

---

# Guidance for Industry

## Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
August 2001  
ICH

# Guidance for Industry

## Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients

*Additional copies are available from:*

*Office of Training and Communications  
Division of Communications Management  
Drug Information Branch, HFD-210  
5600 Fishers Lane  
Rockville, MD 20857  
(Tel) 301-827-4573*

*(Internet) <http://www.fda.gov/cder/guidance/index.htm>*

*or*

*Office of Communication, Training and  
Manufacturers Assistance, HFM-40  
Center for Biologics Evaluation and Research  
Food and Drug Administration  
1401 Rockville Pike, Rockville, MD 20852-1448  
Internet: <http://www.fda.gov/cber/guidelines.htm>.  
Fax: 1-888-CBERFAX or 301-827-3844*

*Mail: the Voice Information System at 800-835-4709 or 301-827-1800*

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)  
August 2001  
ICH**

## Table Of Contents

<b>I. INTRODUCTION (1)</b> .....	<b>1</b>
<b>A. Objective (1.1)</b> .....	<b>1</b>
<b>B. Regulatory Applicability (1.2)</b> .....	<b>2</b>
<b>C. Scope (1.3)</b> .....	<b>2</b>
<b>II. QUALITY MANAGEMENT (2)</b> .....	<b>5</b>
<b>A. Principles (2.1)</b> .....	<b>5</b>
<b>B. Responsibilities of the Quality Unit(s) (2.2)</b> .....	<b>5</b>
<b>C. Responsibility for Production Activities (2.3)</b> .....	<b>6</b>
<b>D. Internal Audits (Self Inspection) (2.4)</b> .....	<b>7</b>
<b>E. Product Quality Review (2.5)</b> .....	<b>7</b>
<b>III. PERSONNEL (3)</b> .....	<b>8</b>
<b>A. Personnel Qualifications (3.1)</b> .....	<b>8</b>
<b>B. Personnel Hygiene (3.2)</b> .....	<b>8</b>
<b>C. Consultants (3.3)</b> .....	<b>9</b>
<b>IV. BUILDINGS AND FACILITIES (4)</b> .....	<b>9</b>
<b>A. Design and Construction (4.1)</b> .....	<b>9</b>
<b>B. Utilities (4.2)</b> .....	<b>10</b>
<b>C. Water (4.3)</b> .....	<b>10</b>
<b>D. Containment (4.4)</b> .....	<b>11</b>
<b>E. Lighting (4.5)</b> .....	<b>11</b>
<b>F. Sewage and Refuse (4.6)</b> .....	<b>11</b>
<b>G. Sanitation and Maintenance (4.7)</b> .....	<b>11</b>
<b>V. PROCESS EQUIPMENT (5)</b> .....	<b>12</b>
<b>A. Design and Construction (5.1)</b> .....	<b>12</b>
<b>B. Equipment Maintenance and Cleaning (5.2)</b> .....	<b>12</b>
<b>C. Calibration (5.3)</b> .....	<b>13</b>
<b>D. Computerized Systems (5.4)</b> .....	<b>14</b>
<b>VI. DOCUMENTATION AND RECORDS (6)</b> .....	<b>15</b>
<b>A. Documentation System and Specifications (6.1)</b> .....	<b>15</b>
<b>B. Equipment Cleaning and Use Record (6.2)</b> .....	<b>15</b>
<b>C. Records of Raw Materials, Intermediates, API Labeling and Packaging Materials (6.3)</b> .....	<b>16</b>

D.	Master Production Instructions (Master Production and Control Records) (6.4)	16
E.	Batch Production Records (Batch Production and Control Records) (6.5)	17
F.	Laboratory Control Records (6.6)	18
G.	Batch Production Record Review (6.7)	19
<b>VII.</b>	<b>MATERIALS MANAGEMENT (7)</b>	<b>19</b>
A.	General Controls (7.1)	19
B.	Receipt and Quarantine (7.2)	19
C.	Sampling and Testing of Incoming Production Materials (7.3)	20
D.	Storage (7.4)	21
E.	Re-evaluation (7.5)	21
<b>VIII.</b>	<b>PRODUCTION AND IN-PROCESS CONTROLS (8)</b>	<b>21</b>
A.	Production Operations (8.1)	21
B.	Time Limits (8.2)	22
C.	In-process Sampling and Controls (8.3)	22
D.	Blending Batches of Intermediates or APIs (8.4)	23
E.	Contamination Control (8.5)	24
<b>IX.</b>	<b>PACKAGING AND IDENTIFICATION LABELING OF APIs AND INTERMEDIATES (9)</b>	<b>24</b>
A.	General (9.1)	24
B.	Packaging Materials (9.2)	25
C.	Label Issuance and Control (9.3)	25
D.	Packaging and Labeling Operations (9.4)	26
<b>X.</b>	<b>STORAGE AND DISTRIBUTION (10)</b>	<b>26</b>
A.	Warehousing Procedures (10.1)	26
B.	Distribution Procedures (10.2)	27
<b>XI.</b>	<b>LABORATORY CONTROLS (11)</b>	<b>27</b>
A.	General Controls (11.1)	27
B.	Testing of Intermediates and APIs (11.2)	28
C.	Validation of Analytical Procedures - See Section 12. (11.3)	29
D.	Certificates of Analysis (11.4)	29
E.	Stability Monitoring of APIs (11.5)	29
F.	Expiry and Retest Dating (11.6)	30
G.	Reserve/Retention Samples (11.7)	30

<b>XII. VALIDATION (12)</b> .....	<b>31</b>
A. Validation Policy (12.1) .....	31
B. Validation Documentation (12.2).....	31
C. Qualification (12.3) .....	32
D. Approaches to Process Validation (12.4) .....	32
E. Process Validation Program (12.5).....	33
F. Periodic Review of Validated Systems (12.6) .....	33
G. Cleaning Validation (12.7).....	34
H. Validation of Analytical Methods (12.8) .....	35
<b>XIII. CHANGE CONTROL (13)</b> .....	<b>35</b>
<b>XIV. REJECTION AND RE-USE OF MATERIALS (14)</b> .....	<b>36</b>
A. Rejection (14.1).....	36
B. Reprocessing (14.2) .....	36
C. Reworking (14.3) .....	36
D. Recovery of Materials and Solvents (14.4) .....	37
E. Returns (14.5) .....	37
<b>XV. COMPLAINTS AND RECALLS (15)</b> .....	<b>37</b>
<b>XVI. CONTRACT MANUFACTURERS (INCLUDING LABORATORIES) (16)</b> .....	<b>38</b>
<b>XVII. AGENTS, BROKERS, TRADERS, DISTRIBUTORS, REPACKERS, AND RELABELLERS (17)</b> .....	<b>39</b>
A. Applicability (17.1).....	39
B. Traceability of Distributed APIs and Intermediates (17.2) .....	39
C. Quality Management (17.3).....	39
D. Repackaging, Relabeling, and Holding of APIs and Intermediates (17.4) .....	39
E. Stability (17.5).....	40
F. Transfer of Information (17.6) .....	40
G. Handling of Complaints and Recalls (17.7) .....	40
H. Handling of Returns (17.8).....	41
<b>XVIII. SPECIFIC GUIDANCE FOR APIs MANUFACTURED BY CELL CULTURE/FERMENTATION (18)</b> .....	<b>41</b>
A. General (18.1) .....	41
B. Cell Bank Maintenance and Record Keeping (18.2).....	42
C. Cell Culture/Fermentation (18.3) .....	42

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.