



Quick NOTES

FDA cGMP Regulations Update

DECEMBER 2008

FDA cGMP Regulations Update



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WHO DOES THIS APPLY TO:

- Manufacturers, importers, and distributors of drug products.

KEY POINTS:

Current Good Manufacturing Practices (cGMP) Revisions

View the most recent version of the cGMPs at:
<http://www.gpoaccess.gov/cfr/index.html>

- CFR Title 21, Food and Drugs Parts 210 & 211 updates are effective December 8, 2008.
- The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the Federal Register by the U.S. Federal Government. Each volume of the CFR is updated once each calendar year and is issued on a quarterly basis. Parts 210 & 211 are updated each April.
- CFR Title 21, Food and Drugs Parts 210 & 211 contain the current Good Manufacturing Practices (cGMP) regulations that must be followed in the manufacture, processing, packing or holding of a drug product.
- There were no changes to the regulations in the April 2007 update. Drastic changes were expected in April 2008, but due to negative public response, many changes were held back. The amendments outlined here are current as per the Final Rule of September 8, 2008.

CFR 21 PART 210 CHANGES

- Section 210.2(c): This section is new. It describes the exemption of investigational drugs used in phase 1 studies from compliance with the regulations in part 211.
- Section 210.3(b)(6): The phrase "All filters composed of asbestos are deemed to be fiber-releasing filters" has been removed.

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CFR 21 PART 211 CHANGES

- Section 211.67 (a): The phrase “Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals...” has been re-phrased to “Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals...”
- Section 211.68(c): This section is new. It addresses automated equipment described in sections 211.101(c) or (d), 211.103, 211.182 or 211.188(b)(11).
- Section 211.72: The phrase “Fiber-releasing filters may not be used in the manufacture... unless it is not possible to manufacture such drug products without the use of such filters” has been re-phrased to “Fiber-releasing filters may be used when it is not possible to manufacture such products without the use of these filters”. The phrase “ ... an additional non-fiber-releasing filter of 0.22 micron maximum mean porosity...” has been re-phrased to “... an additional nonfiber-releasing filter having a maximum nominal pore size rating of 0.2 micron...” The use of an asbestos-containing filter is not prohibited.
- Section 211.82(b): The phrase “... test or examined, as appropriate...” has been re-phrased to “... test or examined, whichever is appropriate...”
- Section 211.84(c)(1): The phrase “... shall be cleaned where necessary, by appropriate means” has been re-phrased to “...shall be cleaned when necessary in a manner to prevent introduction of contaminants into the component”.
- Section 211.84(d)(3): The phrase “... with all appropriate written procedures” has been re-phrased to “... with all appropriate written specifications”.
- Section 211.84(d)(6): The phrase “... closure that is liable to microbiological contamination...” has been re-phrased to “...closure with potential for microbiological contamination...”
- Section 211.94(c): The phrase “Such depyrogenation processes shall be validated” has been added.
- Section 211.101(c)(3): The phrase “If the weighing, measuring, or subdividing operations are performed by automated equipment under §211.68, only one person is needed to assure paragraphs (c)(1), (c)(2), and (c)(3) of this section” has been added.
- Section 211.101(d): The phrase “... verified by a second person” has been extended to “verified by a second person or, if the components are added by automated equipment under §211.68, only verified by one person”.

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CFR 21 PART 211 CHANGES (continued)

- Section 211.103: The phrase “Such calculations shall be performed by one person and independently verified by a second person” has been extended to “Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under §211.68, be independently verified by one person”.
- Section 211.110(a)(6): This section is new. It is a new in-process control procedure.
- Section 211.113(b): The phrase “... validation of any sterilization process” has been extended to “... validation of all aseptic and sterilization processes”.
- Section 211.160(b)(1): The phrase “Determination of conformance to applicable written specifications...” has been re-phrased to “Determination of conformity to applicable written specifications...”
- Section 211.182: The phrase “... cleaning and maintenance shall date...” has been extended to “...cleaning and maintenance (or, if the cleaning and maintenance is performed using automated equipment under §211.68, just the person verifying the cleaning and maintenance done by the automated equipment) shall date...”
- Section 211.188(b)(11): This section has been extended to “Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under §211.68, the identification of the person checking the significant step performed by the automated equipment”.
- Section 211.194(a)(2): “Association of Official Analytical Chemists” has been changed to “AOAC INTERNATIONAL”.

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The newest regulations are available in booklet format.

Contact us to order booklets
or with any questions regarding cGMPs.

Call toll-free: 1-877-877-5152 ext. 210

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Date of last revision: 16 December 2009
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