DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	5/4/2026-5/12/2026* FEI NUMBER 3003153579

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Greg A. Flyte, Global Head of Manufacturing/Supply & General Manager Winnipeg

FIRM NAME	STREET ADDRESS
Emergent BioSolutions Canada Inc.	155 Innovation Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Winnipeg, R3T 5Y3	Biologics Drug 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

Established test procedures and laboratory control mechanisms are not followed and documented at the time of performance.

Specifically,

1. Your firm's procedure SOP018509 - *Sample Handling, Testing, Review and Record Keeping in the QC Lab*, lacks clear instructions requiring that sample receipt be recorded contemporaneously at the time of (b) (4) from collecting personnel to the QC laboratory. This procedural gap resulted in samples being documented as received in (b) (4) LIMS prior to the actual (b) (4) occurring, impacting the accuracy and integrity of chain of custody records. For example, sample (b) (4) WIN VIG was submitted for testing at (b) (4) on January 22, 2026, from the manufacturing floor in Building (b) (4), and was documented as received in (b) (4) LIMS at (b) (4) on January 22, 2026, in the QC laboratory in Building (b) (4) — a (b) (4) (b) (4) that is implausibly (b) (4) given the (b) (4) between the (b) (4) buildings.

   Additionally, twelve (12) deviations related to sample chain of custody failures were initiated between December 2024 and October 2025, despite multiple corrective actions, demonstrating a persistent systemic failure. Examples include:

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- Between (b) (4), (b) (4) samples were not received in (b) (4) LIMS within (b) (4) These included AIG (b) (4) (b) (4) and AIG Plasma Pool (Deviation-010383; opened January 22, 2025).
- Between (b) (4), (b) (4) samples were not received in (b) (4) LIMS within (b) (4) day of collection. These included VIG stability samples (Deviation-010698; opened May 14, 2025).
- Between (b) (4), (b) (4) samples were not received within (b) (4) An additional (b) (4) samples were found still pending receipt in (b) (4) LIMS, some with no chain of custody history dating back to August 2023. These included (b) (4) and BAT Plasma Pool (b) (4) (Deviation-011025; opened October 21, 2025).

2. On May 8, 2026, microbiological plates, including (b) (4) (b) (4) plates used for environmental monitoring (EM), were observed being (b) (4) in an (b) (4) (b) (4) to distribution for (b) (4) and (b) (4) as sampled EM plates. Although the plates were observed to be (b) (4) and (b) (4), the (b) (4) is (b) (4) (b) (4). (b) (4) of EM plates in an (b) (4) temperature environment, without qualification or a supporting risk assessment, introduces risk of temperature excursion that may affect the growth promotion performance of unused plates and the integrity of sampled plates (b) (4) incubation. In addition, your SOP018422 — *Environmental Monitoring (General Facility - 155 Innovation Drive)* — permits viable samples to be staged in the (b) (4) for a (b) (4) of (b) (4)

(b) (4) from the time of sample collection; however, no validation data or risk assessment was available to support this practice.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

Since May 2022, approximately 21 deviations have been initiated in response to the presence of (b) (4) in CBER licensed biological products. Of these, 15 deviations involved (b) (4) (b) (4) and other (b) (4) for which no root cause was identified, including:

Deviation	Product	Batch	Date opened	Date closed	Particle type
011187	VIG	(b) (4)	12/23/2025	02/25/2026	(b) (4)
010251	WinRho	(b) (4)	11/18/2024	12/06/2025	(b) (4)

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					glass
007347	WinRho	(b) (4)	08/01/2023	09/21/2023	(b) (4)
011329	BAT	(b) (4)	03/17/2026	05/04/2026	(b) (4)

Additionally, the investigations state that "No CAPA could be initiated because the root cause for the source of particles was inconclusive"

OBSERVATION 3

Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit.

Specifically,
Your firm blended (b) (4) source plasma into (b) (4) plasma pools for (b) (4) (b) (4) — including VIG (CNJ-016R), HepaGam B, WinRho SDF, and Anthrasil — without an adequate change control process. Deficiencies include:

a) No defined acceptance criteria, including the maximum allowable amount of (b) (4) source plasma permitted in the (b) (4) pool.

b) No adequate in-process controls to ensure product quality is maintained.

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OOS results for total protein and product recovery excursions were observed, as documented in Deviation 010886 ((b) (4) — OOS for Total Protein; VIG Finished Product, (b) (4) (b) (4) and Deviation 010808 (Excursion to (b) (4) product recovery limit; VIG (b) (4)(b) (4) (b) (4)

While your firm initiated CAPA-012801 to assess the plasma pool strategy for VIG (CNJ-016R) Finished Product, this corrective action does not extend to HepaGam B, WinRho SDF, or Anthrasil, of which the same pool strategy is in place. Your firm has not demonstrated that the identified deficiencies have been assessed or remediated across all affected products.

OBSERVATION 4

Routine calibration and checking of mechanical and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically, (b) (4) currently used in manufacturing operations have not been qualified to demonstrate accurate and reliable performance for their intended use.

OBSERVATION 5

Written procedures are not established and followed for the cleaning and maintenance of equipment, including (b) (4), used in the manufacture, processing, packing or holding of a drug product.

Specifically, your firm has not established routine inspection, replacement frequency and other maintenance criteria for the following equipment/components:

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- (b) (4) – (b) (4) observed on (b) (4) during inspectional walk-through on May 04, 2026.
- (b) (4) and (b) (4) used for label detection on the labeling and packaging line.

OBSERVATION 6

Appropriate controls are not exercised over computers or related systems to assure that changes in (b) (4) and (b) (4) records or other records are instituted only by authorized personnel.

Specifically, during the inspection of the labeling and packaging operations, it was observed that multiple operators access the labeling/packaging machine (b) (4) using (b) (4) user credentials (i.e. common (b) (4)) to print product labels that are subsequently affixed to finished drug products. Operators have the capability to adjust operational parameters via the (b) (4) (b) (4) based on product (b) (4) labeling operation. However, parameter adjustments made (b) (4) labeling operation are not documented in the batch record.

OBSERVATION 7

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, individual defect rate limits have not been established for major and minor defect types identified during 100% visual inspection.

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OBSERVATION 8

The quality control unit lacks authority to review production records to assure that no errors have occurred and fully investigate errors that have occurred.

Specifically, change control procedures are not adequate to ensure that modifications to validated equipment recipes and associated (b) (4) are properly controlled, verified, and free of error prior to use in commercial manufacturing operations. For example:

On 16 October 2025, a revision to (b) (4) (b) (4) completed under Change Control CC-004191 introduced a formula error in the AIG (b) (4), whereby the (b) (4) was configured incorrectly. This error was not detected during change control review and verification, and the (b) (4) was released for use in commercial filling. The error was only identified upon triggering of an (b) (4) (b) (4) during filling of AIG (b) (4) on May 5, 2026.

2. On 2023-Dec-22, the SA25 (b) (4) Master Recipe ((b) (4) 053959 v1.0) was versioned up from v2 to v3 during routine HEPA Filter Inspection without initiation of change control, in violation of SOP042308 Recipe Management / Backup / Restore and User Access for the SA25 Aseptic Filling Work cell. The (b) (4) change, (b) (4) was changed from (b) (4) which caused the recipe to version up, was not detected for approximately (b) (4) days. Contributing factors included the absence of recipe (b) (4) (b) (4) in the PM work instruction and the use of a generic (b) (4) account that permitted recipe modifications to be saved without (b) (4) user accountability.

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OBSERVATION 9

Employees are not given training in the particular operations they perform as part of their function.

Specifically, there is no training program for maintenance employees responsible for performing visual inspection of manufacturing tanks for (b) (4). For example, the following work orders were completed by employees who have not been trained for the task:

- WO 4356297, completed 15 October 2024, (b) (6), (b) (7)(C)
- WO 4390185, completed 20 October 2025,
- WO 4397283, completed 04 February 2026

***DATES OF INSPECTION**

5/04/2026(Mon), 5/05/2026(Tue), 5/06/2026(Wed), 5/07/2026(Thu), 5/08/2026(Fri), 5/11/2026(Mon), 5/12/2026(Tue)

X Yonggang Wang
FDA Center Employee
Signed By: 0011760098
Date Signed: 05-12-2026 13:44:33

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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."