ICH Public Meeting Quality Topics

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International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

Overview

- Pharmaceutical Development: Q8 + Q8R
- Quality Risk Management: Q9
- Pharmaceutical Quality System: Q10
- Implementation Q8, 9, 10
- Development and manufacturing of active substances (chemical and biological): Q11
- Pharmacopoeial Harmonisation
  - PDG process
  - Q4B

Introduction: ICH Reminder

- Objective of ICH:

  Technical and scientific harmonisation between Japan, Europe and USA.
- New active substances; However difficult not to apply these principles for known active substances (EU)
- ICH Quality topics so far
  - Scientific/technical guidelines, mostly:

    stability, method validation, impurities, specification, Q5 series (biologicals)
  - System oriented: GMP for APIs
  - Structure: Common Technical Document

Introduction: Quality A New Paradigm

" Develop a harmonised pharmaceutical ***quality system*** applicable across the ***lifecycle*** of the product emphasizing an integrated approach to quality ***risk management*** and ***science***."

Bruxelles July 2003

Q8: Pharmaceutical Development (step 5)

Q8 (R): Pharmaceutical Development Revision (November 08, step 4)

Q9: Quality Risk Management (step 5)

Q10: Pharmaceutical Quality System (June 08, step 4)

Q11: Development and Manufacture of Drug Substances (chemical/biological entities)

New Paradigm

- Main message:

  Science is no more isolated but is living across the lifecycle of the product/process within a Quality Management System

Definition of Product Lifecycle (Q10)

Development	Technology Transfer	Manufacturing	Product Discontinuation
- Drug substance development - Novel excipient development - Formulation development (including container/ closure system) - Delivery system development (where relevant) - Manufacturing process development and scale-up - Analytical method development	- New product transfers from Development to Manufacturing - Transfers within or between manufacturing and testing sites for marketed products	- Procurement of materials - Provision of facilities, utilities and equipment - Production (including packaging and labelling) - Quality control and assurance - Release - Storage - Distribution (excluding wholesaler activities)	- Retention of documentation - Sample retention - Continued product assessment and reporting

Conclusion

- The new Paradigm to Quality is based on a sound combination of science (enhanced scientific knowledge), use of risk management tools and the establishment of an efficient Quality System.
- An integration of these three elements should enhance the process for ensuring quality and facilitate continual improvement,