QUALITY EXCELLENCE SERVICES

Quality Excellence Services
18 Maple Avenue, Ste. 148
Barrington, RI 02806
United States of America
+1 (401) 246-3204 · +1 (401) 252-9653
mweeden@qesisbest.com · https://QESisBest.com

STANDARDS & GUIDANCE BRIEF · INTERNATIONAL · ICH GUIDELINE

ICH Q7

Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients

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ISSUED BY	International Council for Harmonisation	PREPARED BY	Conner Davidson
EDITION	Step 4, November 2000, with a Q&A document (2015); adopted by FDA as guidance and as EU GMP Part II	STATUS CHECKED	October 24, 2026
INDUSTRIES	Pharmaceutical	ONLINE	qesisbest.com/standard-ich-q7.html

CURRENT EDITION Adopted as FDA guidance and as Part II of the EU GMP guide.

What It Covers

GMP for the manufacture of active pharmaceutical ingredients, from the point at which starting materials enter the process to release of the API.

Who It Applies To

API manufacturers, and finished-dose manufacturers who must qualify and audit them.

Key Requirements

- A quality unit independent of production, with defined responsibilities.
- Process validation, cleaning validation, and change control appropriate to the stage of the process.
- Impurity profiles, stability, and retest dates for the API.
- Agents, brokers, traders, distributors, and relabelers held to the same traceability.

What an Auditor Asks to See

- Supplier qualification for API sources, including audits.
- Impurity profile and change notifications from the API maker.

Where Systems Fall Short

- API suppliers qualified on paper, never audited.
- Changes at the API maker not notified, or not assessed when they were.

How QES helps. Supplier audits and quality agreements that make API changes visible before they reach the batch record. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. ICH — Quality guidelines — www.ich.org/page/quality-guidelines; European Commission — EudraLex Volume 4, EU GMP guidelines — health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en.

A summary for orientation, prepared by Quality Excellence Services. It does not reproduce or replace the standard or regulation: read the official text, which governs. Not legal advice.