**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 | 2/10/2026-2/13/2026 |
| | FEI NUMBER<br>3018125942 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ryan B. Kazemi, Co-Owner

| FIRM NAME | STREET ADDRESS |
|---|---|
| MPS Pharma & Medical Inc. | 465 N Berry St |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Brea, CA 92821-3105 | 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.

*The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.*

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

## OBSERVATION 1

One or more processes for risk management in product realization have not been adequately documented.

Specifically,

Your firm's procedure 7-01, *Risk Management*, Rev. A01, Section 7.4.3, requires that hazards be identified by reviewing "(b) (4) (b) (4)" Your firm's risk management files for the Luer Lock Transfer Pin product family, do not adequately identify risks associated with the devices and its production processes.

A) Your firm's risk analysis for the sterilization process, which is outsourced to (b) (4) is documented through *Risk Management Plan for Sterilization Process, RM-015, Rev. A01,* with approvals signed 12/21/2020, and *Risk Management Report for Sterilization Process, RM-015, Rev. B01,* with approvals signed 02/10/2021.

a. Your firm's risk management plan (*RM-015*) did not adequately identify possible hazards associated with your device. For example, it lists *Biological* (2.1) hazards as "No" with rationale that "Sterilization processes ((b) (4) have been validated on VAL-S-008 & VAL-S-009 respectively". Your risk management plan includes similar rationale for

AMENDMENT 1

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| | Alexandria L Capuano, Investigator | X Alexandria L Capuano Investigator Signed By: Alexandria L. Capuano -S Date Signed: 02-13-2026 14:21:05 | 2/13/2026 |

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other known hazards in *User error* (3.2) and *Operating Instructions* (4.2) where it identifies hazards as "no" with the rationale "All required steps are specified in MFG-01 & MFG-02". These rationales are inadequate because validation of sterilization processes and manufacturing instructions do not eliminate a hazard but rather acts as a control measure to mitigate a hazard.

b. Your firm's process FMEA (pFMEA) in Attachment A of the risk management report (*RM-015*) only identifies three failure modes for the sterilization process. Other critical sterilization process failure modes, such as equipment malfunctions, biological indicator failures, load configuration errors, and the aeration process, were not identified as potential hazards that should be evaluated in your risk management.

B) Your firm's risk analysis for internal processes is documented through *Risk Management Plan for Transfer, RM-002, Rev. B01,* with approvals signed 03/17/2021 and 03/25/2021, and *Risk Management Report for Transfer Pins, RM-002, Rev. D02,* with approvals signed 04/23/2025.

a. Your firm's risk management plan (*RM-002*) did not adequately identify possible hazards associated with your device. For example, it lists *Biocompatibility* (2.3) hazards, including toxicity of chemical constituents and allergenicity/irritancy as "No" with rationale referencing biocompatibility reports (VAL-B-002, VAL-B-004, VAL-B-006, and VAL-B-008). This rationale is inadequate because biocompatibility reports do not eliminate a hazard but rather acts as a risk evaluation tool that can support risk acceptability. ~~Your risk management plan also failed to identify *Labeling* as a potential hazard and marked it as "N/A".~~

i. While your firm's design FMEA (dFMEA) in Attachment B of the risk management report (*RM-002*) identifies biocompatibility hazards, your pFMEA does not identify process related factors that could affect biocompatibility, such as contamination during manufacturing or cross-contamination from equipment.

b. Your firm's dFMEA in Attachment B of the risk management report (*RM-002*) only identifies 11 design related hazards for the device. Other critical design hazards, such chemical compatibility with medications and solutions, were not identified as potential hazards that should be evaluated in your risk management.

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c. Your firm's pFMEA in Attachment A of the risk management report (*RM-002*) only analyzed three manufacturing process steps (b) (4) , (b) (4) and (b) (4) (b) (4) with a total of six hazards. Other critical manufacturing processes were not analyzed, such as receiving inspection activities **[QC-005, Sub Assemblies and Bulk Tubing Sets- Non-Sterile, Rev. B01, DCR # 24-025 was provided to show current control measures that are not included in risk management documentation]**, ~~packaging operations, and distribution processes~~. In addition, other critical hazards were not identified, such as dimensional variations, ~~labeling errors, and product mix up~~.

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**OBSERVATION 2**

A design and development file was not adequately maintained for each medical device type or medical device family.

Specifically,

Your firm's procedure, *Design Controls, 7-23, Rev. A01, DCR # 21-001*, defines a Design History File (DHF) as *a compilation of records which describes the design history of a finished device* (3.3) and that it *includes all the documentation necessary to demonstrate that the design was developed in accordance with this procedure … [including] records of all the phase reviews…* (6.4.7.1). However, the design and development file or DHF for your firm's Luer Lock Transfer Pin (K901063) has not been adequately maintained. For example:

- On 02/12/2026, I requested files for design review, which your firm was unable to provide. Section 6.3 of your firm's procedure requires *a phase review shall be conducted at the completion of each phase and documented on the appropriate form.*
- On 02/12/2026, I requested files for design inputs (e.g., user needs), which your firm was unable to provide. Section 6.4.2 of your firm's procedure defines design input requirements, including user needs.
- On 01/12/2026, I requested files for design planning. The document your firm provided, *PROJ-023: 19TPV – Assembly Change*, is not adequate as a design plan. Section 6.4.1 of your firm's

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procedure defines project plan requirements.

On 02/12/2026, your firm's Quality and Operation Specialist explained that the Luer Lock Transfer Pin is a "legacy" device, which was acquired from a different company. They stated that there is a chance that these specific documents do not exist since this is a "legacy" product.

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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."