# *Client Letter*

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***Outsourcing Facility Information***

Outsourcing Facility name, location, audit dates, and auditor.

***Participants***

Participant table that includes names and titles of Outsourcing Facility participants.

***History***

Founding history: headquarters, other facilities under same ownership

***Registrations and Inspections:***

**Named Outsourcing Facility** was last registered as an Outsourcing Facility on MMDDYYYY (FDA registration confirmed). **Named Outsourcing Facility** is also registered with Drug Enforcement Administration (DEA registration confirmed), and various other State Boards of Pharmacy (included will be states that facility is NOT currently registered)

**Named Outsourcing Facility** was last inspected by FDA from MMDDYYYY through MMDDYYYY. There were # observations (list of observations and responses attached). **Named Outsourcing Facility** was last inspected by DEA from MMDDYYYY through MMDDYYYY. There were # deficiencies.

***Executive Summary:***

Overview of completed audit, followed by detailed description of observation types (critical, major, minor, recommendations), number of observations.

***Scope:***

The audit conducted by ***PAC Auditing Solutions*** included, but was not limited to, a virtual building and facilities tour, review of Quality Systems, quality responsibilities, master and working compounding batch records, gowning, environmental monitoring activities, smoke studies, personnel training, corrective/preventive actions, complaint & adverse event handling, stability program, CSP product labeling, documentation, sterility testing, procedures, process simulations, compounding activities, etc. The audit focused on current GMP — Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, applicable chapters of the current USP/NF, and various other regulatory guidance documents (e.g., 21 CFR 210/211, 216, 7.4, 310) as applicable.

***Summary:***

High level report summary discussion including management team, SOP reviews, summary of compounded products, summation of items reviewed, and final conclusion/comparison to other audited facilities.

***Audit Table:***

An Audit Table is included and contains regulatory regulation, regulatory reference section, observations, and classification. “Complies” is listed in the observation column if there were no findings in a section. Otherwise, a descriptive finding will be in the observation column, along with a classification type listed as Critical, Major, Minor, or Recommendation.

*Excerpt from audit table* ***(NOTE: All regulatory references from 21 CFR 211 & FD&C 503B will be included in table of completed report)***

|  |  |  |  |
| --- | --- | --- | --- |
| Description | Regulatory Reference | Observation | Category: Critical, Major, Minor, Recommendation |
| Subpart B - Organization and Personnel | 211.22 Responsibilities of quality control unit | B1. There is an inadequate quality control unit. The responsibilities of the quality control until are not in writing. | Major |
| Bulk Drug Substances | 503B(a)(2) | Y1. There is no C of A review for incoming starting materials. | Minor |
| Labeling of Drugs | 503B(a)(10)(A) | Complies |  |
| Adverse Event Reporting | 503B(b)(5) | Y2.There is an inadequate process for determining and/or reporting adverse events. | Minor |

***Current Product List***

***Examples of Labels***