DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	2/9/2026-2/27/2026*
	FEI NUMBER 3003973577

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Emmanuel Felix, Vice President Belgium Operations

FIRM NAME	STREET ADDRESS
GlaxoSmithKline Biologicals SA	Avenue Fleming 20, Parc De La Noire Epine
CITY, STATE, ZIP CODE, COUNTRY Wavre, Brabant Wallon, 1300 Belgium	TYPE ESTABLISHMENT INSPECTED Vaccine 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

Input to and output from the computer and related systems of formulas are not checked for accuracy.

Specifically,

A. Your firm utilizes electronic formats/recipes configured within the (b) (4) (b) (4) systems to control critical manufacturing parameters for the drug products, including but not limited to fill volume. Your firm manufactured drug product batches using non-validated formats/recipes, as follows:

	Filling lines ((b) (4) Wavre site)			
Products	**Syringe filling line** (b) (4)	**Syringe filling line** (b) (4)	**Vials filling line** (b) (4)	**Vial filling line** (b) (4)
	Format	**Format**	**Format**	**Format**
Adjuvant AS01B (Shingrix)			(b) (4) AS01 (b) (4)	
Adjuvant AS01E (Arexvy)	Pediatric	Pediatric	(b) (4) AS01 (b) (4)	
Adjuvant AS03			(b) (4) as03 VIAL (b) (4) (b) (4)	
Arexvy (RSV OA)				(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shafiq Ahadi, Investigator Thai D Truong, Investigator X Shafiq Ahadi Investigator Signed By: 2000594974 Date Signed: 02-27-2026 04:04:40	2/27/2026

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Boostrix	Pediatric	Pediatric	(b) (4) BOOSTRIX (b) (4)	
Engerix-B	Pediatric / adult	Pediatric / adult	(b) (4) / ENGERIX (b) (4)	
		Adult: (b) (4) (b) (4) / HBV		
Fluarix + T-QIV	Fluarix	Fluarix		
Fluarix + D-QIV NH	Fluarix	Fluarix		
FluLaval + Q-QIV	Fluarix	Fluarix		
FluLaval T QIV	Fluarix	Fluarix		
Havrix	Pediatric / adult	Pediatric / adult	(b) (4) havrix ped (b) (4)	
Hiberix				(b) (4) (b) (4) / hib ads
Infanrix	Pediatric	Pediatric		
Kinrix (Infanrix Polio)	Pediatric	Pediatric		
PenMenvy				(b) (4) / Men (b) (4)
Men ACWY				[(b) (4) / Men (b) (4)
Aseptic Process Simulation (APS)	Mediafill	Mediafill	(b) (4)	
Rotarix (Oral)		Rotarix		
Shingrix				(b) (4)

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Thai D Truong, Investigator

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				/ zoster
Shingrix Fully Liquid [PFS]	Shingrix	Shingrix		
Twinrix	Pediatric	Pediatric		

In addition, your firm used an incorrect format/recipe to manufacture and release commercial drug products. For example, during the manufacturing of SHINGRIX® Batch No. ASFLA026A, (Release date: September 1, 2025), your firm utilized a non-validated format/recipe identified as (b) (4) in the (b) (4) equipment system. However, the executed batch production record documents the use of the (b) (4) format/recipe.

B. Your firm implemented a new Format/Recipe, (b) (4) in the (b) (4) to manufacture SHINGRIX® drug product without subjecting the change to the firm's change control system. This change to the production control procedure was not drafted, reviewed, and approved prior to implementation. For example, your firm implemented the (b) (4) Format/Recipe on filling line (b) (4) to manufacture SHINGRIX® Lot No. ASFLA018A on (b) (4) The implementation of the (b) (4) Format/Recipe, which controls critical parameters such as fill volume, was not documented, reviewed, and approved prior to implementation.

C. Your firm failed to adequately document process performance qualification (PPQ) batches to demonstrate that the process was validated under defined operating parameters. The PPQ batch record for SHINGRIX® Drug Product, Document No. (b) (4) PPQ Report- (b) (4) (b) (4) " did not document which recipe or filling parameters were used during the validation batches. For example, the PPQ batch record for SHINGRIX® Lot No. ASFLA018A, manufactured on (b) (4) lacks documentation of critical parameters such as the (b) (4) Format/Recipe used to manufacture the batch. Without documentation of the correct Format/Recipe and filling parameters (e.g., fill volume) employed during PPQ, your firm cannot

demonstrate that the validated process matches the commercial manufacturing process or that the process has been adequately validated under defined conditions.

OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

A. The Master Batch Record, MBR, No. (b) (4), and executed production batch records for SHINGRIX® specify the use of format/recipe (b) (4) with a target fill volume of (b) (4) (b) (4) However, actual manufacturing operations utilized format/recipe (b) (4) with a target fill volume of (b) (4), representing a (b) (4) deviation from the specified fill volume. Your firm failed to follow the batch record specifications during manufacturing for (b) (4) lots of SHINGRIX® PFS-Pre-Filled Syringe drug products, of which (b) (4) have been released since March 16, 2024. The actual fill volume and format/recipe used in production did not match the fill volume and format/recipe documented in the batch record. For example, your firm manufactured and released SHINGRIX® Batch No. ASFLA026A, release date September 1, 2025, on filling line (b) (4) using format/recipe (b) (4) with a fill volume of (b) (4). However, the MBR and production batch record reflect the use of format/recipe (b) (4) with a target fill volume of (b) (4)

B. Filling parameters are modified and adjusted during production and process control in the (b) (4) by the operator as needed. Your firm has not established procedures governing operator changes to filling parameters and there is no documentation of what changes were made or what fill volumes were actually

used during manufacturing in the batch record.

OBSERVATION 3

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically,

A. Your current APS (Aseptic Process Simulation) design does not challenge or represent worst-case conditions for routine commercial fill volumes and container sizes. Commercial products, such as Boostrix, Engerix, Havrix, Twinrix, Fluarix, FluLaval, Infanrix, Kinrix, Pediarix, Rotarix, Shingrix, Synflorix, Penmenvy, Arexvy, and Hiberix are filled at volumes ranging from (b) (4) (b) (4) syringe containers, (b) (4) syringe containers, and (b) (4) (b) (4) vial containers. However, your APS program uses only the (b) (4) syringe container filled to a target volume of (b) (4) for filling line (b) (4) and (b) (4) vial container filled to a target volume of (b) (4) for filling line (b) (4).

B. Your LSOP 9000002087, version 17, *"Validation of Aseptic Operations – Aseptic Process Simulation (APS)"*, section 6.2.5.2 requires justification and validation of the (b) (4) (b) (4) media fill volumes for each container and validation of incubation conditions. Section 6.2.5.4 requires development and justification of a container (b) (4); otherwise, all container sizes must be (b) (4) during (b) (4) APS requalification. Section 6.2.5.4 further requires that when a single container size has more than (b) (4) fill volume, (b) (4) APS runs must be performed at the (b) (4) fill volume.

Your firm has not validated the (b) (4) media fill volumes for each container, has not developed and justified a container (b) (4) for syringe containers, and has not performed (b) (4) runs at the (b) (4) fill volume for syringe and vial containers with (b) (4) fill volumes, as required by LSOP 9000002087.

OBSERVATION 4

Deviations from written production and process control procedures are not justified.

Specifically, your firm failed to evaluate unexpected events during drug product manufacturing to determine whether they constitute deviations from established procedures. There is no documentation demonstrating that your firm assessed these events or provided justification for why they were not classified and investigated as deviations. For example, your firm manufactured SHINGRIX® Lot No. ASFLA018A on (b) (4). During the manufacturing process, the operator detected a failure of the (b) (4), which monitors the Grade (b) (4) filling line. This event was documented in the batch record as defect code (b) (4). However, your firm failed to evaluate whether this PEMS failure constituted a deviation from established procedures or requirements.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

A.Inadequate Environmental Monitoring Following Planned and Unplanned Shutdowns

Your (b) (4) and (b) (4) units are classified as Grade (b) (4) (ISO (b) (4)) during operations and declassified during shutdown. These Grade (b) (4) areas are used for

aseptic filling of drug substance (DS) and drug product (DP). Following both planned shutdowns (e.g., (b) (4) shutdowns, preventive maintenance) and unplanned shutdowns (e.g., power failures, equipment malfunctions, loss of environmental controls), your firm performs cleaning and/or (b) (4) (b) (4) decontamination of these areas. However, your firm does not perform environmental monitoring, including viable and non-viable monitoring, to verify that the areas have been adequately restored to a state of environmental control prior to resuming manufacturing operations.

B.Inadequate Environmental Monitoring Following Action Limit Excursions

When environmental monitoring action limits are exceeded in your classified areas, including but not limited to the recovery of molds and atypical microorganisms in Grade (b) (4), Grade (b) (4) direct and indirect areas, and Grade (b) (4) classified areas, for example:

-Deviation UE 201159427, initiated on 27Jan2026 due to action limits exceeded for surface sample in Grade (b) (4) room (b) (4).

-Deviation UE 201157043, initiated on 23Dec2025 due to action limits exceeded for surface (b) (4) sample in Grade (b) (4) room (b) (4).

-Deviation UE 201108271, initiated on 29Jan2025 due to action limits exceeded for active air sample in Grade (b) (4) room (b) (4).

-Deviation UE 201125599, initiated on 20May2025 due to action limits exceeded for active air sample in Grade (b) (4) room (b) (4).

-Deviation UE 201095273 initiated on 29Oct2024 due to action limits exceeded for mold recovered in Grade (b) (4) room (b) (4).

-Deviation UE 201076082, initiated on 03Jul2024 due to action limits exceeded for mold recovered in Grade (b) (4) room (b) (4).

-Deviation UE 201061824, initiated on 16Apr2024 due to action limits exceeded for mold recovered in Grade (b) (4) room (b) (4).

-Deviation UE 201046195, initiated on 29Jan2024 due to action limits exceeded for spore recovered in Grade (b) (4) room (b) (4).
-Deviation UE 201037464, initiated on 05Dec2023 due to action limits exceeded for mold recovered in Grade (b) (4) room (b) (4).

Your firm performs cleaning and/or decontamination of the affected areas. However, your firm does not verify the effectiveness of these corrective actions prior to resumption of manufacturing operations.

In addition, you do not assess the impact on batches manufactured between the time of the environmental monitoring action limit excursion and subsequent verification that environmental control was restored.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

Your Grade (b) (4) and Grade (b) (4) classified areas, which provide direct and indirect support to Grade (b) (4) aseptic processing operations, are not monitored for (b) (4) via an environmental management system (e.g., (b) (4)). Your firm monitors (b) (4) in classified areas; however, (b) (4) parameters are not monitored, recorded, trended, or evaluated in Grade (b) (4) and Grade (b) (4) areas.

Furthermore, your firm has not established a documented scientific justification demonstrating that the

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absence of routine (b) (4) monitoring in these classified areas does not adversely impact aseptic processing conditions.

***DATES OF INSPECTION**

2/09/2026(Mon), 2/10/2026(Tue), 2/11/2026(Wed), 2/12/2026(Thu), 2/13/2026(Fri), 2/16/2026(Mon), 2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 2/23/2026(Mon), 2/24/2026(Tue), 2/25/2026(Wed), 2/26/2026(Thu), 2/27/2026(Fri)

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DATE ISSUED
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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."