Pretreatment Categorical User Inspection Report

National Database Information	
Inspection Date: 01/30/2025	Inspection Type: Pretreatment Industrial User
Entry/Exit Time: 09:57 / 13:53	NPDES ID Number: MTPF00103
Inspection ID: 202501_MTPF00103	
Lead inspector and affiliation: Lisa-kay Prideaux, EPA Region 8	

Facility Location Information	
Site/Facility Name & Location: GlaxoSmithKline Vaccines 553 Old Corvallis Road Hamilton, Montana 59840	Email Report to: Paul Melton, Director EHS Paul.x.melton@gsk.com

Contact Information	
	Name(s)/Title
Facility Contacts:	Paul Melton, Environmental Health and Safety Director (primary lead and present during inspection)
	Tyson Burrows, Calibration Supervisor (present during inspection)
	Patrick Ballance, Senior EHS Advisor (present during inspection)
	Curtis Fessler, Site Facility Supervisor (present during inspection)
	Heather Wirt, Production Associate and audit scribe (present during inspection)
	Amber Matzka, Senior EHS Specialist (present during inspection)
	Todd Stewart, EHS Specialist (present during opening conference and records review)
	Joel Thornberg, EHS Specialist (present during inspection)
Authorized Official(s)	Paul Melton, Environmental Health and Safety Director

Areas Evaluated During Inspection		
Permit	**Self-Monitoring Program**	**Pretreatment**
Records	Compliance Schedule	Pollution Prevention
Facility Site Review	Laboratory	Stormwater
Effluent/Receiving Waters	**Operations and Maintenance**	Combined Sewer Overflow
Flow Measurement	Sludge Handling/Disposal	Sanitary Sewer Overflow

Report Review and Signature		
Drafter Signature/Name	Address/Phone Number	Date
LISA-KAY PRIDEAUX Digitally signed by LISA-KAY PRIDEAUX Date: 2025.03.05 13:38:19 -07'00'	U.S. EPA Region 8, Montana Operations Office 10 West 15th Street, Suite 3200 Helena, Montana 59626 406-457-5022	**02.24.2025**
Reviewer Signature/Name	Address/Phone Number	Date
Stephanie Passarelli	U.S. EPA Region 8 1595 Wynkoop Street Denver, Colorado 80202 303-312-6803	**02.28.2025**
Supervisor Signature/Name	Address/Phone Number	Date
EMILIO LLAMOZAS Digitally signed by EMILIO LLAMOZAS Date: 2025.03.05 12:36:59 -07'00'	U.S. EPA Region 8 1595 Wynkoop Street Denver, Colorado 80202	**03/04/2025**
Emilio Llamozas	303-312-6407	

Inspection Narrative and Site Description

GlaxoSmithKline Vaccines (GSK or facility) is subject to 40 CFR Part 403, the General Pretreatment Regulations, as well as the Pharmaceutical Manufacturing Point Source Category Pretreatment Standards at 40 CFR Part 439. GSK is an industrial user of the City of Hamilton's publicly owned treatment works (POTW), which does not have a Pretreatment Program approved by the Environmental Protection Agency (EPA). Therefore, EPA directly oversees compliance of industrial users that discharge to the City of Hamilton POTW and is partnering with the City of Hamilton to ensure the POTW is protected from potential impacts of pollutants discharged from non-domestic sources.

On January 30, 2025, at approximately 10:00 am, an Environmental Protection Agency (EPA) National Pollutant Discharge Elimination System (NPDES) inspector, Lisa-kay Prideaux (inspector) arrived at GSK in Hamilton, Montana, to conduct an Industrial User (IU) inspection. The purpose of the inspection was to evaluate GSK's compliance with the requirements under 40 C.F.R. Part 403 for General Pretreatment Regulations and Part 439 for the Pharmaceutical Manufacturing Point Source Category.

The inspector met with Paul Melton - Environmental Health and Safety Director, Heather Wirt – Production Associate and Audit Scribe, Tyson Burrows – Calibrations Supervisor, Amber Matzka - Environment Health and Safety Specialist, Todd Stewart - Environmental Health and Safety Specialist, Joel Thornberg - Environmental Health and Safety Specialist, Curtis Fessler- Hamilton Site Facilities Supervisor, and Patrick Ballance – Senior Environmental Health and Safety Advisor at the GSK Hamilton office to have an opening conference to discuss the inspection of the facility. After presenting inspector credentials and explaining the purpose of the inspection, Mr. Melton and others presented an overview of the production process and the changes that had occurred at the facility since the last EPA inspection on April 10, 2024. The inspector proceeded to ask a series of questions to help evaluate compliance with 40 C.F.R. Part 439. Observations and photograph descriptions were documented in a bound checklist/notebook. All photographs taken during the inspection are included in the attached photo log and are maintained by EPA in accordance with the Quality Assurance Field Activities Procedure and Standard Operating Procedure.

Facility Description and Process Overview

GSK is one of two vaccine manufacturing facilities in the U.S. for the global healthcare company. GSK's manufacturing facility located in Hamilton Montana, consists of 17 buildings on the campus occupying approximately 241,826 square feet of manufacturing, quality control laboratories, utility operations, and administration. The facility operates five days per week, 20 hours per day, and employs approximately 300 personnel. Approximately 112 of the facility's total employees work in the manufacturing process in two overlapping shifts. The facility shuts down twice a year for maintenance and as an opportunity for invasive projects that would affect the manufacturing processes. These typically occur in the summer for a two to three-week period, and winter for a three to six-week period. Extended shutdowns can occur based on projects and maintenance schedules. At the time of the inspection, the facility was in a shut-down for both manufacturing processes.

The facility manufactures two lines of vaccine adjuvant, an additive carrier to a vaccine to enhance the effectiveness. The first line is a monophosphoryl lipid A (MPL) which is a bacterially derived immunostimulant and is globally approved as an essential component of vaccines. The second adjuvant line is QS-21, an immunostimulant derived from the Chilean Soapbark tree (*Quillaja saponaria*) and was approved in 2023 to be developed at the facility in Hamilton.

The pharmaceutical manufacturing operations for the MPL at the facility consists generally of five parts: fermentation of gram-negative bacteria in growth media (salmonella Minnesota R595 that is inoculated before media growth); extraction of the lipopolysaccharides (LPS) contained in the bacterial cell walls by successive alcohol and chloroform-methanol extractions; the LPS is then converted to MPL by hydrolysis and then purified and reconstituted by triethanolamine (TEOA) before freeze-drying for transportation to other GSK facilities for formulation into final products.

The facility constructed buildings 16 and 17, and in 2023, the facility began the manufacturing of the QS-21 adjuvant. QS-21 naturally occurs in the bark of the Soapbark Tree. The facility receives a 'tea' made from the bark as the primary product to process. The manufacturing process is similar to the MPL process by way of extraction (saponin isotopes from the bark using a chemical process), purifying then freeze-drying the isotopes to create a final API for transportation to other GSK facilities for formulation into final products.

Chemical Storage

Chemicals stored at the facility include Soapbark 'tea', Ethanol, Methanol, Reagent Alchol, Citric Acid, Biocide, and CIP100/CIP200 (cleaning solution), among others. Chemicals are stored in several locations depending on type of chemical. Citric acid and Sodium Hydroxide totes that are in use for the pH neutralization skids are stored on top of dedicated secondary containment (see photos 144 & 148). The facility has an acid storage room, where totes of Citric Acid, Acetic Acid, and other acids are stored (see photo 145); containment is sub-floor and includes leak detection. The facility also has a solvent storage room which includes methanol and reagent alcohol among other chemicals, and includes leak and fume detection and sub-floor containment.

Water usage

The facility acquires its water supply from the City of Hamilton, and according to information submitted as part of the records review, the facility's water usage for 2024 totaled 24,611,000 gallons. The facility uses a portion of the incoming water to create grades of water for use in specific processes; low hydrogen water created using a reverse osmosis system is used in the MPL process, and water for injection (WFI) is created through distillation & recondensing and used in the QS-21 process.

Wastewater

Wastewater is generated from process manufacturing and cleaning operations, utility infrastructure operations consisting of water purification systems, blowdown from the cooling towers and boilers and sanitary wastewaters.

The facility has three evaporative cooling towers, 1900 gallons each cell, and two chillers/booster pumps to push chilled water through the campus and exchange heat. A biocide is used in the cooling system to control growth. Approximately 60 to 120 gallons of biocide are stored on-site, and it is automatically pumped to the cooling system. A daily blowdown occurs automatically at a conductivity of 1,000 µmhos. The facility also has three boilers on site, two at 400 HP and one at 80 HP to provide heat throughout the campus. Boiler treatment chemicals are used to control growth and scaling. The boilers are blown down manually as needed and are evacuated annually for inspection. Boiler blowdown is adjusted with an at-location pH neutralization skid using citric acid. Once neutralized, blow down is sent to the Drain Process (DRP) wastewater collection system.

Waste generated through the MPL process has three avenues of disposal: caustics, solvents, and biowaste. Caustics are produced through the clean in place (CIP) process throughout manufacturing equipment. Caustics includes solutions of CIP 100 and/or CIP 200, caustic potassium hydroxide-based cleaners, and rinse water. Caustic solutions are sent to a pH neutralization tank and adjusted using citric acid (photo 144). The treated wastewater is discharged to the POTW through outfall 001 if the set points are met. The discharge pH setpoints, according to the facility representatives, are between pH 6.2 and 8.8 s.u. All solvent waste (chloroform, methanol, and reagent alcohol) from GSK's fermentation and extraction processes is piped to a 10,000-gallon storage tank, as part of a DRP treatment system (photo 142). The wastewater is initially gravity-fed to a process sump tank, and then an equalization tank prior to moving to the large storage tank. Biowaste is also generated through the MPL fermentation (salmonella) process. Biowaste is fed to the Biokill Decontamination Skid consisting of a buffer tank for storage and then to the autoclave tank where the water is heated to 85°C for ten minutes to kill the salmonella. The wastewater is then cooled back to 60°C and sent to the equalization tank in the DRP treatment system. Both the process sump tank and the biowaste decontamination skid are pumped into the large storage tank (photo 142) prior to being hauled offsite to an approved facility. The process sump tank, Biokill Decontamination Skid and equalization tank are all located in a containment pit that is engineered to handle spills or catastrophic failures of the tanks.

Waste generated through the QS-21 process has two avenues of disposal: caustics and solvents. The process wastewater generated from the cleaning of manufacturing vessels and equipment manufacturing, in the QS-21 process, includes solutions of CIP 100 and rinse water. The rinsate is treated through a dedicated pH treatment system similar to the DRP and pH neutralization skid. The caustic rinsate is adjusted using citric acid (photo 148). The pH of the treated wastewater is measured and when preset parameter limits are reached, it is discharged through outfall 002 to the City of Hamilton’s sanitary sewer system (photo 147). All solvent waste generated from the QS-21 process is piped to the solvent waste storage tank and hauled offsite to an approved facility. According to records provided by the facility, approximately 1,129,394 pounds of waste were hauled off by Veolia in 2024.

Records

After the facility representative provided a background description of the facility operations, the inspector commenced to review facility records. The following records were requested for review in an email dated January 14, 2025, prior to the inspection. Records were made available to review on-site,

as well as electronic copies of the monitoring records sent on January 30, 2025, with a review of the records off-site on February 18, 2025.

- Pretreatment Notice of Discharge Requirements Control Mechanism
- Slug Discharge Control Plan
- Transfer logs for waste materials transferred off-site
- Monitoring records for the timeframe of January to December 2024
  - Discharge Monitoring Reports (DMRs)
  - Original charts from continuous monitoring instruments
  - Daily operational logs
  - In-House Bench Sheets, including flow records and sheets used for completing calculations
  - Laboratory analytical reports
  - Chain of custody forms
  - Quality Assurance Records for Process Control Monitoring
- Records of Laboratory Equipment and Controls
  - Calibration records
  - Maintenance records
- Material Safety Data Sheets for chemicals on facility grounds
- Noncompliance reports

Site review

After facility representative interviews and records review, the inspector was escorted through the facility operations pertinent to wastewater generation, storage and discharge. We started at the DRP waste handling system to include the Biokill Decontamination skid, DRP equalization tank, and large storage tank (photo 142). We then moved to the MPL pH adjustment skid where the continuous pH probe and flow meter were observed (photo 143), as well as the containment for chemicals used at the skid (photo 144). We then went to the acid chemical storage room (photo 145), and the solvent storage room (no photo taken as electronics are not allowed in containment area). The inspector observed where the underground piping is located to transport chemicals from the storage room to the facility operations. We also observed the piping and safety measures for when tank trucks arrive at the facility to reload chemical tanks, or to remove waste from the DRP waste storage tank. We then moved to the QS-21 skid where the continuous pH probes (2), flow meter and sampling port were observed (photo 146), as well as the discharge into the City of Hamilton's sanitary sewer system (photo 147). Containment for chemicals used in the skid were also observed (photo 148).

Closing and Follow-Up

A closing conference was held on-site with Paul Melton, Tyson Burrows, Patrick Ballance, Curtis Fessler, Heather Wirt, Amber Matzka, and Joel Thornberg during which the off-site review of additional records and the process for the issuance of the inspection report was discussed. The inspection concluded at 13:53.