Cleaner Air Oregon Level-1 Modeling Protocol

Building 20 & 21 Project

Prepared for:

Genentech, LLC.

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BRIDGEWATER GROUP, INC.

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1.0 Introduction

Genentech, Inc. ("Genentech") currently operates a fill and finish facility for medical prescription drugs located at 4625 NW Brookwood Parkway Hillsboro, Oregon 97124. A site location map is shown in Figure 1-1 and a site plan is shown in Figure 1-2. The facility has been in operation since 2008 and its pharmaceutical packaging activities are considered categorically insignificant under OAR 340-200-0020(23)(dd) and do not require an air permit. However, the facility also operates two 24.5 MMBTU/hr natural gas-fired boilers that are permitted under a boiler General Air Contaminant Discharge Permit ("ACDP") (Source Number 34-9507-11-1).

Genentech is proposing to modify the existing operations at their Hillsboro facility to include pharmaceutical manufacturing. As such, the facility is proposing to replace its General ACDP with a Simple ACDP to cover all regulated activities at the site. More specifically, Genentech proposes to modify the existing facility to add pharmaceutical manufacturing operations to be located in two new buildings (referred to as Building 20 and 21) as well as construct buildings for support services (e.g., boiler, administrative) on the site.

The Oregon Department of Environmental Quality (ODEQ) has determined that Genentech needs to submit a Cleaner Air Oregon Cleaner Air Oregon (CAO) risk assessment (OAR-340-245) and application as part of their permit submittal. The CAO rules provide for four levels of risk assessment, depending on the facility's impacts. It is anticipated that Genentech can show compliance with the source Risk Action Levels (RALs) using a Level-1 risk assessment.

Under the new CAO regulations, facilities must submit a modeling protocol and emissions inventory prior to submitting the CAO risk assessment. This document is a Level-1 modeling protocol.

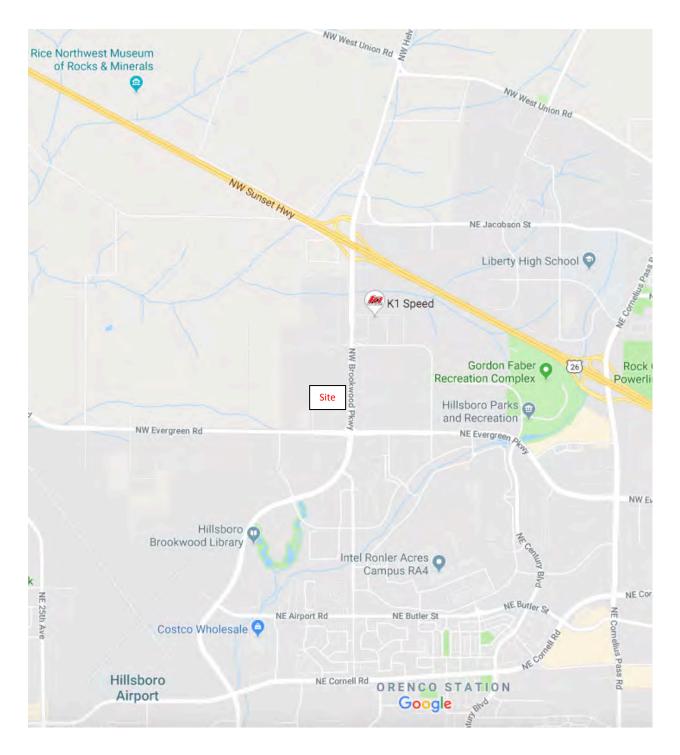


Figure 1 – 1

Site Location Map

Genentech, Inc.



Figure 1 – 2 Site Plan Genentech, Inc.

2.0 Source Description

2.1 Process Overview

The modification of Genentech's existing facility will consist of adding pharmaceutical manufacturing operations to the existing facility. However, as is typical of the industry, Genentech's process operations will be similar to laboratory scale activities with chemical storage, use and disposal occurring primarily within bottles and/or similarly small receptacles. No bulk chemical or waste handling systems are currently planned for the facility. A review of the proposed process operations and planned chemical use indicates that manufacturing activities will not be an air emission source of Toxic Air Contaminants (TACs) listed in OAR 340-245-8020 Table 2.

Emissions of TACs will be limited to isopropyl alcohol (IPA) usage and combustion emissions as described below.

2.2 Source Descriptions

IPA Emissions (IPA)

Isopropyl alcohol (IPA) that is delivered to the site as a moistened wipe or in bulk is used to clean equipment and other surfaces. Fugitive air emissions occur due to the IPA volatilizing and these emissions are estimated in Table 3-1 of the accompanying ACDP application and Form AQ405CAO.

Boilers (BLR-1, BLR-2, BLR-3, BLR-4, BLR-5)

Natural gas combustion in the existing and new boilers results in emission of Toxic Air Contaminants (TACs). Potential emissions are based on the equipment operating at capacity for 24 hours per day and 8,760 hours per year and are estimated in Tables 3-2 and 3-3 of the accompanying ACDP application and Form AQ405CAO.

The natural gas-fired boilers are exempt Toxic Emission Units (TEUs) under the gas combustion exemption of OAR 340-245-0050(5). The risk from TACs emitted from the boilers will be calculated at each exposure location but reported separately from other TEUs.

Emergency Equipment (EGEN-1, EGEN-2, FWP-1)

Diesel combustion in the existing and new emergency generators and fire water pump results in TACs. Emissions are based on the total non-emergency operation of the diesel emergency engines of 100 hours per year (Federal NSPS limit) and up to one hour per day for engine maintenance and testing. Estimated emissions are presented in Table 3-4 of the accompanying ACDP application and Form AQ405CAO.

Table 2-1 shows the source characterization that will be used for the Level-1 Assessment:

Table 2-1: Source Characterization

Stack Sources							
ID	Description	UTM X	UTM Y	Height (m)			
BLR-1	Existing Boiler 1	505645.5	5044496	12.19			
BLR-2	Existing Boiler 2	505645.4	5044491	12.19			
EG-1	Existing Emer. Gen 1	505457.3	5044429	5.0			
FWP-1	Existing Fire Water Pump 1	505287.9	5044396	5.0			
EG-2	New Emer. Gen 2	505230.4	5044467	6.10			
BLR-3	New Boiler 3	505235.7	5044444	6.10			
BLR-4	New Boiler 4	505230.8	5044444	6.10			
BLR-5	New Boiler 5	505225.8	5044444	6.10			
Fugitive Sources							
ID	Description	итм х	UTM Y	Bldg Hgt (ft)	Building Area (sq ft)		
IPA	New IPA Fugitives	505304.8	5044458	>20'	75,000		

2.3 TACs Potentially Emitted

Table 2-2 shows the toxics air contaminants (TACs) potentially emitted from the facility. For the Genentech facility, a total of 30 contaminants were identified in the emissions inventory process. Of these, 3 contaminants did not have an RBC and thus will not be included in the risk calculations. The actual CAO inventory (AQ405CAO.xlsx) is also submitted as an Excel ® attachment.

Table 2-2: TACs Potentially Emitted from the Genentech Facility

CAS#	Compound Name
71-43-2	Benzene
106-99-0	1,3-Butadiene
7440-43-9	Cadmium and compounds
50-00-0	Formaldehyde
18540-29-9	Chromium VI, chromate and dichromate particulate
7440-38-2	Arsenic and compounds
7439-92-1	Lead and compounds
NI_I	Nickel compounds, insoluble
91-20-3	Naphthalene
PAH	Polycyclic aromatic hydrocarbons (PAHs)
75-07-0	Acetaldehyde
107-02-8	Acrolein
7664-41-7	Ammonia
7440-50-8	Copper and compounds

CAS#	Compound Name
100-41-4	Ethyl benzene
110-54-3	Hexane
7647-01-0	Hydrochloric acid
7439-96-5	Manganese and compounds
7439-97-6	Mercury and compounds
7782-49-2	Selenium and compounds
108-88-3	Toluene
1330-20-7	Xylene (mixture), including m-xylene, o-xylene, p-xylene
DPM	Diesel Particulate Matter
7440-39-3	Barium and Compounds*
7440-41-7	Beryllium and compounds
7440-48-4	Cobalt and compounds
1313-27-5	Molybdenum trioxide*
7440-62-2	Vanadium (fume or dust)
7440-66-6	Zinc and compounds*
67-63-0	Isopropyl alcohol

^{*} No RBCs established for these TACs

2.4 Exposure Locations

Figure 2-1 shows the land use around the Genentech facility. The land use was derived from the 2017 Oregon Zoning data layer provided by the Oregon Department of Land Conservation and Development. This data layer is an element of the Oregon GIS Framework and is available through the Oregon Spatial Data Library 1. The feature class contains zoning data from 198 local jurisdictions, including the City of Hillsboro and Washington County. The data set has 55 zoning classifications, which are binned into three categories: residential, industrial/commercial, and open space. The open space category includes parks, forests, beaches, public lands, and agricultural areas. The residential bin includes any category designating a residence. For example, mixed use commercial and residential areas and tribal reservation lands are defined as residential. Residences located in farm land or forested area were manually identified based on aerial imagery.

The zoning dataset does not identify schools or daycares. The closest school and daycare were manually identified using an internet search (e.g., using a search engine and Google Earth).

The Genentech facility is located in an area zoned for industrial/commercial use, and has commercial use on three sides of its property. On the west side, there is a farm land defined as "future urban development". The closest area zoned as residential is 800 meters north of the facility. There are a few residences located closer which were identified. Based on these findings, the proposed exposure location are shown in Figure 2-2. The distances (in meters) from each Toxic Emission Unit (TEU) to the exposure location is shown in Table 2-3. For the risk evaluation, the closest distance for each TEU and receptor type will be used as described below. The shortest distance is highlighted in yellow in Table 2-3.

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¹ https://spatialdata.oregonexplorer.info/geoportal/

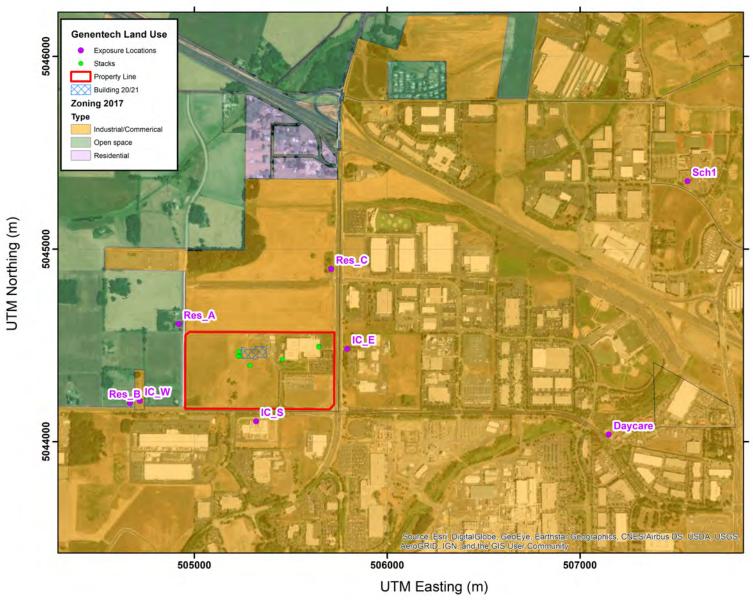


Figure 2-1
Surrounding Land Use
Genentech, Inc.

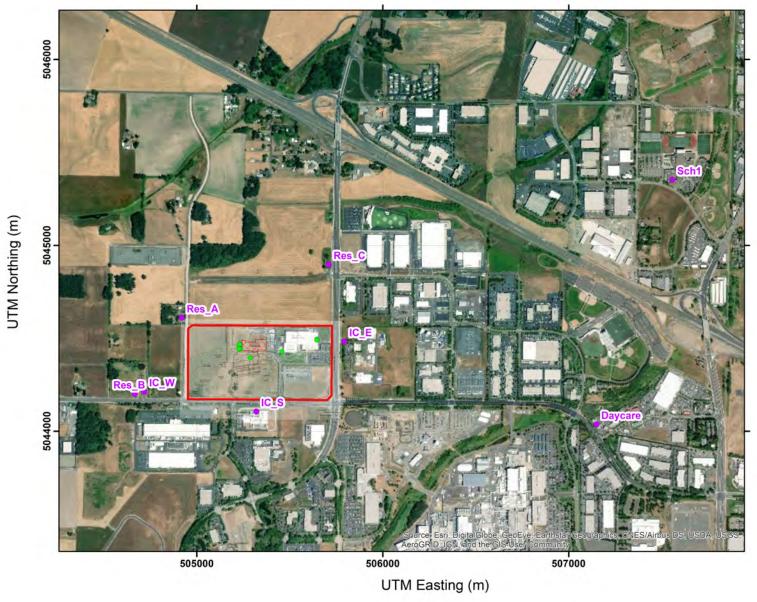


Figure 2-2
Exposure Locations
Genentech, Inc.

Table 2-3: Distances from each TEU to the Exposure Locations

	Distance from TEU to Receptor (m)									
				Industrial			Residential		Child	
		Receptor	IC_E	IC_S	IC_W	Res_A	Res_B	Res_C	Daycare	Sch1
		UTM X	505794	505320	504718	504919	504667	505709	507149	507558
TEU		UTM Y	5044483	5044106	5044213	5044611	5044201	5044897	5044038	5045353
Sktname	UTM X	UTM Y								
BLR-1	505646	5044496	149	508	970	735	1022	406	1572	2096
BLR-2	505645	5044491	148	504	968	736	1021	412	1570	2098
EG-1	505457	5044429	341	351	771	568	823	532	1736	2295
FWP-1	505288	5044396	513	292	599	427	651	655	1895	2463
EG-2	505230	5044467	563	372	573	343	624	643	1966	2490
BLR-3	505236	5044444	559	348	567	358	619	656	1956	2494
BLR-4	505231	5044444	564	349	563	354	614	659	1961	2498
BLR-5	505226	5044444	569	350	558	349	610	663	1966	2503
IPA	505305	5044458	489	353	636	415	688	597	1892	2424

2.5 Evaluation Methodology

To complete a Level 1 Risk Assessment, the owner or operator must comply with OAR 340-245-0210(1) and then assess risk by using the Level 1 Risk Assessment Tool in OAR 340-245-8050 Table 5 to determine toxic air contaminant concentrations at approved exposure locations.

For each TEU stack, the stack heights from Table 2-1 and the closest exposure distance from Table 2-3 will be used to identify the appropriate annual and 24-hour dispersion factors under OAR 340-245-8050 Table 5A and 5B. For the TEU fugitive sources, the area and height of the building from Table 2-1 and closest exposure distance will be used to identify the appropriate annual and 24-hour dispersion factors under OAR 340-245-8050 Table 5C and 5D. Each TEU will be considered individually. The TEU risk will be calculated for each pollutant by multiplying the appropriate dispersion factor by the pollutant emission rate then dividing by the appropriate Risk Based Concentration (RBCs) from OAR 340-245-8050 Table 3. Residential RBCs will be applied at the residential exposure locations, child RBCs at the school and daycare locations, and worker RBCs at the Industrial/Commercial locations. The acute exposure will be evaluated at the closest overall distance, regardless of type.

For each TEU, the pollutant risks will be summed. Since there are seven types of RBCs, seven risk values will be determined for each TEU. The excess chronic cancer risk will be the maximum of the residential chronic cancer risk, the child chronic cancer risk or the worker chronic cancer risk. The chronic hazard risk will be the maximum of the residential chronic non-cancer risk, the child chronic non-cancer risk or the worker chronic non-cancer risk. Then the total risk will calculated as the summation of individual TEU risks and compared to the new source Risk Action Levels shown in Table 2-4. The risk from TEUs which only combust natural gas will not be included in the facility wide risk summation.

Table 2-4: New Source Risk Action Levels

Level Description	Cancer	Non-Cancer
Source Permit Level	0.5	0.5
Community Engagement Level	5	1
TBACT Level	10	1
Permit Denial Level	25	1