DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 555 Winderley Place, Suite 200<br>Maitland, FL 32751<br>(407) 475-4700 Fax:(407) 475-4768<br>Industry Information: www.fda.gov/oc/industry | 09/11/2014 - 09/17/2014*<br>FEI NUMBER<br>3008782867 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Marc I. Parness, President

| FIRM NAME | STREET ADDRESS |
|---|---|
| U S Infusion, Inc. dba Truecare Biomedix-USA | 6356 Manor Lane, Suite 103 |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| South Miami, FL 33143 | Medical Device Specification Developer |

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.

*The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.*

**DURING AN INSPECTION OF YOUR FIRM I OBSERVED:**

## OBSERVATION 1

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been adequately established.

(A) Firm's Purchasing Control procedures (both in Quality Manual and in SOP-011 not dated) do not adequately describe methods by which the firm assures its potential contractors/suppliers will provide products according to its specifications consistently in that it does not assure verification that suppliers/contractors have adequate Quality Control program including but not limited to personnel qualification for bonding, process validation of special and automated processes such as extrusion, and maintenance of equipment. Firm has acquired documentation from its present IV administration set contractor including (b)(4) validation, package integrity validation, and Certificates of Analysis and Sterilization, but these documents are not required to be obtained in the firm's Purchasing Control procedures for any potential future suppliers/contractors.

(B) Firm receives Certificate of Sterilization from its current IV administration set contractor which states in part that product was sterilized by (b)(4) and without microorganism. The firm's President stated US Infusion personnel do not know if this means the contractor does not use biological indicators during routine steriliization and if so whether this method is adequately controlled.

(C) It is stated on firm's website that all suppliers are audited quarterly, however firm's President stated that all suppliers are not audited quarterly.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | DATE ISSUED |
|---|---|---|
| | Richard K Vogel, Investigator<br>Richard K. Vogel | 09/17/2014 |

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**OBSERVATION 2**

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Firm has not reported 3 complaints related to recall in 2012 due to leakage from its IV administration sets which had potential to harm patients as MDR Malfunction reports to FDA.

**OBSERVATION 3**

Procedures for quality audits have not been adequately established.

It is stated in the firm's Internal Audit SOP-001 dated 11/15/2012 that it is required to generate audit schedule and that the schedule is such that all major systems and areas are covered at least once a year. The firm has no documented schedule, no documented specific internal audit criteria, and has not completed any official internal audits.

**OBSERVATION 4**

Corrective and preventive action activities and/or results have not been adequately documented.

Corrective/Preventive Action Request #3 dated 7/18/2012 initiated because of firm's receipt of 3 complaints related to leaking of its IV administration sets which had potential to harm patients was inadequate in that:

(A) Although it is stated all defective sets were to be returned under RMA (Returned Materials Authorization), there is no documentation verifying this action included destruction of the defective products.

(B) Although it is stated the subject contractor, (b)(4) (which was responsible for poor manual bonding of the defective product) was removed from the firm's accepted supplier list, this action does not assure that firm's written Purchasing Control procedures were improved in order to prevent a similar incident in the future with a different contractor. Firm has reportedly required its present contractor to conduct 100% leak testing for its IV administration sets, but this requirement has not been documented as a part of written Purchasing Control procedures.

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**OBSERVATION 5**

Procedures for corrective and preventive action have not been adequately established.

Firm's Corrective Action procedures (Corrective Action System SOP-019 dated 11/15/2012 and Problem Reporting SOP-002 dated 11/15/2012) do not include:

(A) Requirement to verify or validate corrective/preventive action as effective and they will not adversely affect the finished device.

(B) Definition of preventive actions or how preventive actions will be controlled.

**OBSERVATION 6**

Procedures for design validation have not been adequately established.

Firm's Design Control SOP-015 dated 11/15/2012 does not include requirement for design validation including risk analysis. Firm has documented a specific risk analysis in spanish, however english version was not available during this present FDA inspection. Firm has no other documented design validation for its IV administration sets including labeling.

**OBSERVATION 7**

Procedures for design change have not been established.

Firm's Design Control SOP-015 dated 11/15/2012 does not include what methods are used to control design changes.

**OBSERVATION 8**

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

(A) Firm's Complaint procedures (Product Complaint Processing SOP-004 dated 11/15/2012 and Product Reporting SOP-002 dated 11/15/2012) do not include requirement that complaint investigation include identification of most likely underlying cause.

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(B) Firm received 3 complaints in 2012 regarding IV administration sets which were found to leak at the junction between tubing and the luer lock. Firm has not documented attempt to obtain full details (nature of complaint) in that they did not document attempt to determine if patients were involved in the incidents in the complaints or if medical intervention was required for any patients as a result of the IV administration sets leakage.

**OBSERVATION 9**

Written MDR procedures have not been developed.

**OBSERVATION 10**

Document control procedures have not been adequately established.

Firm's Control of Documents SOP-005 dated 11/15/2012 does not include method of how firm will control non-approved (draft) or obsolete documents.

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## Observation Annotations

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|---|---|---|---|
| Observation 1: | Promised to correct by 10/30/2014. | Observation 2: | Promised to correct by 10/30/2014. |
| Observation 3: | Promised to correct by 10/30/2014. | Observation 4: | Promised to correct. |
| Observation 5: | Promised to correct by 11/30/2014. | Observation 6: | Promised to correct by 11/30/2014. |
| Observation 7: | Promised to correct by 10/30/2014. | Observation 8: | Promised to correct by 10/30/2014. |
| Observation 9: | Promised to correct by 10/30/2014. | Observation 10: | Promised to correct by 10/30/2014. |

*** DATES OF INSPECTION:**
09/11/2014(Thu), 09/16/2014(Tue), 09/17/2014(Wed)

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EMPLOYEE(S) SIGNATURE
Richard K Vogel, Investigator
Richard K. Vogel

DATE ISSUED
09/17/2014