DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CDER/OPQ/OPMA/Division of Biotechnology Manufacturing Attn: Zhihao Peter Qiu, PhD, Acting Division Director White Oak Building 22, Room 5112 10903 New Hampshire Avenue, Silver Spring, MD 20993 Industry Information: www.fda.gov/oc/industry	June 21-25, 28-30, and July 1-2, 2021
	FEI NUMBER 3007772056

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Abhay Joshi, PhD, MBA, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Revance Therapeutics, Inc.	7555 Gateway Blvd.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Newark, CA 94560-1152	Drug Substance and Drug Product Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

1) Current release and stability cell bank testing methods (PROT_QC_2711 v1 15 Nov 2019) are insufficient to monitor quality and shelf-life of working cell bank.

a. The current Working Cell Bank (WCB) (b) (4) was produced on November 15, 2012 and assigned an initial expiry of 10 years. Interim stability report for WCB (b) (4) (b) (4) Lot (b) (4) Version 1 03 Mar 2021 which included (b) (4) months of WCB stability data provided no out-of-specification data.

b. Since manufacture of (b) (4) batch (b) (4) using (b) (4) 23-August-2019,) additional production using this WCB (b) (4) resulted in rejected DS GMP lots (b) (4) (manufactured (b) (4) and (b) (4) (b) (4)

c. Quality Investigation QI-20-003 identified the effectiveness of the WCB (b) (4) s the most likely root cause and recommended CAPA 21-017 (initiated 5-May-~~2020~~ 2021; ongoing) to manufacture and qualify new WCB per PROT_QC_2711.

d. New WCB (b) (4) is not yet fully qualified.

2) The current manufacturing process is not the process proposed for licensure. Specifically, the (b) (4) drug substance manufacturing process used to produce the most recently manufactured Development DS batch (b) (4) (manufactured (b) (4)) and GMP DS batch (b) (4) (manufactured (b) (4)) differs from the proposed commercial manufacturing process

a. Per CAPA 21-017 there was a redesign of Growth Performance (b) (4) as a time course to align with the (b) (4) process at the (b) (4) processing steps. This includes the use of (b) (4) (b) (4) According to the report for CAPA 21-017, work instruction (b) (4) for the additional in process control was approved by QA on 15- June-2021 and became effective on 25-June-2021. However, CAPA-21-017 remains open and additional

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	Carla J. Lundi Joao APV	Carla J. Lundi, Investigator Joao Pedras-Vasconcelos, PhD, OBP Primary Assessor	07/02/2021

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change controls may be implemented.
b. Recently manufactured DS lots have used (b) (4) (b) (4) is not included in the license application.

3) The firm's Quality Unit lacks the responsibility and authority for the control, review, and approval of outsourced activities which includes defining the responsibilities and communication processes for quality-related activities in a written agreement. Specifically, the Quality Unit has not approved the current space and services agreement or implemented a quality agreement for (b) (4) provided at the (b) (4) in effect since December 2015 (expiring in December 2022). The quality-related activities provided by the contract giver support the (b) (4) for drug substance and (b) (4) for drug product release and stability testing performed by Revance Therapeutics LLC at the (b) (4) Additionally, this site was not listed in the firm's in the application.

4) Actual yield and percentages of theoretical yield, indicators of process performance, are not determined at the conclusion of each appropriate phase of manufacturing for (b) (4) drug product. Specifically, the firm has not determined the theoretical yield for a batch of drug product based on the quantity of components to be used. There is no basis for calculating the actual yields or percentages of the theoretical yields during the filling, (b) (4) or capping processes without the presence of a vial counter on the (b) (4) Filler and Capper or a control in place for the number of vials issued to the start of filling process. Current yields are based on a count of the number of rejects documented during the process and total vials produced to back calculate the number of vials issued for the manufacturing filling operations.

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5) The responsibilities and procedures applicable to the quality control unit are not always in writing. Specifically, The following procedure and media fill batch record lacks details which are described as control steps:
a. MB the Sr. Director of Quality Control told me that the analyst's self-printed analytical worksheets are controlled through the review for uniqueness by the issuer of the AW number. This step is not in the firm's written procedure titled Quality Control Process for Analytical Record Assignment and Archiving (Doc ID SOP_QC_0080) which describes the responsibilities of the issuer of the AW number. Individual analytical worksheets are not controlled to assure the data captured is original and accurate.
b. The Master Batch Record for the Aseptic Filling, (b) (4) and Bulk Packaging of (b) (4) Injection, (b) (4) U/vial (b) (4) does not include the full instructions for the photo count verification of the vials exiting the filler prior to (b) (4) This step is intended to provide an accurate accountability of integral and non-integral vials produced during the media fill.

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