DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Jay Eltermann, Building 71, Room 6038 Telephone: (240) 402-9168 Industry Information: www.fda.gov/oc/industry	June 15 -19, 2020
	FEI NUMBER 3015434301

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: John Mosack,VP Manufacturing/General Manager, Catalent Maryland Harmans (BWI)

FIRM NAME	STREET ADDRESS
Paragon Gene Therapy/Catalent Maryland Inc.	7555 Harmans Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Harmans, Maryland, 21077	Biologics/Cell Therapy 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. Standard operating procedures (SOPs) are not always followed. Specifically;

a. Manufacturing personnel do not follow SOP 05.0066, Aseptic Techniques Used for (b) (4) in the Biological Safety Cabinets (Revision 07, Effective Date Feb 21, 2020). During the observation of the filling simulation for the (b) (4) (b) (4) (b) (4) into (b) (4) on June 18, 2020, the operator working outside the Class (b) (4) ISO (b) (4) Grade (b) (4) Biological Safety Cabinet was not wearing the required sterile sleeves. Additionally, the operator was handing off the (b) (4) and crossing over the Biological Safety Cabinet barrier to the operator working inside the Biological Safety Cabinet.

b. Twenty-two deviations were initiated in 2019 and 2020 due to environmental monitoring and personnel monitoring excursions that occurred during (b) (4) in the Class (b) (4) ISO (b) (4) Grade (b) (4) Biological Safety Cabinet in Suite (b) (4) The firm attributed the root cause of these deviations to personnel failing to follow SOP 05.0066, Aseptic Techniques Used for (b) (4) in the Biological Safety Cabinets. The three CAPAs initiated did not provide assurance that the environmental and personnel monitoring issue is resolved.

c. Eight deviations were initiated in 2019 because the written procedure for SOP BWI 04.042, Cleaning of GMP Manufacturing Clean Rooms (Revision 03, Effective Date Apr 17, 2020) and SOP 05.0087, Good Housekeeping Guidelines (Revision 08, Effective Date Apr 10, 2020) was not always followed.

d. Fifty deviations were initiated from April 2019 to May 2020 because the written procedure for SOP 05.0013, Good Documentation Practices (Revision 11, Effective Date June 14, 2020) was not always followed.

e. Twelve deviation investigations were not completed within 30 days as stipulated in SOP 05.0240, Event, Deviation and Investigation Management in (b) (4) (Revision 02, Effective Date Sep 17, 2019) and remained open for one day to 71 days after the 30-day target. There was no documentation of extension or approval of an extension before closure per SOP 05.0240.

f. Ten legacy deviation investigations that were not completed within 45 days as stipulated in SOP 05.1033, Legacy Deviation Management and (b) (4) Business Continuity (Revision 01, Effective Date Apr 17, 2020) and remained open for eight days to 89 days after the 45-day target. There is no documentation of extension or approval of an extension before closure per SOP 05.1033.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	/s/	Priscilla M. Pastrana, CSO, Lead Inspector Wanda E. Pagan, Ph.D., Biologist, Andrew Byrnes, Ph.D., Supv. Res. Microbiologist and Bo Liang, Ph.D.,Visiting Associate	06/19/2020

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2. Inadequate review and trending of deviation investigations. Specifically:

a. The Investigational Review Board only reviews the major deviations. There is no oversight or review of minor deviations.

b. Only trending of closed deviations is conducted as stipulated in SOP 02.0029, Trending of Deviations (Revision 07, Effective Sep 09, 2019.) The firm does not conduct the trending of open deviations.

3. Inadequate controls for the prevention of mix-up of materials. Specifically;

Incorrect materials with similar/identical names were inadvertently used in the manufacturing of (b) (4) (b) (4) For example, in Deviation #DV-B-0086, (b) (4) (b) (4) should be used for the preparation of the (b) (4) However, (b) (4) (b) (4) was used, leading to termination of (b) (4) lots. Although a CAPA was initiated, there was no effectiveness check. Similar incidents with other materials and reagents ((b) (4) (b) (4) (b) (4)) have also been documented in subsequent deviations.

4. Measures to prevent the recurrence of cracks and leaking in cell culture vessels used for (b) (4) (b) (4) are inadequate. Specifically, 12 deviations related to cracks and leaking in (b) (4) (b) (4) have been documented. Although a Supplier Corrective Action Report (SCAR) has been initiated with Deviation # DV-B-0011, no follow-up with suppliers has been conducted.

5. The expiration dates of media that are (b) (4) for the manufacturing of (b) (4) (b) (4) are not set and documented. Specifically, (b) (4) types of (b) (4) media for (b) (4) (b) (4) are (b) (4) following established SOPs, no expiration dates are set prior to being released for product manufacturing or documented in the batch record.

/s/ June 19 2020

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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."