

# ICH Q10 Pharmaceutical Quality System - Access & Summary

## **Official Access Issue Note:**

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## **Reliable Access Path:**

Go to: <https://www.ich.org/page/quality-guidelines>

Then select ICH Q10 → Download PDF from official page.

## **Deviation & Change Management (ICH Q10 Core Concept):**

1. Deviations are handled under the CAPA system (Corrective and Preventive Actions).
2. Root cause analysis is required for each deviation.
3. Change Control ensures any modification is assessed before implementation.
4. All deviations and changes must be trended in Management Review.

## **System Flow:**

Deviation → Investigation → CAPA → Change Control (if needed) → Effectiveness Check → Trending

## **Key Inspection Focus:**

- Data integrity of deviation records
- Timeliness of CAPA closure
- Effectiveness of change implementation
- Evidence of trend analysis