DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/OPQ/OPMA/Division of Biotechnology Manufacturing Attn: Christopher Downey, Ph.D., Division Director 10903 New Hampshire Avenue; White Oak Building 51 Silver Spring, MD 20993 E-mail: OPMABLAInspection483Responses@fda.hhs.gov	07/11/2022-07/15/2022
	FEI NUMBER 3007772056

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark Foley, Chief Executive Officer	
FIRM NAME Revance Therapeutics, Inc.	STREET ADDRESS 7555 Gateway Blvd.
CITY, STATE, ZIP CODE, COUNTRY Newark, CA 94560	TYPE ESTABLISHMENT INSPECTED Drug Substance and Drug Product Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Deviations are not always initiated according to SOP_QA_0042 *Deviation Reporting and Handling*. Specifically, (b) (4) drug substance (DS) development lot (b) (4) was aborted on 08 Nov 2021 due to a leak in the (b) (4) (b) (4) (b) (4) system 01-(b) (4) -002 in room (b) (4), which is the same equipment used for commercial production of (b) (4). No deviation was initiated for the leak in the (b) (4) equipment located in room (b) (4).

OBSERVATION 2

SOP_EQ_0419, *Operation and Cleaning of* (b) (4) does not contain adequate information to ensure consistent process performance. Specifically, the SOP requires the performance of either (b) (4) (b) (4) or storage in (b) (4) within (b) (4) of (b) (4). (b) (4) 01-(b) (4) -002 used for manufacture of (b) (4) DS was removed from storage in (b) (4) for a total of (b) (4) (b) (4) (b) (4) (b) (4) (b) (4)), which included manufacturing operations for lot (b) (4) on 08 November 2021, (b) (4), and storage in (b) (4). The (b) (4) stored in (b) (4) was subsequently used to manufacture DS development lot (b) (4) on 15 November 2021. A result of too numerous to count (TNTC) was obtained for the in-process (b) (4) bioburden sample for the (b) (4) (b) (4) for (b) (4). The sample did not meet acceptance criteria of ≤(b) (4) CFU/mL; the organism was identified as *Bulkholderia cepacia complex*.

OBSERVATION 3

Cell bank storage facility information is not listed in (b) (4). Specifically, storage of working cell bank (b) (4) at (b) (4) is not listed in Table 1: Manufacturing and Testing Sites for (b) (4) Drug Substance in eCTD 3.2.S.2.1 Manufacturers.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
SEE REVERSE OF THIS PAGE	Virginia A. Carroll -S Digitally signed by Virginia A. Carroll -S Date: 2022.07.15 13:10:03 -04'00' Patricia F. Hughestroost -S Digitally signed by Patricia F. Hughestroost -S Date: 2022.07.15 13:12:06 -04'00' Sarah Johnson -S Digitally signed by Sarah Johnson -S Date: 2022.07.15 13:14:33 -04'00'	Virginia Carroll, PhD, Senior Pharmaceutical Quality Assessor Patricia Hughes, PhD, Supervisory Microbiologist Sarah Johnson, PhD, Senior Biologist	07/15/2022