**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**FOOD AND DRUG ADMINISTRATION**

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 19701 Fairchild<br>Irvine, CA 92612-2445<br>(949)608-2900 Fax:(949)608-4417 | 6/10/2026-6/18/2026*<br>FEI NUMBER<br>3015190176 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amanda M. Williams, Sr. VP of Clinical and Regulatory

| FIRM NAME | STREET ADDRESS |
|---|---|
| MedAlliance, LLC | 4 Jenner Ste 190 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Irvine, CA 92618-3831 | Manufacturer |

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

## OBSERVATION 1

Your firm did not adequately document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly and packaging processes for sterile medical devices.

Specifically,

On 06/11/26, I observed the manufacturing of multiple Drug (b) (4) Formulation lots which was in part performed inside the ISO 5 certified laminar flow hood (LFH) installed in room (b) (4), asset number ME1301-(b) (4) On that date and during subsequent discussions, I observed the following deficiencies regarding that LFH and operations surrounding it:

a) The surfaces of the HEPA filter and protective (b) (4) that comprise the (b) (4) of the LFH were marked with a black smudge approximately 0.5" in diameter on their upper right quadrants on the afternoon of 06/11/26. I observed the manufacturing of multiple lots of Drug (b) (4) Formulation for use in (b) (4) units performed (b) (4) inside this same LFH while the mark was present.
b) On 06/17/26, your management stated that your firm currently has no written procedure defining the cleaning of the inner side walls, (b) (4), and ceiling of the LFH.
c) During the manufacture of multiple lots of Drug (b) (4) Formulation on 06/11/26, I observed several items placed on the LFH work surface in the air pathway between the HEPA filter and the area where open vials containing in-process materials were being manipulated. These items included the following: a repeating micropipettor and accompanying stand, a (b) (4) bottle of

AMENDMENT 1

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Alexandria L Capuano, Investigator<br>Christopher R Czajka, Investigator<br>Luis P Torres, Microbiologist<br>Jay-Ar C Bendo, Chemist/Biologist<br>X Alexandria L. Capuano Investigator Signed By: Alexandria L. Capuano -S Date Signed: 06-18-2026 12:30:04 | 6/18/2026 |

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(b) (4) with (b) (4) dispensing nozzle attached to the top, (b) (4) vial crimpers, (b) (4) vial de-crimper, and a (b) (4) beaker containing(b) (4) covered by a piece of(b) (4)

d) During the manufacture of multiple lots of Drug (b) (4) Formulation on 06/11/26, I observed the operators performing material and component manipulations inside the LFH in such a way that the air pathway between the HEPA filter and the open vials containing in-process materials were being manipulated was obstructed by the operators' hands and the utensils being used.

**OBSERVATION 2**

Production controls do not include implementation of product release, delivery, and post-delivery activities.

Specifically,

Your firm failed to follow your procedure to review and verify that any FORXXX listed in the "Doc. No." column of the Work Order is documented, accurate, and complete (SOP039, 6.2.1.2). Specifically, during the inspection, I observed that copies of FOR012 form, which are used in the (b) (4) step of in-process (b) (4) products, are not reviewed by your QC unit as part of the completed production records review prior to release and distribution. On 06/**18**/2026, your firm's ~~Senior Manager~~ **Quality Director**, Quality ~~Compliance~~ **Control**, stated that your firm does not confirm that the raw data output from the (b) (4) instrument is accurately recorded in the FOR012.

***DATES OF INSPECTION**

6/10/2026(Wed), 6/11/2026(Thu), 6/12/2026(Fri), 6/15/2026(Mon), 6/16/2026(Tue), 6/17/2026(Wed), 6/18/2026(Thu)

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| | Alexandria L Capuano, Investigator<br>Christopher R Czajka, Investigator<br>Luis P Torres, Microbiologist<br>Jay-Ar C Bendo, Chemist/Biologist | X Alexandria L. Capuano Investigator Signed By: Alexandria L. Capuano -S Date Signed: 06-18-2026 12:30:04 | 6/18/2026 |

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X Christopher R Czajka
Investigator
Signed By: CHRISTOPHER R. CZAJKA -S
Date Signed: 06-18-2026 12:30:34

X Luis P Torres
Microbiologist
Signed By: 2003275850
Date Signed: 06-18-2026 12:31:09

X Jay-Ar C Bendo
Chemist/Biologist
Signed By: JAY-AR C. BENDO -S
Date Signed: 06-18-2026 12:31:41

AMENDMENT 1

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EMPLOYEE(S) SIGNATURE

Alexandria L Capuano, Investigator
Christopher R Czajka, Investigator
Luis P Torres, Microbiologist
Jay-Ar C Bendo, Chemist/Biologist

X Alexandria L Capuano
Investigator
Signed By: Alexandria L. Capuano -S
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## Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."