EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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# ICH guideline Q10 on pharmaceutical quality system

Step 5

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| Transmission to CHMP | May 2007 |
| Transmission to interested parties | May 2007 |
| Deadline for comments | November 2007 |
| Final adoption by CHMP | June 2008 |
| Date for coming into effect | June 2008 |

**Scope:**

This guideline applies to the systems supporting the development and manufacture of pharmaceutical drug substances (i.e. API) and drug products, including biotechnology and biological products, throughout the product lifecycle.

The elements of ICH Q10 should be applied in a manner that is appropriate and proportionate to each of the product lifecycle stages, recognising the differences among, and the different goals of each stage (see section 3).

For the purposes of this guideline, the product lifecycle includes the following technical activities for new and existing products:

- Pharmaceutical development
  - Drug substance development;
  - Formulation development (including container/closure system);
  - Manufacture of investigational products;
  - Delivery system development (where relevant);
  - Manufacturing process development and scale-up;
  - Analytical method development.

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- Technology transfer
  - New product transfers during development through manufacturing;
  - Transfers within or between manufacturing and testing sites for marketed products.
- Commercial manufacturing
  - Acquisition and control of materials;
  - Provision of facilities, utilities, and equipment;
  - Production (including packaging and labelling);
  - Quality control and assurance;
  - Release;
  - Storage;
  - Distribution (excluding wholesaler activities).
- Product discontinuation
- Retention of documentation;
- Sample retention;
- Continued product assessment and reporting.

Link to: Quality guidelines

Link to: ICH Q8/Q9/Q10 Training material

Link to: ICH Q8/Q9/Q10 Points to consider