



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, ILLINOIS 60604**

DATE: MAY 20 2019

SUBJECT: CLEAN AIR ACT INSPECTION REPORT
Catalent Indiana LLC, Bloomington, Indiana

FROM: Albana Bega, Environmental Engineer
AECAB (MI/WI)

THRU: Sarah Marshall, Section Chief
AECAB (MI/WI)

TO: File

BASIC INFORMATION

Facility Name: Catalent Indiana LLC

Facility Location: 1300 South Patterson Drive, Bloomington, Indiana

Date of Inspection: March 27, 2019

EPA Inspector(s):

1. Albana Bega, Environmental Engineer
2. Luke Hullinger, Environmental Engineer

Other Attendees

1. Andrew Smith, Director Environmental Health and Safety
2. Sarah Carman, Senior Quality Assurance Representative
3. Margo Sacha, Senior Manager, Quality Assurance Catalent Biologics

Contact Email Address: Andrew.Smith@catalent.com

Purpose of Inspection: Synthetic minor limit, NSPS Boilers

Facility Type: Biopharmaceutical Manufacturing

Regulations Central to Inspection: NSPS Subpart Db -- six boilers

Arrival Time: 10:00

Departure Time: 13:45

Inspection Type:

- ☒ Unannounced Inspection
- ☐ Announced Inspection

OPENING CONFERENCE

- ☒ Credentials Presented
- ☒ CBI warning to facility provided

The following information was obtained verbally from Mr. Smith unless otherwise noted.

Company Ownership: Catalent Inc. acquired Cook Pharmica LLC in October 2017.

Process Description:

The Cook Pharmica Group started the Cook Pharmica LLC facility in Bloomington Indiana (facility) in 2004 as a contract development and manufacturing facility with biopharmaceutical and fill-finish capabilities. Specifically, the facility provides research and development services, commercial and clinical scale drug substance manufacturing, supply services such as cell bank generation and storage, and stability testing and storage. The facility has one enclosed Mammalian Cell Culture process line, which produces mammalian cell culture-based biopharmaceuticals, including monoclonal antibodies and proteins manufactured using genetically engineered organisms controlled with lab hood. In addition, the facility has two Fill Finish process lines (vial and syringe filling lines), consist of manufacturing of sterile, injectable pharmaceuticals for the medical industry, controlled with lab hood. Fill Filling process lines products manufactured include solutions, suspensions, emulsions and freeze-dried powders encompassing human and veterinary small molecule, vaccine and protein pharmaceuticals.

Staff Interview: The facility operates 24 hours a day, seven days a week and has approximately 1,050 employees. It is a large quantity generator of hazardous waste but a synthetic minor under the CAA program. The manufacturing process is a batch process that uses stainless steel reactors of 600 to 2,500 liters capacity. Each batch takes approximately 4-6 weeks. Clean-in-place (CIP) is the process equipment (reactor) method of cleaning and the two cleaning solutions used contains no hazardous air pollutants/volatile organic compounds. Wastewater from cleaning process collects through facility's drains to the facility's wastewater treatment systems (a total of two). Waste materials not treated onsite are collected in bags and containers and shipped offsite on tanker truck as hazardous waste. The facility has six natural gas-fired boilers and four diesel-fired generators. Boilers are on a preventive maintenance schedule.

TOUR INFORMATION

EPA toured the facility: Yes

Data Collected and Observations: The facility was in full operation on the day of this inspection. The following were observed during the tour:

- Inspection area
- Development lab
- Building A (two boilers and wastewater treatment systems)
- Building B (four boilers)
- Cooling towers
- Emergency diesel-fired generators

Photos and/or Videos: were taken during the inspection.

Field Measurements: were not taken during this inspection.

RECORDS REVIEW

1. Introduction to Cook Pharma PowerPoint presentation (contains information claimed as confidential business information, taken)
2. December 2018 industrial wastewater report and the January 2019 monthly industrial reporting form (taken)
3. Boiler #1 and #2 annual testing reports (taken)
4. Boilers' preventive maintenance schedule (taken)
5. CIP 100 and 200 (cleaning solutions) safety data sheets (taken)

CLOSING CONFERENCE

Requested documents:

- None

SIGNATURES

Report Author: ABg Date: 05/17/2019
Section Chief: [Signature] Date: 5/20/19

Facility Name: Catalent Indiana LLC

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APPENDIX A: DIGITAL IMAGE LOG

1. Inspector Name: Albana Bega	2. Date(s) of Inspection: March 27, 2019
3. Company/Facility Name: Catalent Indiana LLC	4. Street Address, City, State: 1300 South Patterson Drive, Bloomington, Indiana
5. Number of Images: 8	6. Archival Record Location: C:\Users\ABega\OneDrive - Environmental Protection Agency (EPA)\CookPharmicaLLC- Bloomington-IN

Image Number	File Name	Date and Time (incl. time zone and DST)	Description of Image
1	IMG_3647.JPG	3/27/2019 13:46	Boiler Plate for Boiler #2 (Bldg A)
2	IMG_3648.JPG	3/27/2019 12:15	Boiler Plate for Boiler #1 (Bldg A)
3	IMG_3649.JPG	3/27/2019 13:46	Boiler Plate for Boiler #12 (Bldg B)
4	IMG_3650.JPG	3/27/2019 12:30	Boiler Plate for Boiler #11 (Bldg B)
5	IMG_3651.JPG	3/27/2019 12:31	Boiler Plate for Boiler #4 (Bldg B)
6	IMG_3652.JPG	3/27/2019 12:31	Boiler Plate for Boiler #3 (Bldg B)
7	IMG_3653.JPG	3/27/2019 12:33	Certificate of Inspection for Boiler #4 (Bldg B)
8	IMG_3654.JPG	3/27/2019 12:33	Certificate of Inspection for Boiler #3 (Bldg B)