DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Division of Pharmaceutical Manufacturing Assessment 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	03/02 - 10/2026
	FEI NUMBER 1925262

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Ms. Amy Owen, VP, McPherson Site Leader

FIRM NAME	STREET ADDRESS
Hospira, Inc.	1776 North Centennial Dr.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
McPherson, KS, 67460	Drug Product Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1: Failure to establish process controls designed to assure that the drug products manufactured have the identity, strength, quality, and purity that it purports or is represented to possess. Specifically,

a. On 02 March 2026, observed was the setup of the (b) (4) fill line for (b) (4) drug product manufacture lot (b) (4) Including, but not limited to the (b) (4) observed was the equipment sanitized in Grade D space and assembled to the (b) (4) by sanitized (b) (4) hands, with these equipment pieces during manufacture directly above the sterile open (b) (4) Personnel gowning during the assembly process was Grade D gowning, with exposed facial skin within the (b) (4) You failed to (b) (4) sterilize the equipment and assemble the equipment to the (b) (4) in a manner that provides an optimum equipment surface for manufacture that can reasonably be expected to have an impact of product quality.

Furthermore, observed was the (b) (4) sterilized (b) (4) Stopper Bowl and (b) (4) covered, where the equipment (b) (4) was removed in Grade D space, with the equipment transitioning and assembled to the fill line. The remaining (b) (4) covering the (b) (4) stoppering system was removed immediately at time of installation exposing the sterile (b) (4) stopper contact surfaces. Observed was an operator with exposed face skin working near and over the exposed sterile (b) (4) stopper contact surfaces. The (b) (4) stopper contact surfaces were not installed in a manner that maintained the quality of the surfaces intended to remain sterile.

b. On 03 March 2026, observed was the setup of the (b) (4) sterilized drug product fluid pathway laying on the (b) (4) a sanitized surface. The packaging was opened by sanitized (b) (4), with the drug product fluid pathway assembled to the fill line. Although each (b) (4) will be (b) (4) installation, extensive touching of the (b) (4) assembly by sanitized (b) (4) and product pathway tubing interface) failed to maintain the quality of surfaces intended to remain sterile.

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c. On 03 March 2026, observed during the (b) (4) drug product filling process for lot (b) (4) was a forceps tip touching the (b) (4), a sanitized surface. The same condition was again observed on 04 March 2026. You failed to maintain the quality of the forceps tip as to only touch another sterile surface.

d. On 04 March 2026, observed during production of lot (b) (4) at (b) (4) locations of the (b) (4) stoppering system was the (b) (4) partially blocked by packaging material.

e. On 05 March 2026, observed during the production of lot (b) (4) was (b) (4) drug product (b) (4) formation at multiple (b) (4) You failed to optimize the filling process in mitigation of the observed attribute where the drug product should (b) (4) be maintained in the (b) (4)

f. For each (b) (4) into Grade A air space from Grade D, you failed to sanitize the (b) (4). During (b) (4) setup operations, personnel Grade D gowning was observed to come into close proximity with non-classified surfaces, when operators bent over to sanitize equipment on a (b) (4) in the Grade D space. Upon entry to the Grade A (b) (4) the back of these gowns contacted the (b) (4) and gown sleeves contacted production line surfaces during equipment installation, thereby creating a potential contamination pathway to the aseptic processing environment.

Observation 2: Equipment and facilities in (b) (4) drug product manufacture are not adequately designed or located. Specifically,

a. Based on design, the (b) (4) fill line for (b) (4) drug product manufacture fails to have a HEPA filter (b) (4) (b) (4) directly above the (b) (4) stopper bowl. You identified by risk assessment that the area did not have excellent airflow during the (b) (4) smoke study, with the risk assessment failing to account for the (b) (4) stoppering system (b) (4) intervention for installation and any risk mitigation. There are no (b) (4) (b) (4) intervention smoke studies that includes the assembly of the (b) (4) stoppering system, air pattern testing. There is no viable environmental monitoring at the (b) (4) stopper bowl location, with the total non-viable particle cone at an elevated level above the work surface.

b. The (b) (4) room wall mounted signage, holder indicating Code and Lot identification creates a gap between the wall and the holding device, a cleaning challenge.

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c. Your (b) (4) used in (b) (4) drug product manufacture are near (b) (4) (b) (4) The (b) (4) for (b) (4) is the room containing the (b) (4) You fail to have a risk assessment to identify any system location risk and risk mitigation.

Observation 3: Failure to maintain equipment and facilities in a good state of repair in (b) (4) drug product manufacture. Specially.

a. The (b) (4) used in (b) (4) drug product manufacture was observed with deteriorated sealant at (b) (4) (b) (4) mounting. The (b) (4) near the stoppering system was observed with extensive (b) (4) scoring.

b. (b) (4) was observed with a (b) (4) line to an open bucket, along with (b) (4) below the (b) (4) at (b) (4) locations. (b) (4) was observed with an unsecured electrical box, a (b) (4) leak and absorbent pads for a (b) (4) leak. (b) (4) (b) (4) was observed with (b) (4) on the floor from a (b) (4) valve.

c. Your laminar flow hood (LFH) #9589, used during bioburden testing on 4 March 2026, had a rust-like substance on the screws and visible debris on the wipe cloth after wiping the LFH surfaces before testing. Additionally, LFH #9588, located adjacent to LFH #9589, had a rust-like substance on the screws, along the inside upper edges of the hood, and along the inside right edges, as well as (b) (4) substance adhered to several areas on the inside ceiling of the hood.

Observation 4: Procedures in (b) (4) drug product manufacture are deficient. Specifically,

a. Your firm lacks adequate procedures and training for microbiological plate reading, resulting in inconsistent practices among laboratory personnel. There are no written procedures or documented training records that define the methodology for reading environmental monitoring settle plates and touch plates for microbial growth. On 5 March 2026, laboratory personnel were observed using inconsistent techniques when reviewing environmental monitoring plates. Laboratory Technician (b) (6) placed plates on the light table for about one second, while Laboratory Technician (b) (6) and Team Lead (b) (6) placed plates on the light table for several seconds, rotated them, and examined them from multiple angles. These inconsistent practices compromise the reliability and accuracy of

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microbiological results used for environmental monitoring decisions.

During endotoxin testing on 4 March 2026, critical testing operations were not adequately proceduralized. The procedures associated with this testing do not specify using a vortex machine to mix sample solutions or define a timeframe for adequate mixing. Additionally, the procedures do not include the observed use of a (b) (4) to remove bubbles from sample wells prior to placing them in the plate reader (Endotoxin K11715 machine), despite firm personnel stating that bubbles in the wells would invalidate test results. This includes Procedure LAB-27703-30.0 (PR-0728), "Performing the Bacterial Endotoxins Test (USP <85>, USP <86>, EP 2.6.14, JP 4.01)" Effective Date 03 November 2025; procedure TRN-32086, "Performing the Bacterial Endotoxin Test via the Photometric Methods" v3.0, Effective date 04 December 2025; and SOP-96058, "Performing the Bacterial Endotoxin Testing via the Kinetic Assay" v34.0, Effective date 08 November 2025.

b. Your procedure, SOP 95112, "Gowning Procedure for Controlled Class IV/ Grade D Areas" v43, Effective date 25 August 2025 fail to prevent cross-contamination in Gowning Room (b) (4) for the (b) (4) fill line used in (b) (4) drug product manufacture. Your firm has not established a maximum occupancy limit for the gowning room or implemented restrictions to prevent simultaneous gowning and degowning activities. On 3 March 2026, at approximately (b) (4) personnel were observed in Gowning Room (b) (4) personnel were gowning to enter the manufacturing area while one was degowning, all occupying approximately (b) (4) square feet of the available gowning space. Additionally, the Grade D area around the (b) (4) fill line does not have a personnel occupancy limit. On 3 March 2026, during (b) (4) production, (b) (4) people were present in this area, resulting in area congestion.

c. Procedure SOP-95099, "General Rules and Regulations for all Production Areas", v74.0, Effective date 25 January 2026 specifies under Cleaning/Sanitization Lockers: All personnel and plant uniform lockers will be sanitized (b) (4) The lockers will be sanitized with a sporicide, (b) (4) (refer to SOP-94929), (b) (4) (b) (4) by an approved locker cleaning crew with a plant security representative coordinating. Observed on 04 March 2026 was the men's change room lockers with angled top surfaces in an unclean state. Your procedure fails to specify the cleaning of the angled top surfaces.

Observation 5: Your firm failed to establish adequate quality control unit oversight with the responsibility and authority to approve or reject production and quality documents. Specifically,

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a. Your firm lacks adequate quality oversight to ensure Quality Risk Management Reports and change controls are thoroughly conducted and reviewed before approval. For example.

i. Quality Risk Management Report Oversight: A Quality Risk Management Report (QRMR) with an effective date of 6 December 2024, stated that the (b) (4) Change Frequency PM MCP-5490 should be conducted "(b) (4)." However, there are two Preventative Management (PM) for the (b) (4) MCP 5490 with a frequency to (b) (4) and MCP 5209 with a frequency to replace (b) (4) The Quality Unit did not ensure that the current PM aligned with the QRMR, demonstrating inconsistency between the risk assessment and actual preventative maintenance practices.

ii. Change Control Oversight: Preventative Maintenance Program Change Request (PMCR) Task Plan #M-P5490QT, PM Schedule #MCP-5490, dated 7 August 2025, stated "cancel PM due to frequency changes in SOP-95715" and "(b) (4) are no longer changed (b) (4) after SOP 95715 was updated." However, SOP-95715 does not pertain to the frequency change referenced in the PMCR.

b. Your firm lacks adequate quality unit investigations for deviations to implement corrective actions to prevent recurrence. From 2024 to 2026, there have been a total of 6 deviations involving (b) (4) failures on the (b) (4) filling line for (b) (4) drug product manufacture with similar types of failures (b) (4) identified. (b) (4) (b) (4) experienced repeated failures within a 12 month timeframe, with (b) (4) failing on 21 August 2024, and 3 July 2025, and (b) (4) failing on 30 June 2025, 29 January 2026, and 8 February 2026, demonstrating ineffective corrective actions to prevent recurrence.

c. Your firm lacks adequate quality oversight to ensure Acceptable Quality Level (AQL) samples are taken at intervals that are representative of the entire batch. SOP-96072, Auditing of Production Operations, Section E.3 states, "To obtain representative samples for any configuration type, samples must be taken from a minimum of (b) (4) across the batch."

i. During review of Visual Inspection (VI) AQL batch results for Batch #(b) (4) dated 16 February 2026, a total of (b) (4) were produced requiring (b) (4) to be sampled at specified intervals. However, the appropriate (b) (4) within the ranges were not sampled for intervals (b) (4)

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Interval Range (b) (4) Sampled (b) (4)

[redacted]

ii. During review of VI AQL batch results for batch # (b) (4) dated 17 October 2025 a total of (b) (4) were produced requiring (b) (4) to be sampled at specified intervals. However, the appropriate (b) (4) within the ranges were not sampled for intervals (b) (4)

Interval Range (b) (4) Sampled (b) (4)

[redacted]

Observation 6: Your firm failed to establish adequate controls to ensure documentation is complete, accurate, appropriately reviewed and traceable. Specifically,

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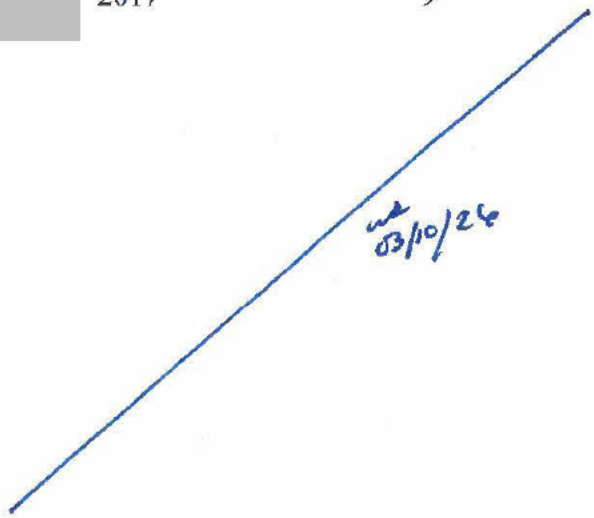
On 6 March 2026, a review of laboratory notebooks managed in the chemistry laboratory revealed deficiencies in the issuance, reconciliation and archiving process. According to SOP 95718, "Chemistry Laboratory Operation Procedure," v71, Effective date 16 November 2025, a (b) (4) audit is conducted to confirm that each CQ laboratory notebook owner has possession of their assigned books and to verify that archive activities have been completed. However, a review of the issuance and reconciliation records showed that multiple notebooks have not been returned, with some dated back to 2004. Specifically, one former employee who left the company in 2021 has five outstanding notebooks. Examples of individuals with a high number of unaccounted notebooks are listed that have not been archived, nor has the justification for their non-archival status been documented.

Employee and Status (b) (6)	Notebook Issued Date	Number of Notebooks Not Returned
	2013	5
	2004	10
	2014	11
	2014	6
	2016	5
	2017	9



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