



Subpart J – Records and Reports: Meeting FDA Requirements

This article provides a comprehensive review of all of the requirements listed below for maintaining compliance with GMP regulation Subpart J-Records and Reports. Auditing applications for each regulation is also provided.

- [FDA 211.180](#) General Requirements for Records and Reports
- [FDA 211.182](#) Equipment Cleaning and Use Log
- [FDA 211.184](#) Component, Drug Product Container, Closure, and Labeling Records
- [FDA 211.186](#) Master Production and Control Records
- [FDA 211.188](#) Batch Production and Control Records
- [FDA 211.192](#) Production Record Review
- [FDA 211.194](#) Laboratory Records
- [FDA 211.196](#) Distribution Records
- [FDA 211.198](#) Complaint Files

ARTICLE EXCERPT

211.196 – Distribution Records

Introduction

Distribution records are one of the most important records required by GMP regulations. The information contained in these records is key for notification of customers in the event of a product recall. Without complete and accurate distribution records, an effective recall is not possible - there would not be a method to assure that all the recalled product could be accounted for.

Requirements

The requirements of GMP regulation 211.196 are simple and concise. Distribution records must contain the name and strength of the product, description of the dosage form, name and address of the customer, date and quantity shipped and lot or control number of the drug product.



Example

Lot # 132A Product 500 mg. Aspirin tablets
Quantity Produced: 500 cases of 12 bottles of 100 tablets

Quantity Shipper	Customer	Date Shipped	Initials
50 cases	ACME Drug Denver, CO	10/15/08	JS
40 cases	ABC Medical St. Louis, MO	10/19/08	SL
150 cases	XYZ INC Cleveland, OH	11/02/08	MJ

211.196 - If You Are Auditing

Here is an effective way to audit compliance with this regulation.

- Request distribution records for several batches of product that have been distributed. Verify the accuracy of the information.
- Request distribution records for several batches of product that have not been completely distributed. Verify that the existing product quantity matches that on the distribution record.

END ARTICLE EXCERPT



This article excerpt is compliments of the FDA Compliance Learning Community of enKap (<http://www.enkap.com>). This article was published in its entirety in the May 2010 Issue of the *FDA Compliance Digest* (<http://enkap.com/page/fda-compliance-digest-may>)