DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Carl Perez Telephone: 301-796-9102 Industry Information: www.fda.gov/oc/industry	October 28-November 1, 2024
	FEI NUMBER 2211100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Patrick Miller, Lentivirus Operations Head

FIRM NAME	STREET ADDRESS
Janssen Biopharmaceuticals, Inc.	1000 Route 202 South
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Raritan, NJ 08869	Lentiviral vector 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 (I) (WE) OBSERVED:

1. Control and maintenance of (b) (4) are deficient. Specifically, from 2022 to 2024, a total of 68 (b) (4) events occurred to the (b) (4) systems and/or their (b) (4) systems on the (b) (4) manufacturing line. More than 30 events occurred over the last twelve months on the same manufacturing line.

2. Investigations (nonconformance reports) are not initiated in a timely manner after detection of a deviation according to (b) (4) SOP-32984, Nonconformance and CAPA Pharm Segment. Specifically, the SOP requires nonconformance reports to be created within (b) (4) after detection/identification. Since January 2024, creation of 19 nonconformance reports exceeded the (b) (4) requirement with at least three reports exceeding 21 days or more after detection.

/s/

SEE REVERSE OF THIS PAGE	/s/	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Carl Perez, Consumer Safety Officer Xiuju Lu, Lead Consumer Safety Officer Kevin Matthews, Consumer Safety Officer	11/01/2024

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."