

Hazardous Waste Section
File Room Document Transmittal Sheet

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Your Name: Heather Sorensen
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Qualitest Pharmaceuticals

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Large Quantity Generator – Compliance Evaluation Inspection (CEI)

NCDENR- Division of Waste Management- Hazardous Waste Section

April 23, 2014

Facility Information: 3700A Woodpark Blvd, Charlotte, NC 28206
Steve Van Buren/Manager
704-596-0516

Present at Inspection: Steve Van Buren – (Qualitest Pharmaceuticals), Laurie Benton - EPA, Heather Sorensen – (ESS, NCDENR)

Inspection Date: April 9, 2014, 9:55 a.m. – 10:35 a.m.

Purpose of Evaluation: To evaluate compliance with regulations described at 40 CFR 261, 262, 265, 268, 273 and 279; and with North Carolina Hazardous Waste Management Rules (Rules).

Type of Business: Qualitest Pharmaceuticals (Qualitest) is a manufacturer of solid dose generic pharmaceuticals. The facility notified as a Large Quantity Generator (LQG) on May 9, 2013 and has renovated this building location to house quality control laboratories “QC Labs” currently located at a Qualitest facility located at 3241 Woodpark Boulevard, Charlotte, NC 28206. The facility currently houses support, training, and IT staff and is waiting for FDA approval to start operating the laboratory. Qualitest rents 40% of the building, which is approximately 50,000 square feet in size. Hazardous waste will be generated from laboratory operations and off-specification products. Manufacturing and packaging of pharmaceuticals will remain at the 3241 Woodpark Boulevard location. The facility’s drinking water and sanitary sewer service is provided by Charlotte-Mecklenburg Utilities. There is one monitoring well located onsite.

The facility will have multiple satellite accumulation areas in the QC laboratories. The satellite waste will then be moved to the less than 90-day hazardous waste storage area. There was no hazardous waste onsite at the time of inspection. The facility was not generating hazardous waste at the time of inspection.

Areas of Inspection

Manifests: There were no manifests to review at the time of inspection.

Inspection Records: There were no inspection records to review at the time of inspection.

Contingency Plan: Qualitest is in the process of developing a written contingency plan for the facility. Steven VanBuren is listed at the Primary Emergency Coordinator. Jeff Newman and Michael Bishop are listed as Secondary Emergency Coordinators.

Waste Minimization: There was no waste minimization plan to review at the time of inspection.

Emergency Preparedness: Qualitest is operated to minimize the possibility of unplanned spills or releases. The facility is equipped with emergency response equipment and communication devices including: PA system that utilizes codes, fire

extinguishers, fire suppression system, and spill kits. Fire extinguishers are inspected annually by Premiere Safety and monthly by facility staff. The fire suppression system receives weekly fire pump test and quarterly water flows. Emergency bells and lights are tested quarterly. The fire alarm system is visual and audial.

Training Records: There were no training records to review during the inspection.

Biennial Report: No biennial reports have been submitted for this facility.

Satellite Accumulation Areas: There were no satellite accumulation areas to inspect during the inspection.

Storage Area: Qualitest is in the process of completing preparations of a <90-day hazardous waste storage area, otherwise called the Warehouse Solvent Room. The storage area will house hazardous waste and solvent product. The room is located within a fire rated room that is equipped with floor pits to contain any spills. It is recommended that the facility include the floor pits as part of their weekly inspections. Any waste spills into the pits must be cleaned immediately. A fire extinguisher is located outside the storage area. It is recommended that a fire extinguisher be located inside the storage area room. The room was not equipped with a communication device or pull alarm. There was no hazardous waste onsite during the inspections.

Universal Waste: There was no universal waste onsite during the inspection. The facility plans to transport universal waste to another Qualitest facility located at 3241 Woodpark Boulevard, Charlotte, NC, from where it will be transported for recycling.

Site Deficiencies:

- No deficiencies noted.

Comments/Recommendations:

- It is recommended that the facility include the Warehouse Solvent Room floor pits as part of their <90-day storage area weekly inspections.
- It is recommended that a fire extinguisher be located inside the storage area room.



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Date

cc: Steve VanBuren, Qualitest Pharmaceuticals
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