DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA / CDER 10903 New Hampshire Ave., Bldg 51 Rm 4225 Silver Springs, MD 20993 1 301 796 3334	3/19/2023 – 3/27/2023
	FEI NUMBER 3012695367

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Albert A. Mazaltov, General Manager

FIRM NAME	STREET ADDRESS
SciVac LTD	13 Gad Feinstein Rd.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Rehovot, Israel POB 580 7610303	Sterile Drug 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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

A. You do not routinely employ the use of sporicidal agent(s) in your Grade (b) (4) filling environments to include the inside and outside of your (b) (4) Grade (b) (4) You have 48 documented recoveries of various spore forming microbes to include molds and bacillus species over the previous approximate two years. These spore forming recoveries are documented in your open (b) (4) filling enclosure, surrounding Grade (b) (4) areas as well as throughout your facility.

   i. You documented Deviation (b) (4) regarding the recovery of (b) (4) (b) (4) on (b) (4) sampled (b) (4) of filling operations inside the (b) (4) door during batch (b) (4) Your CAPA does not address operator error while the investigation includes operator error as a root cause. Sporicide use was not employed on the outside of the (b) (4) doors before filling operations were started for batch (b) (4) dated (b) (4)

B. Your environmental and personnel monitoring plan to include sampling locations and times lack scientific support in your Grade (b) (4) formulation and filling areas as follows:

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i. You do not perform personnel monitoring activities immediately after any of your approximately (b) (4) aseptic connections. Personnel monitoring activities are only performed at the end of each series of operations whereby operator(s) who perform aseptic connections sanitize their hands one or more times before personnel monitoring occurs.

ii. You do not require aseptic operators who perform Grade (b) (4) interventions are tested to Grade (b) (4) personnel monitoring specifications. I observed your operator perform a routine (b) (4) (b) (4) intervention during batch (b) (4) whereby their head entered your (b) (4) who was later tested to Grade (b) (4) specifications regarding head and mask testing.

iii. Your (b) (4) are not representative of your dynamic environment during setup activities in your Grade (b) (4) filling areas located in room (b) (4) While you have a (b) (4) (b) (4) during setup activities, it is located in your (b) (4) area which is separated from your filling area by a partition. You perform various setup activities in your filling area to include aseptic connections, filling head placement, etc.

iv. Grade (b) (4) formulation area room (b) (4) surface sample locations are inadequate such that sampling does not occur proximal to the area where aseptic activities to include aseptic connections are performed. Instead, you surface sample near the (b) (4) which is approximately (b) (4) (b) (4) or more away from your aseptic connections.

v. Your (b) (4) located in your Grade (b) (4) room (b) (4) formulation area are not in or near your work surface and therefore, are not representative of your dynamic / working environment.

C. Areas and surfaces of your Grade (b) (4) open (b) (4) are not cleaned adequately. I observed aseptic operators cleaning your open (b) (4) during filling operations and after batch (b) (4) was completed. The aseptic operator failed to completely clean the opened (b) (4) door(s) upon completion of an open door (b) (4) intervention. Operator(s) were also observed failing to clean the partition separating the (b) (4) area from the filling area inside your (b) (4)

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OBSERVATION 2

Employees engaged in the manufacture and processing of a drug product lack the training required to perform their assigned functions.

Specifically,

A. You lack scientific justification supporting your defect categories and establishment of your defect kits. Cracks are categorized with scratches and cracks are not included in your qualification kits. Furthermore, you have failed to include glass particles in your kits.

   i. AQLs are not scientifically established per defect or criticality.

   ii. Statistical analysis of defects by type is not scientifically established. You established trending limits of approximately (b) (4) by defect type when defect rates allow for tighter trending limits. An increase of defects over time was observed regarding cracked / scratched vial category where counts per batch ranged from (b) (4) to (b) (4)

OBSERVATION 3

Deviations from written production and process control procedures are not recorded or justified.

Specifically,

A. You discovered (b) (4) glove (b) (4) failure on 2/28/2023 for a tear compromising integrity of the glove. A deviation was only opened 3/19/2023 after discussing this failure with your quality management. Media fill batch (b) (4) was filled during the use of this glove.

B. You are not required to perform investigations upon failures regarding visual inspections and (b) (4) retraining efforts as well as gowning failures per written procedures.

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i. Your visual inspection operator failed multiple requalification efforts during the approximate period of 7/3/2022 through 7/28/2022 and no deviation was opened.
ii. Your gowning qualification SOP does not require investigations if the operator fails (b) (4) gowning qualification.

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

A. Procedures are not established and / or followed to manage reconciliation of visual inspection personnel qualification documentation, media fill unit inspection documentation, etc.
   i. Your visual inspection qualification documentation does not reconcile all vials during operator qualifications.
   ii. Your media fill inspection vials do not reconcile across various documents included in media fill inspection records.

B. Your retain inspection procedures do not review labeled and representative vials. Your retain inspection program include vials which are not labeled and you only inspect (b) (4) of (b) (4) vials retained from each lot. Furthermore, you do not inspect your labeled vials.

SEE REVERSE OF THIS PAGE	Robert J. Ham, Investigator	Robert J. Ham -S Digitally signed by Robert J. Ham -S Date: 2023.03.27 04:35:14 -05'00' X	3/27/2023

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 judgment, 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."