**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<br>10903 New Hampshire Avenue, Silver Spring, MD 20993<br>Attention: Jay Eltermann, Building 71, Room 6038<br>Telephone: (240) 402-9168<br>Industry Information: www.fda.gov/oc/industry | Dec 2-6, 2019 |
| | FEI NUMBER<br>3003683714 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tommaso Paoli US Director of Quality

| FIRM NAME | STREET ADDRESS |
|---|---|
| Kedrion BioPharma, Inc. | 155 Duryea Road |
| CITY, STATE AND ZIP CODE<br>Melville, NY 11747 | TYPE OF ESTABLISHMENT INSPECTED<br>Biologic 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. Written production and process control procedures were not followed in the execution of the various production and process control functions during the PPQ runs for RhoGAM (b) (4) Incidences include, but are not limited to, the following:

a. Deviation 117124 due to operator not following SOP (b) (4) (version 12) "Production of RhoGAM (b) (4) by incorrectly proceeding with the unnecessary (b) (4) (b) (4) and adding (b) (4) directly into the (b) (4) instead to the (b) (4) resulted in a (b) (4) of an initiated PPQ Lot (b) (4) and rejection (b) (4) due to not being suitable for further processing.

b. Deviation 121827, the operator did not follow SOP (b) (4) (version 10) (b) (4) (b) (4) and entered non-approved (b) (4) results from the QC laboratory resulting in need to perform the (b) (4) adjustments based on the erroneous results which is not part of the SOP (b) (4) (version 10) for PPQ Lot (b) (4)

c. Deviation 121766, the operator did not follow SOP (b) (4) (version 10) "Production of RhoGAM (b) (4) and added the incorrect quantity of (b) (4) to (b) (4) for PPQ Lot (b) (4).

d. Deviation 123472, QA verified the dosage calculation for fill, but did not verify that the (b) (4) value was transcribed appropriately per SOP GQC-00-025 "Review of Test Data and Release of Test Results." Therefore, the (b) (4) based on the incorrectly transcribed (b) (4) value for PPQ Lot (b) (4)

2. Deviation investigations are not well documented. Specifically, a deviation of an operator not following procedure and incorrectly preparing and using (b) (4) instead of (b) (4) for dilution of (b) (4) (b) (4) at the (b) (4) step, which may affect the validity of the (b) (4) was found during the

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|---|---|---|---|
| | /S/ | Pete Amin CSO<br>Holly Brevig CSO<br>Margo Zeta Norton Biologist<br>Linda Thai, CSO<br>Timothy Martin, Regulatory Officer | 12/06/2019<br>12/6/2019<br>12/6/2019<br>12/6/2019 |

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| FDA/CBER/OCBQ/Division of Manufacturing and Product Quality<br>10903 New Hampshire Avenue, Silver Spring, MD 20993<br>Attention: Jay Eltermann, Building 71, Room 6038<br>Telephone: (240) 402-9168<br>Industry Information: www.fda.gov/oc/industry | Dec 2-6, 2019 |
| | FEI NUMBER<br>3003683714 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tommaso Paoli US Director of Quality

| FIRM NAME | STREET ADDRESS |
|---|---|
| Kedrion BioPharma, Inc. | 155 Duryea Road |
| CITY, STATE AND ZIP CODE<br>Melville, NY 11747 | TYPE OF ESTABLISHMENT INSPECTED<br>Biologic Manufacturer |

investigation of a related deviation 117124 and was not investigated separately for root cause and no CAPA was assigned. The separate deviation was also not recorded in the batch record.

3. Procedures designed to control microbiological contamination are not established. Specifically, WFI point of use is QC sampled after a (b) (4) flush according to SOP MQC-00-056. However, it was verbally confirmed by RhoGAM Manufacturing Supervisor that operators are not required to flush the WFI prior to use during production; and that there is no written procedure.

4. Appropriate controls for data integrity were not exercised over computers used during PPQ lots. Specifically, data integrity remediation project as per Document # (b) (4) is ongoing as of this inspection (December 2-6, 2019); however, PPQ lots were prepared between November 2018 to January 2019. The following systems and equipment used during RhoGAM (b) (4) production are a part of this ongoing project:

(b) (4)

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|---|---|---|---|
| | /S/ | Peter Jemmi CSO<br>Holly Brewer CSO<br>Malgorzata Norton Biologist<br>Linda Thacker CSO<br>Timothy Martin, Regulatory Officer | 12/06/2019<br>12/6/2019<br>12/6/2019<br>12/6/2019 |

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."