Pretreatment Categorical User Inspection Report

National Database Information	
Inspection Date: 04/10/2024	Inspection Type: Pretreatment Industrial User
Entry/Exit Time: 09:00 / 16:25	NPDES ID Number: MTPF00103
Inspection ID: 202404_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)
	Heidi Sanderson, Site Quality Director (present during opening conference)
	Christian Pruitt, Operations Manager (present during inspection)
	Curtis Fessler, Site Facility Supervisor (present during inspection)
	Theresa Jaqua, QA Systems Lead (present during inspection)
	Ritesh Mahna, Engineering Director (present during opening conference)
	Amber Matzka, EHS Specialist (present during opening conference)
	Todd Stewart, EHS Specialist (present during opening conference)
	Joel Thornberg, (present during site visit and closing conference)
	Amy Cabral, Audit Support (present during inspection)
Person/Company meeting definition of Owner/Operator	GlaxoSmithKline Vaccines
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
Prideaux, LisaKay Digitally signed by Prideaux, LisaKay Date: 2024.06.27 14:20:20 -06'00'	**U.S. EPA Region 8 Helena Office** **10 W 15 Street, Suite 3200** **8-MO** **Helena, Montana 59626** **406-457-5022**	**06/27/2024**
Reviewer Signature/Name	Address/Phone Number	Date
Al Garcia	**U.S. EPA Region 8** **1595 Wynkoop Street** **8WD-CWW** **Denver, Colorado 80202** **303-312-6382**	**06/21/2024**
Supervisor Signature/Name	Address/Phone Number	Date
EMILIO LLAMOZAS Digitally signed by EMILIO LLAMOZAS Date: 2024.06.27 14:12:32 -06'00'	**U.S. EPA Region 8** **1595 Wynkoop Street** **8ECA-W-N** **Denver, Colorado 80202**	**06/27/2024**
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 April 10, 2024, at approximately 9:00 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, Theresa Jaqua - QA systems Lead and Audit Scribe, Heidi Sanderson - Hamilton Site Quality Director, Amber Matzka - Environment Health and Safety Specialist, Todd Stewart - Environmental Health and Safety Specialist, Ritesh Mahna - Engineering Director, Curtis Fessler- Hamilton Site Facilities Supervisor, Christian Pruitt - Hamilton Site Operations Manager, and Amy Cabral -audit support 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 May 6, 2019. 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. 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, 14 hours per day (6 AM to 8 PM), and employs approximately 277 personnel. Approximately 88 of the facility's total employees work in the manufacturing process in two overlapping shifts. The first shift operates from 6 AM to 6 PM and the second shift operates from 8 AM to 8 PM. 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.

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.

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 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.

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 1000 µmhos.

The facility 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 in Building 6 is adjusted with an at-location pH neutralization skid using citric acid. Once neutralized, blow down is sent to the drain process wastewater collection system.

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 February 27, 2024, prior to the inspection. Records were made available to review on-site, as well as electronic copies of the Monitoring records sent with a review of the records off-site on April 11, 2024.

- 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 2023
  - 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

The facility had three pH exceedances for monitoring periods ending May 31, 2023, June 30, 2023, and July 31, 2023. The facility did not complete the notification requirements for the exceedances. The EPA issued a notice of warning on March 5, 2024, for the exceedances and failure of notification requirements. On April 3, 2024, the facility responded with corrective actions taken to prevent pH exceedances as well as provided assurances for future notification requirement adherences.

Site review

After facility representative interviews and records review, the inspector was escorted through the facility operations pertinent to wastewater generation, storage and discharge. Wastewater is generated from process manufacturing, cleaning in place operations, utility infrastructure operations consisting of water purification systems, blowdown from the cooling towers and boilers and sanitary wastewaters.

Waste generated through the MPL process has three avenues of disposal: caustics, biowaste, and solvents. 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, adjusted using citric acid (photos 1 & 2) and then hard piped to the City of Hamilton's sanitary sewer system (photo 3). The process wastewater generated from the MPL pharmaceutical fermentation and extraction processes are piped to a Drain Process Wastewater (DRP) treatment system. According to the Slug Discharge Control Plan the facility discharges approximately 46,000 gallons per day of wastewater. The wastewater is initially gravity-fed to a process sump tank, and then an equalization tank prior to moving through the pH neutralization process. Biowaste is generated through the MPL fermentation (salmonella) process. The biowaste generated from this process is sent to the bio-kill decontamination system (photos 4 & 5) where it is heat treated, cooled, and sent to the DRP tank neutralization process. All processed wastewater moving through the pH neutralization skid is discharged through outfall 001 (photo 4) to the City of Hamilton's sanitary sewer system. Solvents are produced through the MPL extraction processes. All solvent waste (chloroform, methanol, and reagent alcohol) from the MPL process is piped to a solvent waste storage tank located in Building 9 and hauled offsite to an approved facility.

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 pH treatment system similar to the DRP and pH neutralization skid. The caustic rinsate is adjusted using citric acid (photos 1 & 2). The pH of the treated wastewater is measured and when preset parameter limits are reached, it is discharged through outfall 002 (photo 3) to the City of Hamilton's sanitary sewer system. All solvent waste generated from the QS-21 process is piped to a solvent waste storage tank located in Building 17 and hauled offsite to an approved facility.

Closing and Follow-Up

A closing conference was held on-site with Paul Melton, Theresa Jaqua, Curtis Fessler, Joel Thornberg, and Heidi Sanderson during which preliminary findings and the process for the issuance of the inspection report was discussed. The inspection concluded at 16:25.

Findings, Corrective Actions and Recommendations

Finding #1: Discharge of pollutants beyond allowable pH limits.

Specifically, the facility reported a discharge of pH below minimum effluent limit requirements on May 4, 2023 (2.64 S.U.), June 14, 2023 (4.69 S.U.) and July 11, 2023 (3.9 S.U.). The Facility's Notice of Discharge Requirements set a minimum pH effluent limit of 5.0 S.U. with continuous monitoring.

Pretreatment Requirement:

Regulations in 40 C.F.R. § 403.5(b)(2) state pollutants shall not be introduced into a POTW "which will cause corrosive structural damage to the POTW, but in no case Discharges with pH lower than 5.0, unless the works is specifically designed to accommodate sch Discharges." The facility exceeded this limit.

Part II(B) of the Facility's Notice of Discharge Requirements #MTPF00103 indicates the regulated process wastewater discharged through Outfalls 001 and 002 meet the limits identified in the Table 2. The limits in Table 2 are based on the Pharmaceutical Manufacturing, Subpart B Pretreatment Standards for New Sources (PSNS) at 40 CFR §439.27; table 2 shows an instantaneous pH limit of ≥5.0.

Corrective Action:

On April 3, 2024, GSK sent a letter to the EPA with a response to the March 5, 2024, Notice of Warning which included the pH limit exceedances. GSK initiated an internal corrective and preventive action plan which identified seven tasks to address contributing factors, including, but not limited to preventative maintenance practices, reconfiguring data displays and tightening neutralization targets. No additional corrective action is required at this time.

Finding #2: Failure to report effluent exceedances to the EPA and POTW within the required timeframes.

Specifically, the facility did not contact the EPA and the POTW to report the pH exceedances noted in Finding #1 within the required 24 hours of becoming aware of the violation. The facility exceeded the

required pH limits on May 4, 2023, June 14, 2023, and July 11, 2023. The facility notified the EPA and the POTW on July 28, 2023.

Pretreatment Requirement:

Part III.D of the Facility's Notice of Discharge Requirements and in 40 C.F.R. § 403.12(g)(2), the facility is required to provide notification to the EPA and the POTW within 24 hours of becoming aware of the violation. The facility shall also repeat the sampling and analysis and submit the results of the repeat analysis to the EPA within thirty (30) days after becoming aware of the violation.

Corrective Action:

On April 3, 2024, GSK sent a letter to the EPA with a response to the March 5, 2024, Notice of Warning which included the noncompliance notification. GSK initiated an internal corrective and preventive action plan which identified seven tasks to address contributing factors, including, but not limited to improved callout instructions, alarm functions, and real-time management notifications to, in turn notify both the EPA and POTW. The facility's sampling of pH is a continuous monitor, resulting in automatic repeat sampling. No additional corrective action is required at this time.

Finding #3: Late submittals of DMRs.

The July 31, 2023; August 31, 2023; September 30, 2023; October 31, 2023; November 30, 2023, and December 31, 2023, DMR self-monitoring reports, as well as the second semi-annual periodic compliance report including their semi-annual flow and pH data, were submitted on February 5, 2024, 5 days after the end of the reporting period. Part II(B) and Table 3 of the Facility's Notice of Discharge Requirements #MTPF00103, and 40 C.F.R. §403.12(e), require self-monitoring reports and periodic compliance reports be submitted to the EPA and the Hamilton POTW. The periodic compliance reports need to be submitted at the end of the reporting period because the report is certifying compliance for the complete monitoring period. The semi-annual periods are January 1 to June 30 and July 1 to December 31. Therefore, reports would be due respectively by July 31 for the first half of the year and by January 31 for the second half of the year (one month after the compliance period ends).

Pretreatment Requirement:

According to the requirements at 40 C.F.R. §403.12(e), states "Any Industrial User subject to a categorical Pretreatment Standard (except a Non-Significant Categorical User as defined in §403.3(v)(2)), after the compliance date of such Pretreatment Standard, or, in the case of a New Source, after commencement of the discharge into the POTW, shall submit to the Control Authority during the months of June and December, unless required more frequently in the Pretreatment Standard or by the Control Authority or the Approval Authority, a report indicating the nature and concentration of pollutants in the effluent which are limited by such categorical Pretreatment Standards. In addition, this report shall include a record of measured or estimated average and maximum daily flows for the reporting period for the Discharge reported…"

Part II(B)(1) of the facility's Notice of Discharge Requirements #MTPF00103 states "All regulated process wastewater discharged through Outfalls 001 and 002 shall meet the limits identified in the

Table 1. The limits in Table 1 are based on the Pharmaceutical Manufacturing, Subpart B Pretreatment Standards for New Sources (PSNS) at 40 CFR §439.27."

Part III(B)(1) of the facility's Notice of Discharge Requirements #MTPF00103 states, "Periodic Compliance Reports are due by the dates listed below and shall not be submitted until the compliance monitoring period is complete. The report shall contain information from the associated compliance monitoring period."

Table 3 - Periodic Compliance Reporting Frequency

Compliance Monitoring Period	Due Date
January through June	July 31
July through December	January 31

Corrective Action:

Submit self-monitoring reports to the EPA by July 31 (for the first half of the year) and by January 31 (for the second half of the year). No additional corrective action is required at this time.

Recommendation #1:

The facility should consider including the requirements identified in Finding #2, notification of noncompliance within 24 hours, and resample within 30 days of becoming aware of the noncompliance, in the facility's Emergency Response Plan. The facility should also consider including the notification of noncompliance requirement as a part of annual employee training for all environment health and safety employees.

Recommendation #2:

The facility should consider including specific training for waste stream health indicators, reporting, emergency response, spill prevention control and countermeasure plan, and possible corrective actions as a part of annual employee training for all personnel working with or around any waste stream activity.