas inspections.

Regulators also agreed to provide updated and comprehensive training on GMP standards for APIs. This training will focus on the interpretation and understanding of the ICH Q7 guideline that is the accepted international API GMP standard, and the training will be open for other national regulatory agencies to participate. The regulators will also collaborate on updating and publishing new Q&As that enhance understanding of GMP interpretations relating to API manufacture.

The EMA, FDA and TGA held a teleconference in February in order to follow up on these and other detailed actions arising from the Washington meeting and have agreed to hold regular teleconferences to maintain progress on those actions.