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Enclosure 2

GSK-Hamilton Fact Sheet

Pretreatment ICIS Number:	MT-PF00103
Facility Name and Address:	Corixa Corporation dba GlaxoSmithKline Vaccines – GSK-Hamilton 553 Old Corvallis Road Hamilton, MT 59840
Authorized Representative and Facility Contact:	Suzette Smith EHS Manager 553 Old Corvallis Road Hamilton, MT 59840 406-375-2748/suzette.m.smith@gsk.com
Applicable Pretreatment Regulations:	Pharmaceutical Manufacturing Point Source Category, Subpart B-Extraction, New Source
Categorical Reference:	40 CFR Part 439 (Pretreatment Standards for New Sources at 40 CFR § 439.27)
Receiving POTW/Collection System:	Hamilton POTW MTDEQ Permit No. MT-0020028 1001 New York Avenue Hamilton, MT 59840
POTW Contact:	Donny Ramer, Public Works Director 920 New York Avenue Hamilton, MT 59840 (406) 363 -6717/dpw@cityofhamilton.net

Section 1 GSK-Hamilton Process Description Operation

1.1 GSK-Hamilton Facility Overview

The GSK Pharmaceuticals location in Hamilton is one of two vaccine manufacturing facilities in the U.S. for the global healthcare company. The manufacturing facility at GSK-Hamilton (facility), consists of 15 buildings on the campus located in Hamilton, MT. The facility's buildings occupy approximately 193,000 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 200 people. Fifty 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 (40 employees) and the second shift operates from 8 AM to 8 PM (10 employees). The facility shuts down twice a year for maintenance and as an opportunity for invasive projects that would affect the manufacturing processes. These occur in the summer for generally a shorter 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's primary business activity is classified by the North American Industry Classification System (NAICS) as 325412. NAICS # 325412 comprises establishments primarily engaged in manufacturing in-vivo diagnostic substances and pharmaceutical preparations (except biological) intended for internal and external consumption in dose forms, such as ampoules, tablets, capsules, vials, ointments, powders, solutions, and suspensions.

The facility manufactures monophosphoryl lipid A (MPL), a bacterially-derived immunostimulant or adjuvant, that is an essential component of vaccines. The facility produces MPL on a batch basis that may occur over a period of days. The MPL produced at the facility is shipped offsite to other GSK locations for formulation in vaccines. In addition, the facility constructed Buildings 16 and 17 in calendar year 2020 to manufacture QS-21, another adjuvant, which will be produced and shipped offsite for formulation into final products at other GSK locations.

The buildings on the facility comprise of the following:

- Building 1 and 2 – Building 1 demolished in 2018 and Building 2 is converted to storage of documents.
- Building 3 – labs, office
- Building 4-5 – idle buildings
- Building 6 – Boilers, pH neutralization skid for boiler blowdown and cooling tower
- Building 7 – Chiller/cooling tower
- Building 8 – Electrical gear, generator
- Building 9 – Testing/Receiving/Storage of chloroform, methanol, alcohols, – methanol, ethanol, (1250L) and chloroform (1000L) storage totes, lab chemical storage units. Solvent storage and distribution to building 12, solvent waste storage – a spill containment trench is located in this building.
- Building 10 – Generator
- Building 11 – Manufacturing support – acid storage and waste treatment, room 106 is a CIP-100 acid storage area, includes secondary containment, pH neutralization skid for MPL wastewater
- Building 12 – MPL production- building constructed in 2006-2007

- Building 13 – QC-Production
- Building 14 – Administrative
- Building 15 – cafeteria – training room
- Building 16 – QS-21 production– anticipated 2021, pH neutralization skid for QS-21 wastewater
- Building 17 – QS-21 Chemical Storage

The Google Earth view of the facility's campus is shown in Figure 1 (note: Building 16 is not shown in Figure 1 but will be located on the NW quadrant of the campus).

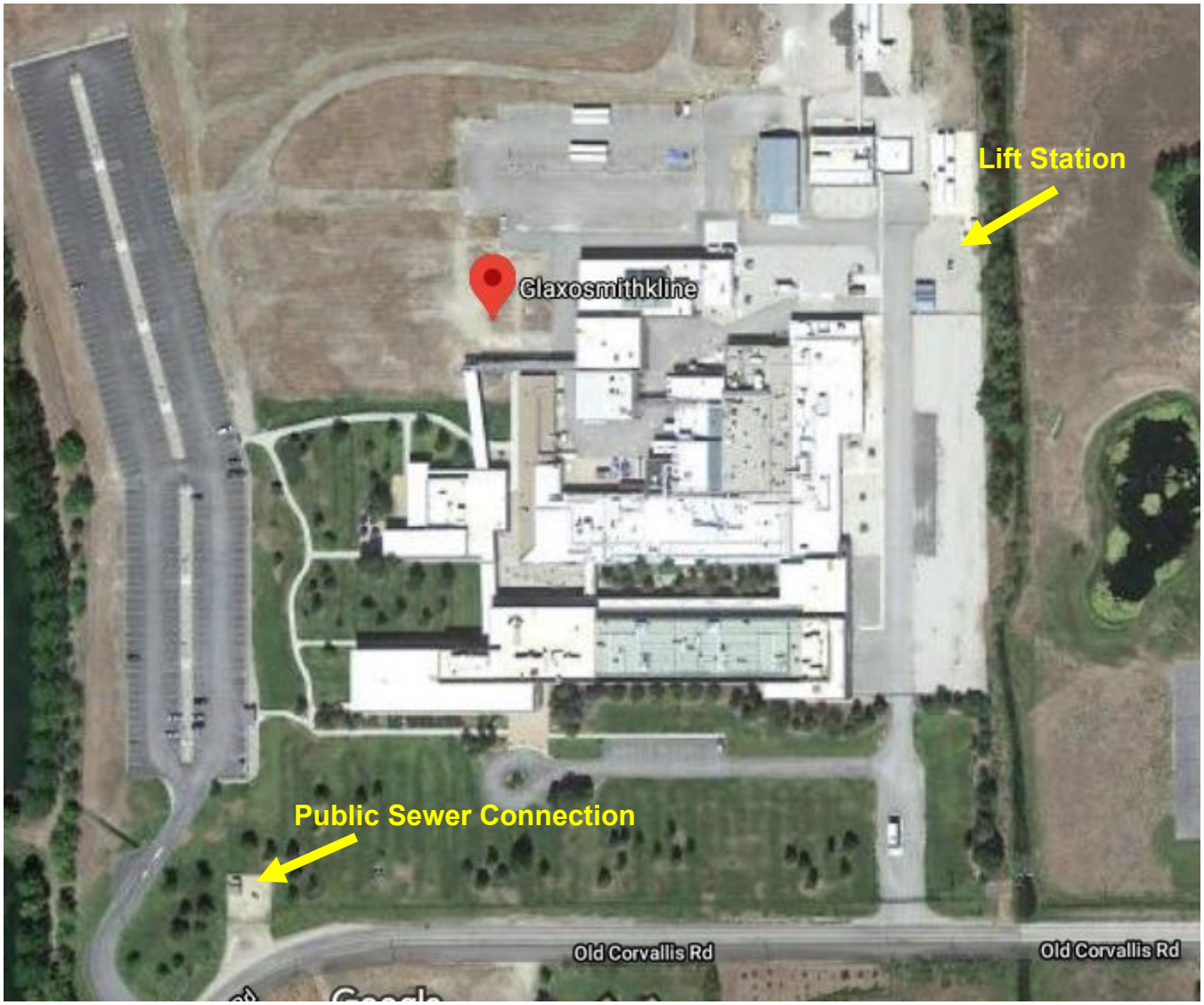

Figure 1 - GSK-Hamilton Facility, Google Earth View

The facility layout for the campus shown in Figure 2 was excerpted from Site Drainage and Dry Well Layout- document # HA 00 01.00 00280 submitted by the facility to identify the planned location of Building 16 on the campus. Note: The MPL production in Building 12 is illustrated by a pink color and the planned QS-21 production in a Building 16 is illustrated by a light blue color on the facility layout.

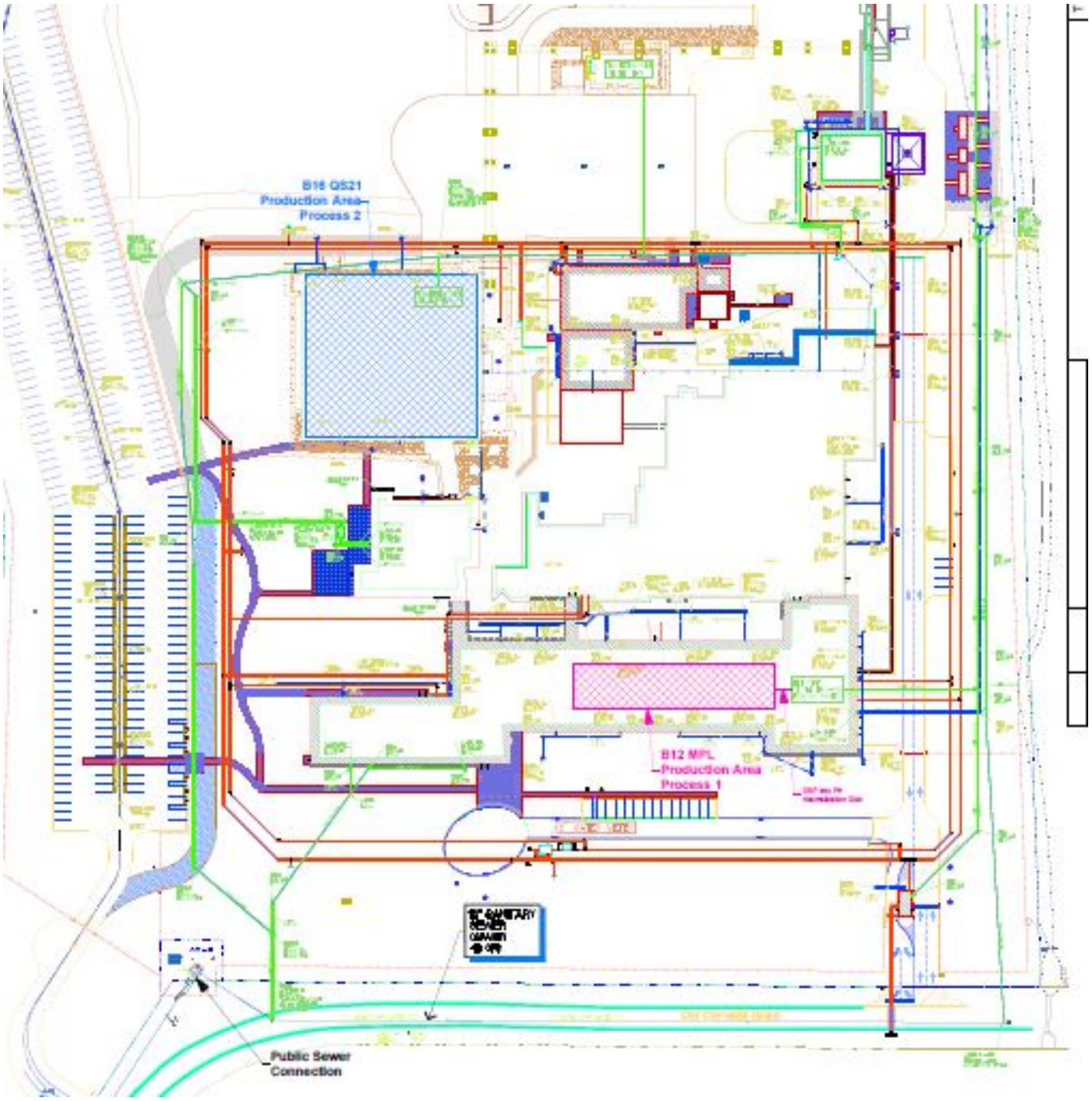

Figure 2 - GSK-Hamilton Facility Layout

1.2 Raw Materials and Chemicals Storage and Spill Potential

Table 1 lists the chemicals the facility uses in its MPL and QS-21 adjuvant manufacturing processes. EPA did not receive specific volumes or mass for all chemicals, but the daily usage of these chemicals and the handling of these chemicals were evaluated for spill and slug discharge potential. (Note: The daily usage of chemicals is classified as Confidential Business Information (CBI) by the facility and is not included in Table 1).

Table 1 – Raw Materials and Chemicals Overview

Chemical	Volume/Mass	Storage Location	Process/Equipment Use
Acetic Acid	(1)	Chemical Storage in BLDG 11	MPL/QS-21 Batch Processes
Acetone	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Acetonitrile	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Ammonium Acetate	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Ammonium Hydroxide	~12 Liters	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
CB Resin	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Casamino Acid	55,200 grams	Chemical Storage in BLDG 11	MPL/QS-21 Batch Processes
Chloroform	8,000 Liters (closed system)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
CIP 100	3,000 Liters (closed system)	Chemical Storage in BLDG 11	MPL/QS-21 Batch Processes
CIP 200	(1)	Chemical Storage in BLDG 11	MPL/QS-21 Batch Processes
Citric Acid	(1)	Chemical Storage in BLDG 11	MPL/QS-21 Batch Processes
Dextrose	60 Kilograms	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Electrolyte Solution	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes

Chemical	Volume/Mass	Storage Location	Process/Equipment Use
Ferric Chloride	4.56 grams	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Hydrochloric Acid	(1)	Chemical Storage in BLDG 11	MPL/QS-21 Batch Processes
Isopropyl Alcohol Spray	10 cans	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Isopropyl Alcohol	10-gallon containers	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Magnesium Sulfate	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Methanol	8,000 Liters (closed system)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
pH Buffers 4 and 7	Six 500 mL bottles	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Phenyl resin	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Polystyrene	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Potassium bicarbonate	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Potassium carbonate	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Potassium hydroxide	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
PVPP	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Reagent Alcohol	8 Liters	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Sodium chloride	6,600 grams	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Sodium hydroxide	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Sodium Trihydrate	~300 grams	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes

Chemical	Volume/Mass	Storage Location	Process/Equipment Use
Triethylamine	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
YMC Resin	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes
Vesta Syde 5Q	(1)	Chemical Storage in BLDGs 9 or 17	MPL/QS-21 Batch Processes

(1) The chemicals are contained in various types of containers, which include small glass and plastic bottles of varying capacity (mL up to gallons, drums, totes, and tanks). Drums are typically constructed of painted carbon steel, stainless steel, or plastic depending on the material stored. Totes are constructed of stainless steel or plastic depending on the material stored. The facility's tanks are constructed of steel or stainless steel depending on the material stored.

Bulk chemicals for processing are currently stored in Building 9. Chloroform, methanol, and reagent alcohol are stored in totes filled and supplied by the manufacturer. These raw materials are hard piped into the production areas of Building 12. The chloroform totes are 1,000 liters and the methanol and reagent alcohol are 1,250 liters. The process waste involving solvents is then hard piped back into Building 9 where it is stored in a 10,000-gallon aboveground storage tank. Building 9 is a fit-for purpose building designed for the safe storage of solvents and solvent waste, contains no floor drains and the building is equipped with sufficient secondary containment in the event of a leak/spill where the contents will not exit the building.

Hard piping for supply solvents and waste solvents are located in a containment trench that runs outside from Building 9 to Building 12. This containment trench has solvent and liquid detection, which alarms if solvent is detected, at which time the facility Emergency Response Team (ERT) will investigate and act as needed.

Supply acetonitrile for QS-21 manufacturing will be stored in Building 17 in a 30,000-liter stainless steel tank. Similar to Building 9, this will be a fit for purpose with adequate secondary containment and control in place to detect any potential leaks. Acetonitrile is hard piped from Building 17 to Building 16 for manufacturing use, and waste will be hard piped back to Building 17 and stored in a 60,000-liter stainless steel solvent waste tank.

According to the facility's slug discharge control plan, the facility's production activity is mainly a hard-piped closed process. Solvents used in the process are hard piped to the equipment. CIP100 is used for clean in place of the process equipment and is also hard piped. There is limited chemical handling and addition by personnel in the process. The facility employs numerous engineering controls to prevent spills, notify facility personnel of spills, and control spills if they occur. Examples of these controls include:

- Engineering controls
- Secondary containment
- LEL metering
- Chloroform detection

- Low level exhaust
- Interlocks to shut down solvent supply
- Flammable and corrosive cabinets

Transfer and transport of materials occurs at multiple locations throughout the facility. Most of the processes are hard piped, but transfer and transport of materials are conducted by trained personnel, who are aware of the spill prevention and cleanup procedures. Minor spills and leaks occur due to handling of chemicals used in laboratories and for processing, these are all captured under facility incident reporting program and investigated for root cause and corrective actions are put in place as results of investigations. Operators are required to immediately escalate any spill or non-routine activity that would enter a drain. The most likely scenario for a slug discharge would be a process batch inadvertently drained to a process waste system instead of solvent waste, which leads to the pH skid and then to sanitary sewer if this was not identified by the operator.

In the event that the spill or emergency condition cannot be managed by the facility's on-site personnel or the ERT, the facility will call in the local fire department to support the containment and the facility's emergency response contractor, WCEC, to handle the cleanup. Any release of hazardous material off-site, such as during transport, would be handled by Verisk 3E, the Department of Transportation's (DOT) emergency responders.

1.3 Pharmaceutical Manufacturing Process Overview

1.3.1 Water Supply

According to the permit application, the facility acquires its water supply from the City of Hamilton, water service account number 410000-00. The facility averages 54,746 gallons per day (gpd) and estimates its onsite water consumption by the following:

- Non-contact cooling water –12,500 gpd
- Boiler feed – 1,900 gpd
- Manufacturing process – 15,697 gpd
- Domestic Use – 20,369
- Other – 4,280 gpd

Figure 3 provides a water balance for the facility's premises.

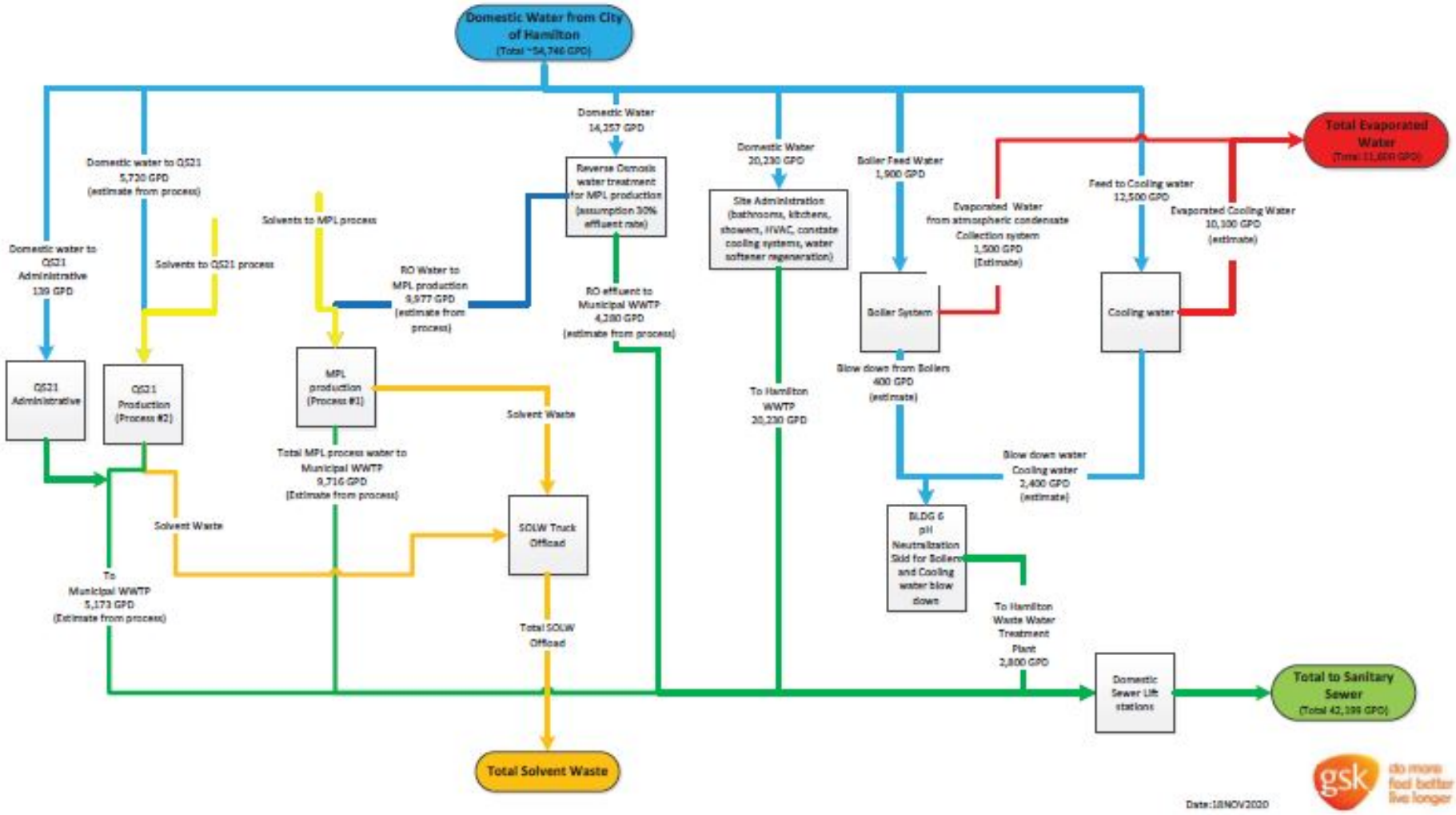

Figure 3 – GSK-Hamilton Facility Water Balance

The MPL pharmaceutical manufacturing operations at the facility consists of the following process stages: (Note: The specific MPL manufacturing processes for fermentation, extraction and purification were claimed as CBI by the facility in the application. The following is a general description of the MPL manufacturing process and the wastestreams generated.)

- Fermentation of gram-negative bacteria in growth media,
- Extraction of the concentrated cell mass, and
- Purification of this intermediate product.

1.3.2 Fermentation Process

Master seed stock is grown in growth media into working seed; the facility uses a species of salmonella (Minnesota R595) that is inoculated in the fermenter vessel. Working seed are added with a nutrient base until a turbidity criterion is reached. The 750-liter process fermenters are cleaned with a clean-in-place (CIP) unit contained in separate rooms and uses solutions of CIP 100, CIP 200, and rinse water. The cleaning wastewater is discharged into the Drain Process Wastewater Collection (DRP). The biowaste generated from this process is first sent to the bio-kill decontamination system, then to the DRP.

The intermediate product (i.e., cell mass) from the process fermenters are harvested in a 625-liter holding tank. The product is sent to refrigeration and the holding tank is rinsed with water to dispose of the media. The process wastewater from the holding tank is discharged to the DRP. For every two fermentations, one extraction is done.

The glassware from the fermentation processes are washed in two washers that operate about fifteen hours/day or about six washes/day using CIP 100 detergent and 300-liter LPW. The dishwashing wastewater is neutralized and discharged to the DRP.

1.3.3 Extraction Process

The concentrated cell mass then undergoes extraction. The extraction process runs overnight, and the excess solvents are evaporated. The 50-L glass vessels are cleaned using a CIP process with a solution cycle and five rinse cycles, the cleaning wastewater is sent to the DRP. The product is crude MPL at this stage of the process. The next step in the process uses solvents to further refine the MPL. The waste solvent from this process is piped to the solvent waste storage tank in Building 9. The product is reconstituted and the final product in bulk powder form is inspected, stored and shipped.

1.3.4 Solvent Waste Management from the MPL and QS-21 Extraction Processes

All solvent waste (chloroform, methanol, and reagent alcohol) from the MPL extraction process in Building 12 is piped to a 10,000-gallon storage tank located in Building 9. The solvents are captured in satellite containers, dispersed in water and hauled offsite to Buzzi Unicem in Cape Girardeau, Missouri for fuels blending. According to the facility's permit application, the facility generates about 45,000-gallons of solvent waste from the MPL process annually and anticipates generating 300,000 gallons of solvent waste from the QS-21 process annually. The MPL process schematic is shown in Figure 4.

The facility will be employing a similar process for the QS-21 manufacturing process in Building 16. The supply acetonitrile for QS-21 manufacturing will be stored in Building 17 in a 7,925-gallon stainless steel tank. Acetonitrile is hard piped from Building 17 to Building 16 for manufacturing use and waste solvent

from the QS-21 manufacturing process will be hard piped back to Building 17 and stored in a 15,850-gallon stainless steel solvent waste tank, as shown in the QS-21 process schematic in Figure 5.

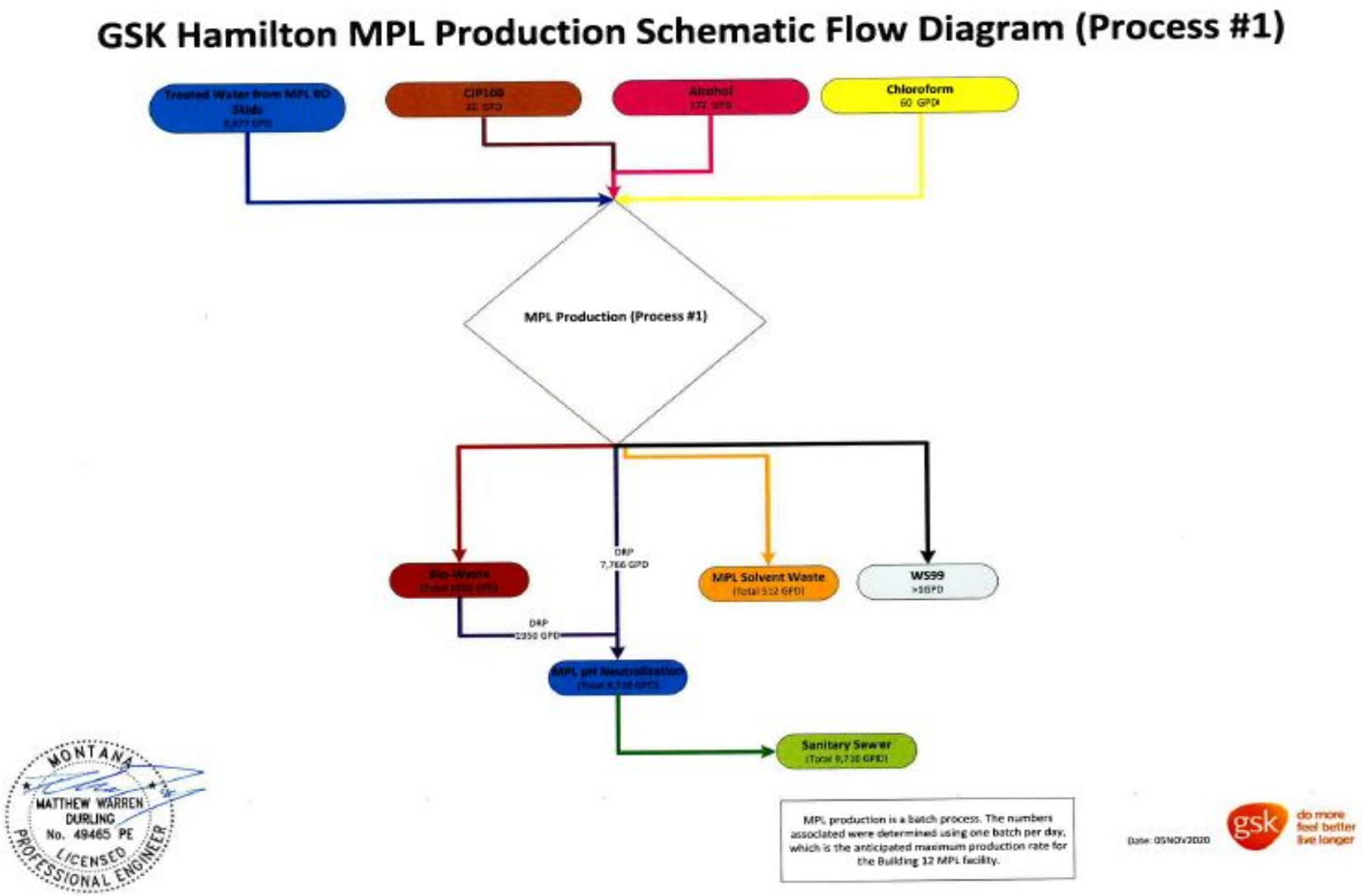

Figure 4 - MPL Process Schematic

1.3.5 Building 16 – QS-1 Production (estimated in 2021)

In 2021, the facility is adding a new manufacturing building and production line for QS-21 adjuvant. QS-21 naturally occurs in select wood bark. The manufacturing process is similar to the current MPL extraction process: (Note: The specific QS-21 manufacturing processes for extraction and purification are claimed as confidential business information in the application. The following is a general description of the QS-21 manufacturing process and the wastestreams generated.)

- Extraction of the QS-21 isolate from the bark using chemical processes,
- Lyophilizing to create the final API, which will be shipped to other GSK locations for formulation into final products.

The annual output will increase to several kilograms of product per year total as manufacturing increases upon successful completion of the initial engineering lots into final production. The process will create three independent aqueous waste streams:

1. Process wastewater generated from the cleaning of manufacturing vessels and equipment using CIP 100, a caustic potassium hydroxide based cleaner. This cleaning rinsate will be hard piped into a pH neutralization system and the pH will be adjusted prior to discharge into the City of Hamilton POTW system. The estimated volume of process wastewater from the QS-21 manufacturing process is 3,980 gal/day.
2. Sanitary sewer from office and administrative activities discharging into the City of Hamilton POTW system; and,
3. A solvent wastewater stream hard piped into a 60,000-liter solvent waste storage tank located in building 17 and which will be hauled offsite to a RCRA permitted transfer, storage and disposal facility.

The QS-21 process schematic is shown in Figure 5.

1.3.6 Building Cooling and Boiler Systems

The facility has three evaporative cooling towers 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 @ 400 HP and one @ 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.

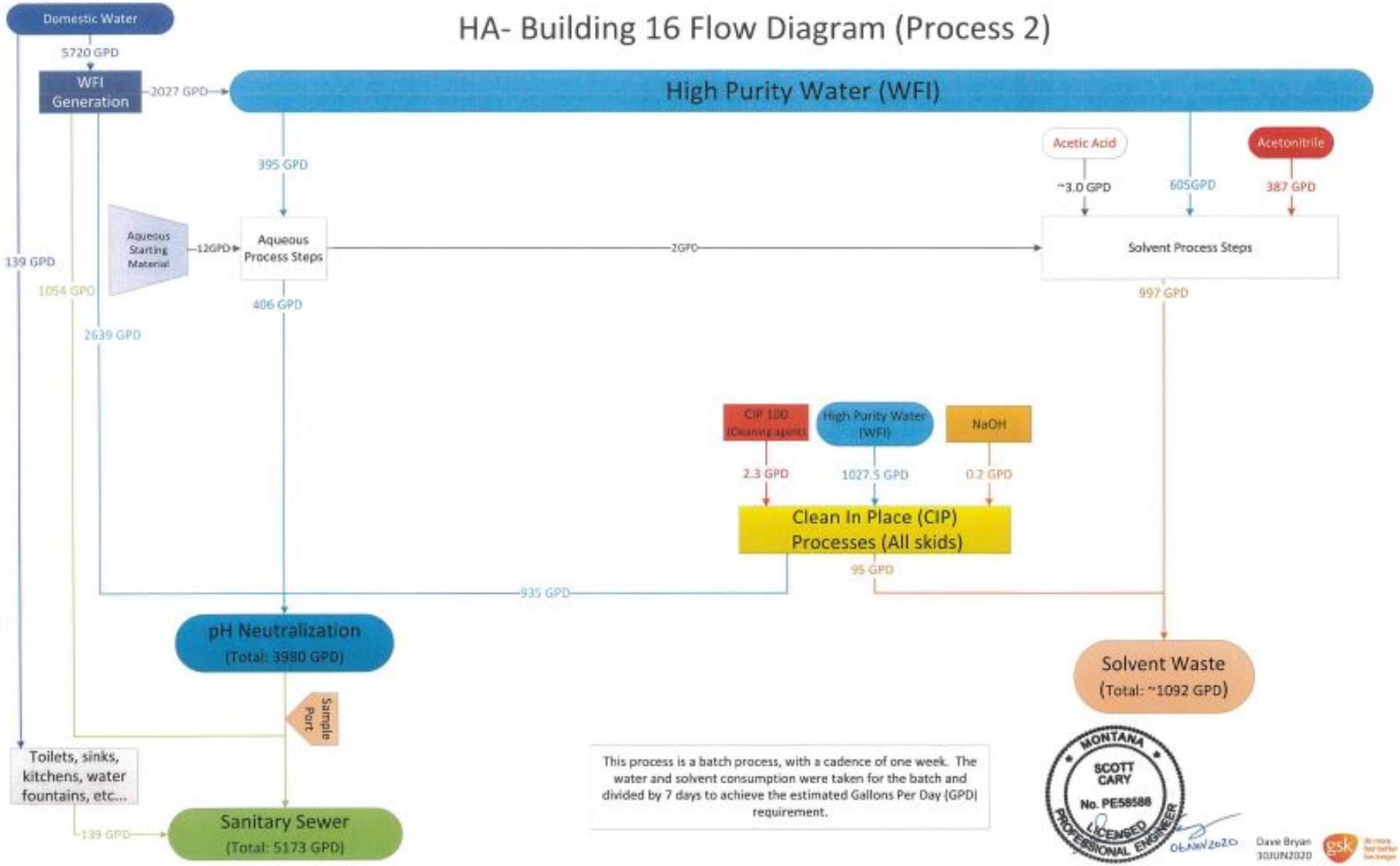

Figure 5 - QS-21 Process Schematic

1.3.7 Process Wastewater Treatment

1.3.7.1 Building 11 – MPL Wastewater Treatment

The process wastewater generated from the pharmaceutical fermentation and extraction processes in Building 12 are piped to a DRP treatment system, located in Building 11. The wastewater is initially collected in a 1,000-liter DRP sump tank (Figure 6) and then a 12,000-liter DRP equalization or buffer tank (Figure 7). Both tanks are located in a containment pit that is engineered to handle spills or catastrophic failures of the tanks.

The salmonella-containing biowaste from the cell culture and harvest stages in the MPL fermentation process is sent to the bio-kill decontaminant system and is collected in a 5,000-L holding tank to autoclave for thermal disinfection (Figure 8). The autoclaved and decontaminated wastewater is then discharged to the DRP treatment system's equalization tank.

Figure 6 - Building 11, DRP Sump Tank-1,000-L

Figure 7 - Building 11, DRP Equalization Tank, 12,000-L

Figure 8 - Building 11, Bio-Kill Decontamination

The wastewater from the DRP 1,000-L sump tank and 12,000-L equalization tank is sent to a pH neutralization skid for pH adjustment. The pH neutralization skid (Figure 9) is an automated system that uses citric acid to adjust the pH of the DRP wastewater prior to entering the sanitary sewer. The neutralization tank is approximately 500 liters. The treated wastewater is discharged to the sanitary sewer if it is between the pH setpoints from 6.5 to 8.5 and a temperature <40°C. Any exceedances of these pH and temperature setpoints triggers alarms within the building management system and shuts down the pH neutralization and discharge. This requires an investigation by technical staff to determine the fault and restart the system. The treated wastewater is discharged to a 6-inch sewer line leading east from Building 11 (Figure 10). This discharge location is identified as Outfall 001.

Figure 9 - Building 11, pH Neutralization Skid

Figure 10 - Outfall 001-Discharge from pH Neutralization Skid in Building 11

1.3.7.2 Building 16 – QS-21 Wastewater Treatment

The planned QS-21 manufacturing process will only generate cleaning wastewaters that will be treated through a pH treatment system, similar to DRP and pH neutralization skid in Building 11. The pH neutralization skid will operate and discharge if the treated wastewater is between the pH setpoints from 6.5 to 8.5 and temperature < 40°C. The planned pH neutralization skid was submitted in the permit application and is shown in Figure 11. The discharge from the pH neutralization skid, identified as Outfall 002 is shown in Figure 12.

There are no cell growth stages and biowastes generated in the QS-21 manufacturing process, therefore autoclave thermal disinfection is not necessary.

Figure 11 - Building 16- pH Neutralization Skid

Figure 12 - Outfall 002, Discharge from pH Neutralization Skid in Building 16

1.3.7.3 Building 6 – Boiler and Cooling Tower Blowdown

The boilers and cooling tower blowdown wastewaters in Building 6 are pH treated to setpoints of 6.5 to 8.5 and a temperature setpoint of 32°C to minimize high or low pH from entering the sanitary sewer system. The pH neutralization system discharges an average of 2,800 gpd. pH adjustment is attained by a combination of citric acid and sodium hydroxide solutions.

1.3.8 MPL and QS-21 Process Discharges to the Sanitary Sewer

The treated MPL process wastewater is discharged from Building 11 into a 6-inch sewer line that flows 130 feet east and connects to a 6-inch sewer line that flows approximately 400 feet north to the East Duplex lift station located on the east side of the campus. The lift station pumps the wastewater 764 feet south through a 4-inch force main. The 4-inch main ties into an existing 10-inch sewer line that flows west along Old Corvallis Road. The 10-inch sewer main connects to a 12-inch sewer main that ties into a public sewer utility parcel located on the southwest corner of the facility.

The treated QS-21 process wastewater will be discharged from Building 16 into an 8-inch sewer line that flows 244 feet west into the West Duplex lift station. The wastewater is pumped 780 feet through a six-inch force main, where it connects to the 12-inch sewer main located along Old Corvallis Road and to the public sewer utility parcel. See Figure 2 for the sewer service lines from Buildings 11 and 16 to the City of Hamilton sanitary sewer collection system.

1.4 Wastewater Discharge Sources and Flows

The facility provided the following wastewater source and discharge volumes:

1.	MPL process wastewater	8,100 gpd
2.	QS-21 process wastewater (estimated)	1,000 gpd for validation and is projected to increase
3.	Non-contact cooling water	2,400 gpd
4.	Boiler blowdown	400 gpd
5.	Sanitary	20,369 gpd
6.	Reject RO water - MPL Water Treatment (Figure 3)	5,334 gpd

Section 2 Applicable Pretreatment Regulations

The facility is subject to the Pharmaceutical Manufacturing Point Source Category found in 40 CFR Part 439, Subpart B – Extraction Products. These regulations in this subpart applies to discharges of process wastewater resulting from the manufacture of pharmaceutical products by extraction.

Subpart A-Fermentation of the Pharmaceutical Point Source Category is applicable to "process operations that utilize a chemical change induced by a living organism…to produce a specified product" – (40 CFR § 439.11(a)). Further, 40 CFR § 439.11(b) defines product as "pharmaceutical products derived from fermentation processes." The facility uses the fermenters solely to increase cell mass and there is no pharmaceutical product generated in the fermentation process. The facility generates the pharmaceutically active product in the extraction process. Therefore, Subpart A-Fermentation of the Pharmaceutical Point Source Category does not apply.

The facility constructed Building 12 in 2006 and 2007 and consolidated MPL manufacturing in this

building. The facility will begin QS-21 manufacturing in Building 16 in 2021. The facility is considered to be a new source to the Pharmaceutical Regulations found in 40 CFR Part 439, Subpart B-Extraction. The new source date for the Pharmaceutical Categorical Pretreatment Standards, Subparts A-D is May 2, 1995. "New Source" is defined in 40 CFR § 403.3(m)(1).

Section 3 Pretreatment Requirements

The Pretreatment Regulations found in 40 CFR Part 403 impose Pretreatment Requirements on the facility and its process wastewater discharge to the POTW. These Pretreatment Requirements include monitoring, reporting, and notification requirements found in 40 CFR Sections 403.12, 403.16, and 403.17 and requirements specific to the Pharmaceutical Point Source Category found in 40 CFR Part 439. The applicable effluent limits are listed in the Pharmaceutical Pretreatment Standards for New Sources (PSNS) at 40 CFR § 439.27.

The Pretreatment Requirements apply at Outfalls 001 and 002. The outfalls are defined as follows:

Outfall 001: Discharge of the treated MPL process wastewater from the pH neutralization skid in Building 11 to a 6-inch sewer line (Figure 11).

Outfall 002: Discharge of the treated QS-21 process wastewater from the pH neutralization skid in Building 16 to an 8-inch sewer line (Figure 12).

3.1 Discharge Limitations

The Pharmaceutical PSNS found in 40 CFR §439.27 establish the limitations for listed pollutants. Any new source subject to this subpart that introduces pollutants into a POTW must comply with 40 CFR part 403 and achieve the following PSNS at Outfalls 001 and 002:

Table 2 - Pharmaceutical Subpart B PSNS -- 40 CFR § 439.27

Pollutant	Daily Maximum (mg/L)	Monthly Average (mg/L)
Acetone	20.7	8.2
n-Amyl acetate	20.7	8.2
Ethyl acetate	20.7	8.2
Isopropyl acetate	20.7	8.2
Methylene chloride	3.0	0.7

3.2 Reporting, Monitoring, Notification and Record-Keeping Requirements

The reporting, monitoring, notification, and record keeping requirements are found in 40 CFR Part 403 of the General Pretreatment Regulations and include the following:

- **Baseline Report and 90-Day Compliance Report Monitoring Requirements** (40 CFR § 403.12(b) and (d); 40 CFR § 403.12(g));

- **Periodic Compliance Report Monitoring Requirements** (40 CFR§ 403.12(e); 40 CFR§ 403.12(g))
- **Potential Problem and Slug Reporting** (40 CFR § 403.12(f))
- **Effluent Violation Reporting and Resampling** (40 CFR § 403.12(g)(2))
- **Notification of Changed Discharge** (40 CFR § 403.12(j))
- **Hazardous Waste Discharge Notification** (40 CFR § 403.12(p))
- **Upset Effect, Notification, and Reporting** (40 CFR § 403.16)
- **Bypass Requirements Notification** (40 CFR § 403.17)
- **Report Signatory Requirements** (40 CFR § 403.12(l))
- **Retention of Records** (40 CFR § 403.12(o))

3.2.1 QS-21 Baseline Monitoring Report

The facility submitted a baseline monitoring report on September 16, 2020, as required by 40 CFR § 403.12(b). The regulations require IUs to submit information on new sources (QS-21 manufacturing process) at least 90 days prior to commencement of discharge. The baseline monitoring report provides the required information regarding the QS-21 manufacturing process in Building 16, scheduled to commence in 2021. In addition, the baseline monitoring report provided information on the method of pretreatment the source intends to use to meet applicable pretreatment standards as required in 40 CFR § 403.12(b).

3.2.2 Reporting Requirements

40 CFR § 403.12(e) requires industrial users "subject to a categorical Pretreatment Standard" to monitor and report twice per year "unless required more frequently…by the Control Authority," which is the EPA in this case. The reporting requirements for the facility are twice a year, as required in 40 CFR § 403.12(e) to ensure compliance with the Pretreatment Standards found in Subpart B of the Pharmaceutical regulations (40 CFR § 439.27).

The facility will submit reports through the NetDMR electronic reporting system, as described in §3.3.1(1). Table 3 lists the deadline due dates based on semi-annual reporting:

Table 3 – GSK-Hamilton Reporting Frequency

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

3.2.3 Monitoring Requirements

40 CFR § 403.12(g)(3) requires that periodic compliance reports "must be based upon data obtained through appropriate sampling and analyses performed during the period covered by the report, which data are representative of the conditions occurring during the reporting period."

The facility has a daily process discharge that averages about 9,716 gallons per day from Outfall 001 and is projecting a daily discharge of 3,980 gallons per day from Outfall 002. The EPA is requiring a quarterly

monitoring frequency to gather an adequate dataset and determine compliance with the Pharmaceutical Categorical Pretreatment Standards. The monitoring for the pollutants of concern must be performed as a grab sample since these are EPA Method 624 volatile organic compounds (purgeable organics).

Based on the EPA's evaluation of the facility's discharge characteristics, EPA is establishing a monitoring frequency of grab samples taken at 4-hour or equally-spaced timed intervals to generate four grab samples for the discharge throughout the production day at Outfalls 001 and 002 to ensure the analytical data is representative. In addition, the facility is required to continuously measure the wastewater discharges at Outfalls 001 and 002 for pH and flow. At a minimum, the pH and flow measurements shall be recorded at one-minute intervals on a continuous recording device. The discharges from the facility at Outfalls 001 and 002 are subject to the following monitoring requirements, listed in Table 4.

All analyses shall be performed in accordance with test procedures established in 40 CFR Part 136. Sampling methods shall be those defined in 40 CFR Part 136 and 40 CFR Part 403, as further described in the Notification of Discharge Requirements.

Table 4 – GSK-Hamilton Monitoring Frequencies for Outfalls 001 and 002

Pollutant	Sample Type	Sampling Frequency
Flow	Continuously measured	Continuously recorded
pH	Continuously measured	Continuously recorded
Acetone	Grab samples taken at 4-hour or equally timed intervals to generate four grab samples for the discharge throughout the production day. (1)	Quarterly
n-Amyl acetate	Grab samples taken at 4-hour or equally timed intervals to generate four grab samples for the discharge throughout the production day. (1)	Quarterly
Ethyl acetate	Grab samples taken at 4-hour or equally timed intervals to generate four grab samples for the discharge throughout the production day. (1)	Quarterly
Isopropyl acetate	Grab samples taken at 4-hour or equally timed intervals to generate four grab samples for the discharge throughout the production day. (1)	Quarterly
Methylene chloride	Grab samples taken at 4-hour or equally timed intervals to generate four grab samples for the discharge throughout the production day. (1)	Quarterly

(1) The grab samples taken throughout the daily discharge may be combined into a single sample for analysis using lab-compositing techniques. Otherwise, the separate results from all grab samples

taken throughout the day may be averaged into a single daily average.

3.3 Signatory Requirements

Per 40 CFR Section 403.12(l), the Baseline Report, 90-day Compliance Report, and Periodic Compliance Reports shall include the following signed certification statement:

> *I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.*

The certification statement shall be signed as follows:

1. By a responsible corporate officer, if the Industrial User is a corporation. For the purpose of this paragraph, a responsible corporate officer means:
    a. A president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy- or decision-making functions for the corporation, or
    b. The manager of one or more manufacturing, production, or operating facilities, provided, the manager is authorized to make management decisions which govern the operation of the regulated facility including having the explicit or implicit duty of making major capital investment recommendations, and initiate and direct other comprehensive measures to assure long-term environmental compliance with environmental laws and regulations; can ensure that the necessary systems are established or actions taken to gather complete and accurate information for control mechanism requirements; and where authority to sign documents has been assigned or delegated to the manager in accordance with corporate procedures.
2. By a general partner or proprietor if the Industrial User is a partnership, or sole proprietorship respectively.
3. By a duly authorized representative of the individual designated in (1) or (2) of this section if:
    a. The authorization is made in writing by the individual described in paragraph (1) or (2);
    b. The authorization specifies either an individual or a position having responsibility for the overall operation of the facility from which the Industrial Discharge originates, such as the position of plant manager, operator of a well, or well field superintendent, or a position of equivalent responsibility, or having overall responsibility for environmental matters for the company; and
    c. The written authorization is submitted to the EPA.
4. If an authorization under (3) of this section is no longer accurate because a different individual or position has responsibility for the overall operation of the facility, or overall responsibility for environmental matters for the company, a new authorization satisfying the requirements of (3) of this section must be submitted to EPA prior to or together with any reports to be signed by an authorized representative.

3.3.1 Reporting and Notification Contacts

1. On October 22, 2015, the Environmental Protection Agency (EPA) published in the federal register the NPDES Electronic Reporting rule for all NPDES permit reporting and notification requirements (40 CFR Part 127). The deadline for the electronic reporting of Periodic Compliance Reports for CIUs/SIUs in municipalities without an approved Pretreatment (Phase 2 of the Rule) is December 21, 2020 (40 CFR §127.16).

   On September 23, 2020, EPA signed the final "Phase 2 Extension Rule," which provides states and EPA additional time to implement electronic reporting for certain Clean Water Act discharge permitting requirements. In this final rule, EPA is extending the compliance deadline for implementation of Phase 2 of the Electronic Reporting Rule by five years from December 21, 2020, to December 21, 2025. Upon the effective date of the NPDES Electronic Reporting Rule, the facility will be required to:

   a. Establish a NetDMR account to electronically submit DMRs and notifications and must sign and certify all electronic submissions in accordance with the signatory requirements of the control mechanism. NetDMR is accessed from the internet at https://netdmr.zendesk.com/home. Additionally, the facility can contact the EPA via our R8NetDMR@epa.gov mailbox for any individual assistance or one-on-one training and support.

   b. Effluent monitoring results shall be summarized for each month (flow and pH), quarterly for other pollutants of concern and recorded on a DMR to be submitted via NetDMR to the EPA on a **semi-annual** basis. If no discharge occurs during a month, it shall be stated as such on the DMR.

2. Until the effective date of the NPDES Electronic Reporting Rule, the facility may either submit Periodic Compliance Reports electronically, as described above, or submit hard copies to the address below. Other written reports and notifications to the EPA shall be submitted at the following address:

   NPDES and Wetlands Enforcement Section (8ENF-W-NW)
   US EPA Region 8
   1595 Wynkoop Street
   Denver, CO 80202
   Attention: Pretreatment

3. All written reports and notifications must also be submitted to the POTW at the following address:

   Donny Ramer, Public Works Director
   920 New York Avenue
   Hamilton, MT 59840

4. Verbal notifications required to be submitted to the EPA shall be made by calling either number below and asking to speak with NPDES Enforcement, Pretreatment.

303-312-6312 or 800-227-8917

5. Verbal notifications required to be submitted to the POTW shall be made by calling the number below.

406-363-6716