

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA/CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Carolyn Renshaw, Building 71 Rm. 4042 Telephone: (240) 402-7343 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION August 28- September 1, 2023
	FEI NUMBER 1000122198

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: RJ Fitch, Chief Operating Officer & General Manager

FIRM NAME WuXi Advanced Therapies	STREET ADDRESS 4751 League Island Blvd
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CITY, STATE AND ZIP CODE Philadelphia, PA 19112	TYPE OF ESTABLISHMENT INSPECTED Drug Product Manufacturer
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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. The aseptic operator qualification program is deficient, specifically,
 - i. There was an increase of excursion rates in personnel monitoring in the (b) (4) environmental monitoring trend report. This negative trend was attributed to inadequate aseptic technique and training.
 - ii. The standard operating procedures (SOPs) used to perform aseptic operations (b) (4) are not adequate to ensure sufficient aseptic technique as noted by the lack of detail in describing the flow of materials (b) (4) (b) (4) including disinfection and material transfer practices.
 - iii. There is lack of supervisory oversight of operators working within the cleanroom. For example, during observation of production, a supervisor was seen to not provide corrective instruction to an operator who was not following proper aseptic techniques.
 - iv. There is no verification that operators are up to date with training requirements before performing aseptic operations. Although the supervisor receives notification of expiration of an operators' training, there is no assurance and/or documentation that the operators are sufficiently trained to work in the cleanroom prior to performing aseptic operations.
 - v. Operators are not following SOPs for general aseptic technique, in addition to, batch record instructions as evidenced during observation of aseptic operations. For example, during observation of (b) (4) procedure, (b) (4) operator did not use (b) (4) (b) (4) as explicitly stated in steps (b) (4) of the batch record.

SEE
REVERSE
OF THIS
PAGE

/S/

EMPLOYEE(S) NAME AND TITLE (Print or Type) Hector Carrero, CSO (Lead) Karin Knudson, Biological Reviewer Brian Niland, Biologist Grace Forsythia Cortesini, Biological Reviewer	DATE ISSUED 09/01/2023
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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."