DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax:(312) 596-4187 Industry Information: www.fda.gov/oc/industry	06/19/2012 - 07/13/2012* FEI NUMBER 3005579246

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Ms. Zena G. Kaufman, Senior Vice President Global Quality

FIRM NAME	STREET ADDRESS
Hospira Inc.	275 N Field Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Lake Forest, IL 60045-2579	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.

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 WE OBSERVED:

OBSERVATION 1

An individual medical device manufacturer report submitted per FDA Form 3500A did not contain in Block B a description of the event or problem to include the nature of the problem.

Specifically,

MDR # 2921482-2009-00107 (referencing an event documented in Complaint # 202629) which involves an event occurring while having infusion with a PLUM A+ version 13.4 Infusion Pump does not include the following:

a) The outcome of death that occurred for a 3 year old patient was not reported correctly as the "Death" box was not checked off with a date in Section B2.

b) The MDR in Section B5 only contains a portion of statement/sentence from the complaint communication log: "We believe the child would have died anyway based on the condition coming in." The following is the full statement/sentence from the complaint communication log: "We believe the child would have died anyway based on the condition coming in, **but it was a concern about the tubing and the pump.**" The highlighted parts are from the complaint communication log and are not included in the MDR.

OBSERVATION 2

Complaints representing events that are MDR reportable were not promptly reviewed, evaluated, and investigated by a designated individual.

Specifically,

Parent Exception Report # 34094 was created on 4/6/2011 with event classification "High" regarding the Plum family of infusion pumps and "events of operator error in programming or setup of the device resulting in the patient receiving more or

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less medication than expected." The corrective and preventive actions associated with this exception report will address "Plum A+ and A+ 3 Delivery Accuracy Complaints." The following issues were noted by me (JAV) after reviewing the Status Report #87754 created 6/22/2012 for Exception Report #34094:

a) The firm had a final draft revision of the investigation report that was completed in 2/17/2012. On 6/26/2012, I (JAV) was able to retrieve a copy of the draft revision of the report. The status report states that the approval was "stopped" on 3/15/2012. On 6/26/2012, Hospira management at Lake Forest, IL was unaware of the status of this draft report (e.g. what needs to be finished and/or corrected).

b) According to the firm's Deviation and CAPA Management Procedure, status reports are required every (b) (4) calendar days and "any delays shall be promptly documented and justified in the respective section/form" (See Section titled, "Overall Timing Requirements"). The status report #87754 states in the Section titled "Extension Request / Justification of Delay", "In addition, this Status Report covers Status Report missed on May 2012" and gives no explanation as to why the status report was "missed."

c) On 6/26/2012, an employee stated to me that a meeting "to determine the scope of the investigation" (listed on Status Report Section titled, "Current Status," line item 19) had yet to be scheduled. There were two discrepancies with what was stated as:

i. The status report states that the date of the meeting will be on 6/27/2012 (next day)

ii. "The scope of the investigation" had already been determined by Exception Report #34094.

d) According to the firm's Deviation and CAPA Management Procedure, status reports shall be approved by a QA manager or delegate. On 6/26/2012, the extension of the due date until July 28, 2012 had no "Quality Unit Approval" on the designated line on the CAPA and Investigation Status Report Form.

OBSERVATION 3

Complaints involving the possible failure of a device to meet any of its specifications were not evaluated and investigated where necessary.

Specifically,

a) The investigation summary conducted under CAPA ER-DVCMH-001299 signed 12/19/2011 states, "(b) (4) (b) (4) (in Plum LC5000, Plum XL, and Symbiq pumps) do not have issues at high temperature and high-humidity environment as found in (b) (4) (in Gemstar pumps).... To mitigate Gemstar's failure mode in high-temperature and high-humidity environment, Site Engineering Team recommends that a CAPA be open to correct the Gemstar design by replacing (b) (4) protective layers for the strain gage and verifying the design." On 7/10/2012, this information was relayed to employees of Hospira. In response, I (JAV) was told that in lieu of a CAPA, this "preventive action" was placed under an Engineering Change Project. On 7/10/2012, I (JAV) found that neither a CAPA nor an Engineering Change Project had been initiated for this quality issue prior to my discussion with the Hospira employees.

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b) The firm's CAPA investigation (ER Parent ID 33380) uncovered that one of the root causes related to a known open recall (Recall Z-0292-2012) was an uncertified employee with ID # 80078136. An attachment memo dated 9/28/2011 to the CAPA investigation only identifies 9 lots which were affected by this known quality issue. On 7/5/2012, I (JAV) found that more than 90 lots could be associated to this known quality issue.

c) The CAPA investigation under Exception Report Number 62294 created 12/16/2011 found that the foreign supplier's ((b) (4) manufacturing process for the crimping uses an older technology and is manually controlled and therefore found that the crimp is a probable root cause. The investigation into this issue did not uncover that a Hospira Supplier Audit Report for (b) (4) critical device component supplier of touch screen and connector for the Symbiq infusion pumps) conducted on August 7, 2009 cited an observation for "No validation procedure or program has been established for the validation of the manufacturing process, equipment, test methods, and test equipment" along with 5 other "major" observations.

d) A portion of an investigation into complaints regarding the PCA Family of infusion pumps "non-delivery" of infusion was conducted under ER-DVC/MH-001552 and the root cause was documented as a component manufacturer's defect of the microswitch. The microswitch is not received directly from the component manufacturer but received as part of an assembly from (b) (4) a third party assembler. The investigation into this defect was closed on 12/1/2011 and did not uncover that the supplier (b) (4) [supplier of the assembly that includes the microswitch] had a supplier audit conducted on July 19, 2011 which has two open observations that have yet to be documented as addressed by the supplier (b) (4). The titled references for these observations are: "Control of Monitoring and Measurement" and "Control of Nonconforming Product."

OBSERVATION 4

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

Specifically,

a) Through the investigation conducted under Exception Report Number 62294 created 12/16/2011, Hospira found that "one probable root cause has been determined to be the bad crimp on the touchscreen connector." The product impact for this issue was found to be the Symbiq single and dual channel infusion pumps with list numbers 16026 and 16027. On 6/29/2012, Hospira had yet to conduct a corrective and preventive action for all product and/or customers impacted on the US market.

b) Through the investigation conducted under Exception Report Number 62294 created 12/16/2011, Hospira also found that the supplier's manufacturing process for the crimping uses an older technology and is manually controlled and therefore found that the crimp is a probable root cause. No subsequent corrective and preventive action regarding the manufacturing process was conducted at the foreign manufacturer ((b) (4) of the touch screen and its connector.

c) On 6/25/2012, the Exception report number 77265 created on 4/10/2012 with short description, "Devices R&D

utilizing Suppliers not on the Approved Supplier List (ASL)" did not have an extension of the due date of 5/25/2012 and had the status of "pending conclusion."

d) The current Deviation and CAPA Management procedure (QCP.05.001) appears to have different requirements for a "Quality Unit Approval" on CAPA status reports:

i. The CAPA procedure states, "Status reports shall be approved by a QU manager or delegate. If more than one extension is requested, Site Quality Head shall review and approve the request."

ii. The CAPA procedure continues on to state, "Attachment H defines the approvals required at the different process steps. Site Quality Unit shall be the final approval on all investigations, status reports."

iii. Here is a representation of the corresponding table in Attachment H relevant to CAPA Status Reports / extension approval requirements:

Event classification →	High	Medium	Low
F • *CAPA Status report / extensions*	• QU Manager (1st extension) • Site Quality Head (Subsequent extensions)		N/A

iv. The firm's CAPA and Investigation Status Report Form (Attachment G) states the following, "*** Approval Requirements: *** High Level Investigations = Site Quality Head *** Medium Level Investigations = QU Manager ***."

OBSERVATION 5

Requirements that must be met by suppliers have not been adequately established.

Specifically,

On 10/2/2009, the written Hospira Supplier Audit Report for (b) (4) critical device component supplier of touchscreen and connector for the Symbiq infusion pumps) describing a one-day inspection conducted on August 7, 2009 from a third-party auditor cited an observation for "No validation procedure or program has been established for the validation of the manufacturing process, equipment, test methods, and test equipment" along with 5 other "major" observations (classified as such by the third party auditor):

a) The audit report required a (b) (4)-day response (plan) from the foreign manufacturer to address the issues and no response (plan) was ever received

b) No follow-up action is documented at Hospira for these "major" observations nor for the foreign supplier's non-response to the 6 "major" observations

c) A subsequent audit was not conducted at the foreign manufacturer/supplier until April 16, 2012 (approximately 3 years later).

OBSERVATION 6

The report to FDA of the correction or removal of a device did not identify the device's 510(k) status.

Specifically,

On November 8, 2011, Hospira previously reported to the FDA that the 510(k) for the Recall (Z-0292-2012) of the LifeShield® Latex-Free GraviTech Flow Controller IV Sets [LATEX-FREE 100 ml Burette Set, Convertible Pin, 77 Inch] (List: 19208-01, Lot: 83-107-5H) initiated in November 2011 was K063239. During the inspection, I (JAV) also found that the firm also uses this 510(k) number to import the medical device into the United States from Costa Rica. On 7/2/2012, I (JAV) was told that this number is incorrect and that the DMR for the product identifies K030002 as the 510(k). Neither of these two 510(k) numbers [K063239 nor K030002] could be directly related to the LifeShield® Latex-Free GraviTech Flow Controller IV Sets (List: 19208-01, Lot: 83-107-5H) as approval of this product to the market.

OBSERVATION 7

Procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics have not been adequately established.

Specifically,

During the inspection, I (JAV) questioned the validity for having only one lot included in Recall #Z-0292-2012 [Recall of The LifeShield® Latex-Free GraviTech Flow Controller IV Sets {[LATEX-FREE 100 ml Burette Set, Convertible Pin, 77 Inch]}(List: 19208-01, Lot# 83-107-5H) initiated in November 2011]. According to Hospira employees, two factors for choosing this lot were: number of complaints and one uncertified employee. In response to my interview, on 7/5/2012, a Hospira management employee created a normalized chart titled, "Complaints per Million Rate" which included all the lots which had complaints compared to their CPM rate. Based on this chart, Hospira management decided to extend the Recall (Z-0292-2012) to include Lot # 96-098-5H, a lot where the "uncertified employee" was not a factor.

OBSERVATION 8

Changes to documents were not communicated to appropriate personnel in a timely manner.

Specifically,

Exception Report #50588 is the "parent" document for several other Exception Reports ("child" documents). As of

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6/29/2012, the investigation for this Exception Report is currently still in progress. A risk assessment was conducted for the PLUM family of infusion pumps in Exception Report # 50588 as the CAPA was created to further investigate issues with categories of an unacceptable risk. The PLUM Risk Assessment Report original document was completed on 8/11/2011. Subsequent revisions of the risk assessment were made on 8/30/2011 and 5/7/2012 (Revsions 2 and 3). None of these revisions are attached or referenced in the Exception Report # 50588.

OBSERVATION 9

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

Specifically,

a) An Issue Elevation Assessment Form is used by Hospira in documenting the description and analysis of a known quality issue for further review by upper management. The Issue Elevation Assessment Form related to Recall (Z-0292-2012) of The LifeShield® Latex-Free GraviTech Flow Controller IV Sets [LATEX-FREE 100 ml Burette Set, Convertible Pin, 77 Inch] (List: 19208-01, Lot: 83-107-5H) initiated in November 2011 states the following," Two (2) root causes were identified during the investigation of this issue: Excessive solvent vapor trapped in the burette chamber after assembly.... A buildup of electrostatic charge on the components of the burette, during the manufacturing process, causing them to stick to each other." The form does not document or reference the other two root causes identified and known by the Hospira Investigation team at the time: "Lack of personnel training performing burette assembly; and Bonding method to attach the burette and lower lid produces splashes."

b) The following field for Exception Report Number 62294 with short description, "SYMBIQ TOUCHSCREEN FAILURE TO RESPOND (NON RESPONSE) or FAILURE TO RESPOND WITH CORRECT KEY (NON LINEARITY)" is not completed although the information appears to be reasonably known:

Product Name(s) and/or Grid - Item(s) [affected known line of products is the Symbiq infusion pumps]

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OBSERVATION 10

Complaint files are not adequately maintained.

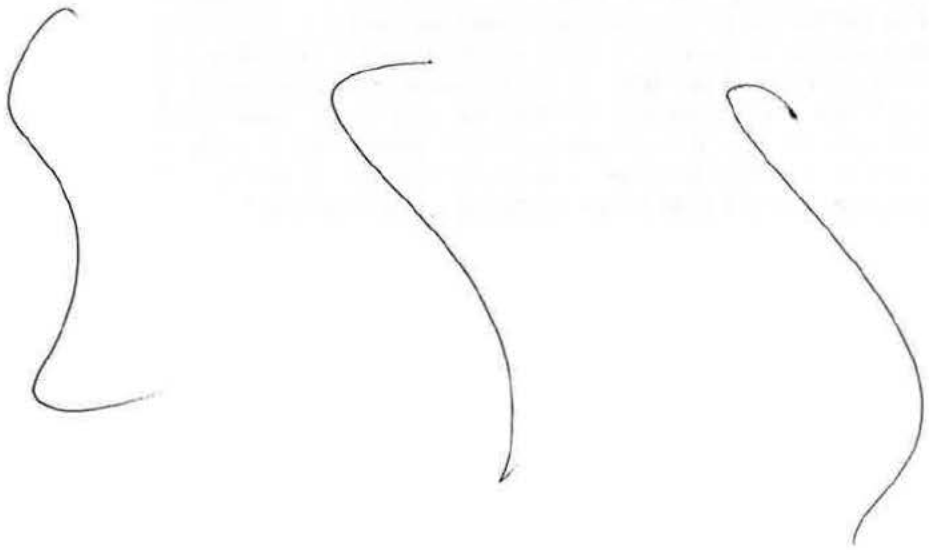
Specifically,

a) Hospira's GPSC Serialized Device Complaint Registration Worksheet for Complaint 202692 (regarding a complaint while using a PLUM infusion pump and an MDR reportable death of a pediatric patient) has the following issues:

   i. The worksheet is not signed or dated.

   ii. The worksheet documents, "Occlusion Alarms" in the "Event Description" which are never described in the electronic copy of the firm's "Complaint Summary" ((b) (4) nor reported in MDR 2921482-2009-00107 (202629-0). Hospira only reported through MDR # 2921482-2009-00107 the following: "too high of a pressure" alarms.

b) The firm's communication log for Complaint 202629 documents on 3/2/2009 that the pediatric patient was a "male", then on 3/24/2009 the same communication log documents that "This was a 3 year old girl..." There is no explanation in the complaint file or communication log for this change in information.



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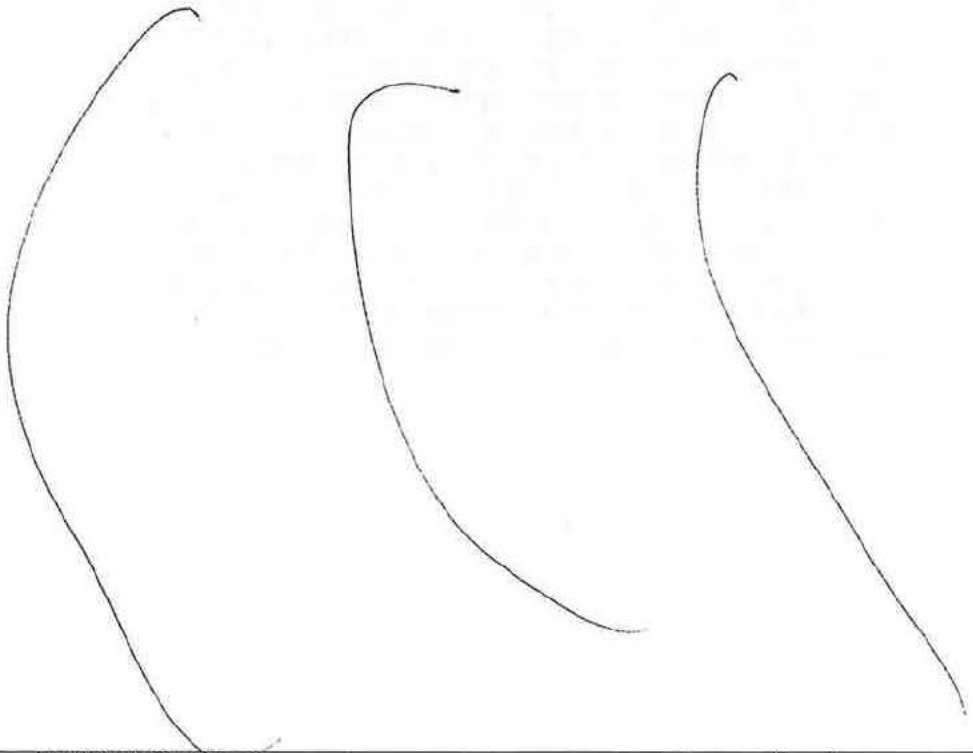
Observation Annotations

Observation 1:	Under consideration.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Reported corrected, not verified.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.
Observation 9:	Reported corrected, not verified.	Observation 10:	Promised to correct.

*** DATES OF INSPECTION:**
06/19/2012(Tue), 06/20/2012(Wed), 06/21/2012(Thu), 06/25/2012(Mon), 06/26/2012(Tue), 06/29/2012(Fri), 07/02/2012(Mon), 07/05/2012(Thu), 07/09/2012(Mon), 07/13/2012(Fri)



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