

**ENVIRONMENTAL PROTECTION AGENCY**

**REGION 1 – NEW ENGLAND**

5 POST OFFICE SQUARE, SUITE 100  
BOSTON, MASSACHUSETTS 02109-3912

**RCRA Compliance Inspection of:**

**Pharmaron Manufacturing Services LLC**

**498 Washington St**

**Coventry, RI 02816**

April 25-26, 2023

Dates of Inspection

Linda Brolin, Environmental Engineer  
Waste and Chemical Compliance Section

July 26, 2023

Date Inspection Report Approved

Mary Jane O'Donnell, Manager  
Waste and Chemical Compliance Section

July 26, 2023

Date Inspection Report Finalized

July 23, 2023

Date Inspection Report Transmitted to Facility

*Disclaimer: Unless otherwise noted, this report describes conditions at the facility/property as observed by EPA inspector(s), and/or through records provided to and/or information reported to EPA inspector(s) by facility representatives and as understood by the inspector(s). This report may not capture all operations or activities ongoing at the time of the inspection. This report does not make final determinations on potential areas of concern. Nothing in this report affects EPA's authorities under federal statutes and regulations to pursue further investigation or action.*

# RCRA HAZARDOUS WASTE INSPECTION REPORT

## I. GENERAL INFORMATION

- a. **Facility Name:** Pharmaron Manufacturing Services LLC (“Pharmaron” or the “facility”)
- b. **Inspection Dates:** April 25-26, 2023
- c. **Inspection Type:** RCRA Compliance Evaluation Inspection (CEI)
- d. **EPA Inspectors:** Cheryl Wilkinson, Life Scientist, EPA Region 1  
Linda Brolin, Environmental Engineer , EPA Region 1  
Justin Young, Physical Scientist, EPA HQ  
Janosh Wolters, Energy Engineer, Contractor  
George Wieber, Chemical Engineer, Contractor
- e. **EPA ID Number:** RIR000015727  
RID001805670
- f. **NAICS:** 325411 – Medicinal and Botanical Manufacturing
- g. **Street Address:** 498 WASHINGTON ST, COVENTRY, RI, 02816  
(address for RIR000015727)
- h. **Mailing Address:** 498 WASHINGTON ST, COVENTRY, RI, 02816  
(address for RIR000015727)
- i. **Facility Contact(s):** Bob Deady, EHS Director  
Phone: (401) 298-1130  
Email: [Bob.deady@pharmaron.com](mailto:Bob.deady@pharmaron.com)
- j. **Generator Status:** Large Quantity Generator (LQG) – RIR000015727  
Small Quantity Generator (SQG) – RID001805670
- k. **Date first notified as a generator (per RCRAInfo):** 05/14/1998  
(for ID RIR000015727)
- l. **Date of most recent notification in RCRAInfo:** 07/02/2022  
(for ID RIR000015727)
- m. **Current Property Owner:** Pharmaron Manufacturing Services LLC
- n. **Current Operator:** Pharmaron Manufacturing Services LLC

- o. **Wastes generated (per most recent RCRAInfo notification):** D001, D002, D003, D004, D005, D006, D007, D009, D011, D018, D022, D038, F001, F002, F003, F005, P030, P101, U002, U003, U044, U056, U080, U082, U091, U092, U117, U123, U133, U154, U156, U188, U213, U218, U220, U359, U404

Report Attachments:

ATTACHMENT 1 – Waste Determination for Mother Liquor Tank (T0102)

ATTACHMENT 2 – Photo Log

ATTACHMENT 3 – Veolia Waste Management Agreement

ATTACHMENT 4 – RCRA Air Emissions Standards Compliance Program

ATTACHMENT 5 – Daily Tank Inspections

ATTACHMENT 6 – Contingency Plan

ATTACHMENT 7 – Training Records

## **II. FACILITY DESCRIPTION**

Pharmaron operated the facility since acquiring the site in July 2021 from Noramco. The site was formerly owned and operated by Rhodes Technologies, which was bought by Noramco. The facility is comprised of a manufacturing area and an office area. The facility also operates two separate EPA ID numbers. The building located at 498 Washington St. is a LQG of hazardous waste and the building located at 500 Washington St. is a SQG of hazardous waste. The SQG is comprised of laboratories and the LQG is comprised of manufacturing and support staff operations. At the time of the inspection, neither location was operating any large-scale operations. Pharmaron anticipates starting contract manufacturing for active pharmaceutical ingredients (API) at varying scales of production in the future. The facility had a small client base at the time of the inspection with only lab-scale manufacturing. Pharmaron operates two 12-hour shifts, 24 hours per day, 365 days per year. Pharmaron employs approximately 67 staff members who are spread across administration, manufacturing, safety, and security. Pharmaron purchased the facility in July 2021, and finished cleaning all manufacturing equipment in September 2021. The facility operates two 8,000-gallon hazardous waste tanks (Tank T0102 and Tank T0103). Additionally, the site has two Central Accumulation Areas (CAAs) (one at the LQG and one at the SQG), a universal waste storage area, and satellite accumulation areas (SAAs) throughout the laboratories. Mr. Deady mentioned that more CAAs and more SAAs would be established when the facility increase production.

## **III. INSPECTION OPENING CONFERENCE**

EPA inspectors arrived unannounced at the LQG facility at 498 Washington Street, Coventry, RI at approximately 10:00 AM on the 25<sup>th</sup> of April, 2023. The EPA inspection team (“inspection team”) consisted of Cheryl Wilkinson (EPA Region 1), Linda Brolin (EPA Region 1), Justin

Young (EPA Headquarters), Janosh Wolters (Contractor, Eastern Research Group, Inc. [ERG]), and George Wieber (Contractor, ERG).

The inspection team met Bob Deady, EHS Director, near the entrance of the facility at approximately 10:00 AM. The inspection team signed in, presented EPA credentials, and followed Mr. Deady to a conference room for a safety briefing and the opening conference. The inspection team met with Laura Brennan, Environmental Safety Engineer, as well for the opening conference. Inspector Young discussed inspection procedures at this time, including the right to claim confidential business information (CBI). The following personnel were present at the opening conference:

EPA:	Cheryl Wilkinson, Life Scientist, EPA Region 1 Linda Brolin, Environmental Engineer, EPA Region 1 Justin Young, Environmental Protection Specialist, EPA HQ Janosh Wolters, Energy Engineer, Contractor George Wieber, Chemical Engineer, Contractor
Pharmaron:	Bob Deady, EHS Director Laura Brennan, Environmental Safety Engineer

Pharmaron employees and EPA inspectors discussed the following information about the facility processes and operations during the opening conference and inspection walkthrough:

The inspection team first asked the facility representatives for an overview of Pharmaron's operations. Pharmaron has operated the facility since acquiring the property on July 1, 2022. Prior to Pharmaron, the facility was owned and operated by Rhodes Technologies who manufactured class 1 narcotics and was a regulated Drug Enforcement Administration (DEA) facility. Pharmaron currently operates two shifts, 24 hours per day, 365 days per year. Pharmaron employs approximately 67 personnel. Phase 1 and phase 2 drug development occurs primarily at Pharmaron facilities in the United Kingdom and China, and Pharmaron purchased the facility in Coventry, RI to aid in late-stage commercial drug development and contract manufacturing. At the time of the inspection, the facility was only operating small, 20-Liter laboratory-scale research and development studies within the SQG site address under contract with a client. In addition, general maintenance activities generated waste at the site. The facility also had one universal waste storage area under the management for each of the EPA ID numbers. Pharmaron ceased manufacturing operations upon acquiring the facility and began cleaning all manufacturing vessels and associated tanks, including both hazardous waste tanks. By August 2022, process vessels were cleaned and a majority of the facility's hazardous waste was no longer being generated. Hazardous waste Tank T0102, previously used to accumulate aqueous mother liquor, was cleaned and out of service on July 11, 2022. According to updated 2018 waste determination documentation (Attachment 1), the waste stream accumulated in Tank T0102 was no longer hazardous for corrosivity following a process change that occurred after a previous determination in 2009. Hazardous waste Tank T0103, previously used to accumulate solvent wastes, was cleaned and out of service on October 7, 2022. This information corresponds with what is observed in RCRA Info and all manifests reviewed on site.

Pharmaron explained that no LDAR monitoring under RCRA had been conducted since the purchase of the property on July 1, 2022. According to facility personnel, the facility under previous ownership conducted LDAR monitoring for components on an annual or semi-annual basis using a MiniRAE 3000 photoionization detector calibrated with zero air and isobutylene. The inspection team provided Pharmaron with information regarding compliance with Subpart BB using Method 21. Pharmaron uses physical tags to mark equipment subject to Subpart BB on site, with tags corresponding to identification numbers in facility documentation. At the time of the inspection, hazardous waste lines and tanks were not operational and had been cleaned out.

#### **IV. FACILITY TOUR**

The walkthrough began at approximately 1:15 PM on April 25, 2023 with the inspection team initially being led by Mr. Deady. The following personnel were present for all or part of the tour:

EPA:	Cheryl Wilkinson, Life Scientist, EPA Region 1 Linda Brolin, Environmental Engineer, EPA Region 1 Justin Young, Physical Scientist, EPA HQ Janosh Wolters, Energy Engineer, Contractor George Wieber, Chemical Engineer, Contractor
Pharmaron:	Bob Deady, EHS Director Laura Brennan, Environmental Safety Engineer Robert “David” Schroder, Environmental Engineer

Inspector Wolters took photographs to document the inspection which are included in Attachment 2.

Mr. Deady led the inspection team through the designated manufacturing areas, which were not in operation at the time of inspection. The inspection team used a forward-looking infrared (FLIR) camera to screen various components and vessels that could potentially have stored or transported hazardous waste when the facility was operational. The inspection team observed and evaluated pieces of equipment for compliance with Subparts AA, BB, and CC where applicable. The inspection team observed multiple reactors, filtration systems, waste stations, fume hood locations, one CAA, universal waste storage area, and SAAs. Photographs of pieces of equipment observed are provided in Attachment 2.

The inspection team first proceeded to Warehouse 6, where a universal waste accumulation area was located. No universal waste was present in the area at the time of the inspection. The inspection team then proceeded to a former hazardous waste CAA in Warehouse 8, but facility personnel stated that the area had not been used for hazardous waste accumulation since late 2022 (see Attachment 2, Photo 1). The inspection team then visited the CAA located outside of Warehouse 8 in a sheltered, fenced area. There was a “Hazardous Waste Storage” sign on the front gate and a fire extinguisher, safety shower, spill kit, and alarm systems present inside the gate (see Attachment 2, Photos 2 through 4). The gate was locked at the time of inspection, and Mr. Deady stated only himself and designated staff are able to access this area. There were no

containers of waste accumulated inside the CAA at the time of inspection. The CAA also had a concrete blind sump in case of spills.

The inspection team then moved inside Buildings 3, 5, and 7 in order to observe the primary manufacturing areas. Manufacturing equipment was not in use and had tags to indicate that they had been cleaned. The inspection team observed former CAAs and SAAs, and no hazardous waste was observed at the time of inspection (see Attachment 2, Photos 5 and 10). The inspection team did also observe containers of methanol that were labeled as work in progress, or “WIP”, that are used for cleaning parts (see Attachment 2, Photo 9). While inside the buildings, the inspection team ensured hazardous waste tanks were empty during the visual inspection by observing the monitors inside a maintenance room (see Attachment 2, Photos 6 through 8). The inspection team then briefly visited the Tank Farm area and observed labeling on the hazardous waste tanks and associated equipment (see Attachment 2, Photos 11 through 14).

The inspection team then moved to Building 500A at approximately 3:15 PM. The inspection team first observed the universal waste storage area located in the basement of Building 14. One 5-gallon container of universal waste batteries and one 10-gallon container of non-PCB ballasts were observed (see Attachment 2, Photo 15). The containers were closed, in good condition, and were labeled “Universal Waste” with the appropriate content and dated. The earliest accumulation start date was 3/29/2023, which is within one year of the inspection. The inspection team also observed laboratories in operation at the time of the inspection, including Labs 109, 107, and 110. Lab 109 was used for the development of a lab-scale toll manufacturing process. Pharmaron anticipates setting up a SAA once the process is running. Labs 107 and 110 had SAA containers that were labeled as hazardous waste, indicated the nature of the hazard, and closed at the time of the inspection. The inspection team also observed the CAAs associated with Building 500A. The CAA consisted of an indoor room on the south end of the building as well as two small prefab flammable storage sheds immediately outside. The indoor portion of the CAA contained primarily empty containers. The inspection team also observed containers with residual liquid and labeled with the indication of the hazard such as “toxic” (see Attachment 2, Photo 21) but did not have an accumulation start date on the container. The inspection team also observed the two CAA sheds outside the building. The CAA shed doors were closed and locked, and the inspection team observed a “No Smoking” sign near the CAA. Inside the first CAA shed (east shed), the inspection team again observed residual waste material in the bottom of several containers, including one 5-gallon container and four 10-gallon containers (see Attachment 2, Photos 23 and 24) that did not have an accumulation start date. Mr. Deady stated that the facility has an agreement with Veolia, who manages the facility’s waste pickups and shipments off site. Mr. Deady explained that Veolia employees are supposed to consolidate hazardous waste prior to putting empty containers back into the CAA. Mr. Deady stated this may have been Veolia employees that did not empty the containers that had residual hazardous waste left inside them. The Statement of Work (SOW) for Veolia in agreement with Pharmaron is included as Attachment 3. The remaining containers without labels in the CAA shed were observed to be RCRA empty. One hazardous waste container in the CAA shed contained hazardous waste and was labeled as hazardous waste with an indication of hazard, closed, in good condition, and had an accumulation start date of April 14, 2023. The second CAA shed (west shed) contained empty containers and no hazardous waste was observed. The inspection team then concluded with a short debrief back at the office building and then departed at 5:30 PM on April 25, 2023.

The inspection team returned on April 26, 2023 to review hazardous waste tanks and associated equipment in more detail observed outside of Building 500A by the property line and conduct limited on-site records review. The inspection team first proceeded to the hazardous waste tanks at approximately 9:45 AM and screened components on the hazardous waste tanks and associated piping using the FLIR camera. Mr. Deady confirmed all lines were purged and cleaned as part of the cleaning that occurred in September 2022. Photos of various pieces of equipment and lines were taken during the inspection of the hazardous waste tanks. The inspection team explained to the facility that if the facility were to become operational, the facility should complete a thorough review of their current LDAR program because certain components visually inspected may be applicable to Subparts BB and CC. However, at the time of the inspection, the facility did not have components contacting hazardous waste based on the statements that the facility purged the hazardous waste lines and were not operating.

The inspection team then proceeded to Building 500A and observed 55-gallon drums that appeared to be abandoned on land that is not owned by Pharmaron property. Mr. Deady explained these were not Pharmaron drums and were not placed there by any Pharmaron staff. Photos were taken documenting what the inspection team visually observed (see Attachment 2, 38 through 41). The inspection team then returned to the office at approximately 11:05 AM. This concluded the walkthrough portion of the inspection for the day.

## **V. RECORDS REVIEW**

### LDAR Program Review

At the time of the inspection, the facility was not in operation and therefore, an LDAR program would not be required until the facility begins operations. However, the facility was acquired by Pharmaron on July 1, 2022 and the hazardous waste tanks and associated equipment transferring hazardous waste were in use until September 2022. Therefore, the facility would have been required to conduct LDAR monitoring to applicable equipment subject to LDAR monitoring during this time. Mr. Deady explained the facility was actively cleaning shutting down the process equipment from July 1, 2022 through September 2022 but was unable to provide LDAR monitoring records for equipment that had not been cleaned during this time. At the time of the inspection, Pharmaron provided documentation of their current LDAR program, including a list of applicable equipment and control levels determined for hazardous waste tanks. Upon further review, EPA directed Pharmaron to the regulations in 40 CFR 265 to ensure complete compliance. EPA may follow up to determine if the facility's LDAR program management practices are implemented correctly during startup to ensure compliance with the respective RCRA subparts. The LDAR program documentation is provided in Attachment 4.

### Hazardous Waste Tanks

The inspection team reviewed the integrity certification for the hazardous waste tanks completed by a professional engineer. The tanks are certified every five years. Both 8,000-gallon tanks (Tank 0102 & T0103) were empty and cleaned out at the time of the inspection. Prior to the tanks being emptied and cleaned out, they were inspected every operating day. An example of the daily inspection forms is provided in Attachment 5.

### Weekly Inspections

Pharmaron conducts weekly inspections of the SAAs and the CAAs. Weekly inspection logs were observed during the inspection. There were periods of time between 12 to 20 days in between inspections. Ms. Brennan stated that weekly CAA inspections are not conducted if no waste containers are present in the CAA.

### Contingency Plan

The contingency plan was reviewed and no issues were noted based on current operations. The contingency plan is provided in Attachment 6.

### Training:

Ms. Brennan stated that she conducts the RCRA training on site for other employees, and Ms. Brennan receives training from a third party. Inspector Young reviewed the training presentation and quiz while onsite. Training records are provided in Attachment 7.

### Hazardous Waste Manifests:

The inspection team reviewed the hazardous waste manifests for years 2022 and 2023. The inspection team observed the facility did not have the signed copy available for review. Ms. Brennan explained that the destination TSD emails the final copy to the facility. The following are the inspection team's observations:

Manifest #	Ship Date	Observation
017775024FLE	01-17-23	No LDR
002278719VES	04-24-23	No signed destination copy
002278720VES	04-24-23	No signed destination copy
024311052JJK	07-20-22	No LDR
002188211VES	08-09-22	No signed destination copy
002188214VES	08-09-22	No signed destination copy
002188215VES	08-09-22	No signed destination copy
002188216VES	08-09-22	No signed destination copy
024311085JJK	08-11-22	No signed destination copy
001946518VES	08-25-22	No signed destination copy
001946517VES	08-25-22	No signed destination copy
024311111JJK	08-30-22	Not signed by transporter, and no signed destination copy
0021884191VES	09-08-22	No signed destination copy
002188490VES	09-08-22	No signed destination copy
001945486VES	09-15-22	No signed destination copy
001945485VES	09-14-22	No signed destination copy
002181014VES	09-27-22	No signed destination copy
002186689VES	10-06-22	No signed destination copy
001946505VES	10-11-22	No signed destination copy
002186885VES	10-11-22	No signed destination copy
002186886VES	10-11-22	No signed destination copy

002186888VES	10-13-22	No signed destination copy
002186654VES	10-27-22	No signed destination copy
002186654VES	10-27-22	No signed destination copy
002186739VES	11-01-22	No signed destination copy
002186738VES	11-01-22	No signed destination copy
002186740VES	11-01-22	No signed destination copy
002186741VES	11-01-22	No signed destination copy
002186743VES	11-22-22	No signed destination copy
002186742VES	11-22-22	No signed destination copy
002181292VES	12-20-22	No signed destination copy
002181291VES	12-20-22	No signed destination copy
002188219VES	12-20-22	No signed destination copy

## VI. Areas of Concern

The presentation of areas of concern does not constitute a formal compliance determination or violation.

1. The facility was acquired by Pharmaron on July 1, 2022 and the hazardous waste tanks and associated equipment transferring hazardous waste were in use until September 2022. Therefore, the facility would have been required to conduct LDAR monitoring to applicable equipment during this time. Mr. Deady explained the facility was actively cleaning and shutting down the process equipment from July 1, 2022 through September 2022 but was unable to provide LDAR monitoring records for equipment that had not been cleaned during this time.
2. The inspection team also observed containers with residual liquid and labeled with the indication of the hazard such as “toxic” in the indoor portion of the CAA (see Attachment 2, Photo 21) but did not have an accumulation start date on the container. Inside the first CAA shed (east shed), the inspection team again observed residual waste material in the bottom of several containers, including one 5-gallon container and four 10-gallon containers (see Attachment 2, Photos 23 and 24) that did not have an accumulation start date. Mr. Deady stated that the facility has an agreement with Veolia, who manages the facility’s waste pickups and shipments off site. Mr. Deady explained that Veolia employees are supposed to consolidate hazardous waste prior to putting empty containers back into the CAA. Mr. Deady stated this may have been Veolia employees that did not empty the containers that had residual hazardous waste left inside them.

## VII. INSPECTION OUTBRIEF

An outbrief was conducted on April 26<sup>th</sup>, prior to leaving the facility. The following personnel were present for the outbrief:

EPA: Cheryl Wilkinson, Life Scientist, EPA Region 1

Linda Brolin, Environmental Engineer, EPA Region 1  
Justin Young, Physical Scientist, EPA HQ  
Janosh Wolters, Energy Engineer, Contractor  
George Wieber, Chemical Engineer, Contractor

Pharmaron: Bob Deady, EHS Director

The inspection team then relayed compliance information regarding LDAR calibration and Subpart CC inspections. Other best practices were relayed and discussed throughout the inspection.

Following this discussion, the inspection team left the premises at approximately 1:00 PM on April 26, 2023 and concluded the on-site portion of the inspection.