DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax:(913) 752-2111 Industry Information: www.fda.gov/oc/industry	01/30/2012 - 02/13/2012* FEI NUMBER 1950222

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Stephen C. Natsch, Vice President and General Manager

FIRM NAME	STREET ADDRESS
Meridian Medical Technologies a Pfizer Company	2555 Hermelin Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brentwood, MO 63144-2504	Pharmaceutical 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:

The observations listed on this FDA 483 relate to conditions and practices observed at the manufacturing facility located at 2555 Hermelin Dr., St. Louis, MO 63144 referred to as the Brentwood facility and at the corporate office located at ~~1045~~ 1945 Craig Rd., St. Louis, MO 63146, registered under CFN/FEI 1937280.

SB 2/13/12 MHH 2-13-12

OBSERVATION 1

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically,

A. Supervisor (b) (6) reported times recorded for specific steps in the batch record are not the actual times steps started and stopped, but rather theoretical times. For example, step (b) (4) for the filling batch record of AtroPen lot #1PT716 on (b) (4) is documented with a start time of (b) (4) and stop time of (b) (4). However, (b) (6) stated the start time is recorded and the stop time is immediately written for when the step should theoretically end. In step (b) (4) this is (b) (4) minutes later. It is not recorded when the step actually ended.

B. During the filling of lot #1PT716 of AtroPen on (b) (4) operator (b) (6) exited the aseptic area at (b) (4) and did not return that day. Operator (b) (6) signed off that they verified step (b) (4) and performed step (b) (4) of the batch record, both of which occurred after (b) (4). Step (b) (4) could not have been performed until at least (b) (4) minutes after the (b) (6) exited for the day. Supervisor (b) (6) reported the batch record would have been pre-filled out by (b) (6) before (b) (6) exited the aseptic area.

C. The "performed by/date" was not recorded for the inspection of the gasket on the active air sampling forms for (b) (4) and (b) (4) on (b) (4) at the time of performance.

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D. Batch 1M1726 - Multichambered Autoinjector 2.1 mg Atropine/0.7 mL dose 600 mg Pralidoxime Chloride/2.0 mL Dose states to pull a sample of [redacted] basic units and check for proper plunger placement per SOP-PRO-FIL-00109-SL. If the plunger depth is out of range, the batch record allows for a retest. If the retest is out of range, an operator would segregate to the last good test and perform 100% inspection. Only the final result of the rework inspection is documented on the observation sheet and not the raw data obtained from the 100% inspection. This rework is not reviewed or approved by the Quality Unit.

E. Batch 1M1726 - Multichambered Autoinjector 2.1 mg Atropine/0.7 mL dose 600 mg Pralidoxime Chloride/2.0 mL Dose states in step [redacted] *"***Prior to inspecting each bag/container, verify the count of each container using a weight counting scale per SOP-MAN-PKG-00103-SL. Notify SPM if weight count quantity varies more than -/+ [redacted]% of the transfer sheet quantity***"*. The weights from this verification are not documented.

F. SOP-MDP-GEN-00013-SL - In-process Product Transfer procedure was not followed during the transfer of Atropine, batch 1M1726. The Product Transfer Form for 1M1726 states that [redacted] tubs were transferred to Westport on (b) (4), but the Carrier signed off on the transfer on (b) (4).

G. The annual review of product reserves for AtroPens were not approved by the statistical quality control supervisor or designee by the (b) (4) reserve report due date, (b) (4) listed in SOP-QLC-SQC-00384-SL. The listed lot numbers were approved by the statistical quality control supervisor or designee on 6-27-2011.

- AtroPen, 2 mg, Lot Number: 954408
- AtroPen, 2 mg, Lot Number: 954821
- AtroPen, 2 mg, Lot Number: 954409
- AtroPen, 1.0 mg, Lot Number: 95L847
- AtroPen, 0.5 mg, Lot Number: 75M749
- AtroPen, 1.0 mg, Lot Number: 05L214

OBSERVATION 2

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

Specifically,

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A. "SOP-PRO-FIL-00001-SL General Aseptic Procedure" was not followed. The (b) (4) (b) (4) is a component of the finished product. During aseptic assembly of (b) (4) lot (b) (4) in room #(b) (4) on (b) (4) the following was observed:

1) Operator (b) (6) was observed to pick (b) (4) Sheath components off the assembling turret and toss them back in the (b) (4) Sheath bowl. Section (b) (4) of the procedure states "***To clear a component, use sterile forceps to remove the item(s) from the area***".
2) Operator (b) (6) was observed to shake a bag of (b) (4) and allow the bag to touch the inside of the (b) (4) bowl while adding (b) (4) Section (b) (4) of the procedure states "***When adding components, one smooth motion is used to pour components into the bowl***".
3) Operator (b) (6) was observed to make unnecessary hand movements and reach over the assembling turret area. Section (b) (4) of the procedure states"***Personnel will eliminate**unnecessary hand or arm movements***".

B. On (b) (4) "SOP-PRO-FIL-00001-SL General Aseptic Procedure" was not followed. Supervisor (b) (6) was present in the class 100 area and performing batch record step (b) (4) and weight checks during the filling of AtroPen lot #1PT716, but did not sign the filling operation sign in sheet. Section (b) (4) of the procedure states "***Any person entering a class 100 area while production is in progress must sign the batch record***" and section (b) (4) of the filling batch record states "***All APA personnel entering this filling area must sign the appropriate table below***".

C. SOP-PRO-FIL-00002-SL Aseptic Processing Area Gowning was not followed in that:
1) On 2/3/2012 two of the (b) (4) individuals observed aseptically gowning placed their foot on the bench while putting their boots on. After 8:50am on 2/3/2012 an additional two of (b) (4) individuals were observed to also don sterile boots by placing them on the bench and then proceed to enter the Aseptic Processing Area. Under (b) (4) of the procedure it states "***don boots one at a time over the shoe covers, allowing only the boots to touch the floor on the other side of the bench.***"
2) One employee was observed to don the sterile coveralls and then reach across the boot cart allowing the coveralls to rub against the cart while retrieving boots.

D. During the cleaning / sanitization in Room (b) (4) on 2/2/2012 one individual was observed cleaning from the ceiling to and including the return air vent and the second employee was observed cleaning the floor. Neither individual cleaned the "Cove Base", the portion between the return air vent and the floor.

E. The microbial alert and action levels established to initiate investigations of environmental monitoring results are not based on historical environmental monitoring sampling data.

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E. Media Fill OP-11-808 is inadequate to qualify personnel in that it does not adequately document the
F. process manipulations that simulate the routine filling operations and exposure that the product itself would undergo. According to Attachment 5.12A: List of Filling Events, several operators ((b) (6) (b) (6)) were qualified during media fill OP-11-808 without performing any filling events.

2/13/12 SB MHH 2-17-12

OBSERVATION 3

Established laboratory control mechanisms are not followed.

Specifically,

The identity of the incubator used to store environmental monitoring plates is not recorded. There are (b) (4) incubators at (b) (4) C and (b) (4) at (b) (4) °C for environmental monitoring samples. Records do not indicate which incubator was used for environmental monitoring plates. Therefore, quality personnel reviewing results can not verify the correct temperature conditions were used.

The times environmental monitoring microbial plates are placed into the incubator is not recorded. Therefore, quality personnel reviewing results can not verify the plates were incubated for the specified period of time.

OBSERVATION 4

Written procedures are not followed for the handling of components.

Specifically, batch records call for the washing of needles per SOP-PRO-CLP-00050-SL - Preparation of (b) (4) Needles. The firm does not document to assure the validated soak time is met during the preparation of the needles.

* DATES OF INSPECTION:
01/30/2012(Mon), 01/31/2012(Tue), 02/01/2012(Wed), 02/02/2012(Thu), 02/03/2012(Fri), 02/06/2012(Mon), 02/07/2012(Tue), 02/08/2012(Wed), 02/09/2012(Thu), 02/13/2012(Mon)

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