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	01/29/2013 - 02/07/2013 FEI NUMBER 3005579246

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Francis Michael (Mike) Ball, President / CEO

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 indicate in Block B that the outcome attributed to the adverse event was death.

Specifically,

The following MDRs had did not have checked off the "Death" box with a date when the information was already known through the complaint:

a) MDR # 2921482-2011-00074 (related to Complaint # 905637 and potential Gemstar Pump overdelivery of morphine) dated 5/3/2011

b) MDR # 9615050-2011-00233 (related to Complaint # 851299 and potential Plum A+ E321 battery error) dated 3/7/2011.

c) On 2/6/2013, Hospira found exactly 20 other MDRs (dated from 12/12/2008 - 12/31/2011) that needed an "MDR Follow-up" report to check the "Death" box. The MDRs referenced the following product families:

Product Family	Number of MDRs
Plum	9
Gemstar	5
PCA	3
Symbiq	2
APM	1

****** This is a repeat observation from the last inspection conducted 6/19/2012 - 7/13/2012 ******

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OBSERVATION 2

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

Specifically,

Your complaint investigation for complaint # 781360 did not uncover that Error code "E403" reported by the customer is not a code that is obtainable from the Plum A+ device. The complaint included a life-threatening serious injury with delay of critical drug delivery that was reported under MDR #2921482-2011-00016. The complaint documented that the Plum A+ History log showed an "E321 Battery timeout error" on all 3 channels but never showed an "E403" error. The complaint was opened on December 16, 2010 and was closed on May 27, 2011. On 1/31/2013, I (JAV) uncovered the inadequate data evaluation after interviewing employees and reading the device's Technical Service Manual.

****** This is a repeat observation from the last inspection conducted 6/19/2012 - 7/13/2012 ******

OBSERVATION 3

Procedures for design control have not been established.

Specifically,

Your design control of your Plum A+ is inadequate in that:

a) You do not clearly define your battery specifications as design inputs, for example: amp hours (capacity), volts, dimensions, weight, terminal type, charge current and discharge time.

b) You did not specify which type of battery, lead acid, lithium as a design input.

c) You do not specify the life expectancy of your battery when the battery does not last for the 10 year life expectancy of your infusion pump and a battery failure can result an interruption of therapy. You currently have 311 complaints indicating the battery failed which stops the drug/fluid infusion.

d) Your design verification was inadequate in that you did not verify your battery could consistently meet your specification over time. Your design verification did not prove your battery would last for the life expectancy of your plum A+ which is 10 years.

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OBSERVATION 4

Procedures for design change have not been adequately established.

Specifically,

According to the Hospira's, "Design and Development Plan Procedure" (QDO.11.011), updates to the project schedule are needed throughout the product development process. A Quality team member that would approve the new revision of the plan is located at Hospira (Lake Forest). On 2/5/2013, the "Design and Development Plan" for the "(b) (4) (b) (4) (CAPA ER/MH-001441)" which was opened on 4/18/2012 was found to be still under the design "Concept" phase. On 2/5/2013, you failed to update and/or approve a new revision of the "Design and Development Plan" for the (b) (4) (b) (4) (CAPA ER/MH-001441)" when the following milestone dates were never met:

	Dates
Design Input Review complete	(b) (4)
Design Output Review complete	
First Article of Inspection of Prototypes complete	
Verification Report Complete	
Design Transfer Review complete	
CR Structure Package approved / released	
First Lot to Stock	

OBSERVATION 5

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

Specifically,

a) Your CAPA ER-DVC/MH-001441 has failed to address the issue of "X091 - Backward Motor Movement" (Hazards: Potential undelivery, overdelivery, and/or pump stoppage) and (b) (4) Gemstar pump motor (b) (4) CAPA ER-DVC/MH-001441 was opened on July 1, 2010 to handle complaints for Gemstar pumps of "X091 - Backward Motor Movement." On 7/1/2010, a risk analysis documents 232 related complaints from June 1, 2008 to June 1, 2010. A subsequent risk analysis found another 448 related complaints (with 1 MDR report) from November 1, 2010 to October 31, 2012. During the inspection, I (JAV) requested a listing of complaints dated from 1/28/2011 to 1/28/2013 for "X091 - Backward Motor Movement" and found 496 related complaints.

b) Your CAPA system implementation is inadequate in that you do not trend component failures, for example:
   i. You did not analyze/trend (b) (4) component failures identified in your Plum A+

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infusion pump complaint investigations.

ii. You replaced 58,438 failed components in (b) (4) of your infusion pumps since July 2012 and you do not trend these failed components in your CAPA system to assess whether a preventative or corrective action is indicated and to ensure components are performing per your infusion pump design specifications.

c) Your implementation of your CAPA system is inadequate in that you documented an "effectiveness check is not required" for 18 of the last 20 "closed" Lake Forest Device CAPAs.

d) You opened a CAPA (PR: 38753) in 05/25/2011 to address Plum A+ battery failures which can cause a stoppage in critical therapy. Your design team stated the following actions were being undertaken as part of this corrective action:

- Software upgrade: to change the risk profile
- Battery replacement to reduce the probability of occurrence
- Battery supplier approval/controls
- Notification to customers

None of these corrections have been implemented when you currently have 311 E321 complaints documenting battery failures and 11 MDRs documenting a stoppage of critical drug delivery as of 01/31/2013.

e) You failed to follow your procedures which state each site will track and trend event and root cause for use in management review meetings when your San José, California site repaired/refurbished (b) (4) infusion pumps since July 17, 2012 and the site does not track and trend the failed component replacements to provide to you for management review meetings.

f) Your identification of data sources to analyze is inadequate in that you do not identify post market component failures as data sources needing to be analyzed when you have hundreds of post market field component failures.

g) Your complaint trending is inadequate in that you had approximately 33, 238 device complaints since July 17, 2012. You do not trend your complaint "analysis" codes which are determined as a result of your investigation on returned devices to evaluate whether a corrective or preventative action would be indicated.
For example:

i. Omniflow infusion pump: you have confirmed failures in your "analysis" data field documenting failures of blown fuses, motor base assemblies, power supply printed wire assemblies, battery and transducer failures for your Omniflow infusion pump.

ii. Plum A+ infusion pump: you have confirmed failures in your "analysis" data field documenting failures of bubble sensor PWA (printed wire assemble within the printed circuit board), battery, touch key pad assembly and front case assembly for your Plum A+ infusion pump.

h) Your CAPA system is inadequate in that you had 339 (b) (4) complaints which stopped the Plum A+ from functioning and you failed to address the issue as of 02/01/2013.

i) On 2/1/2013, approximately nineteen open CAPAs were documented to have as "CAPA Task Owner (b) (6) (b) (7)(C)" who recently retired on (b) (6) (b) (7)(C)

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**** This is a repeat observation from the last inspection conducted 6/19/2012 - 7/13/2012****

OBSERVATION 6

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

Specifically,

Your complaint handling system is inadequate in that:

a) Your repair facility replaced 58,438 failed components in (b) (4) infusion pumps from July 2012 to January 2013 and you did not enter these device component failures into your complaint system when a complaint is defined in your procedures as: any communication that alleges deficiencies related to the reliability, durability, or performance of a product after its release for distribution.

b) Your infusion pump complaint investigations are inadequate in that you replace components and close complaints with no further investigation, for example assessing whether the failure is expected, is a design issue, is a manufacturing issue, is a supplier issue and determining whether the failure is occurring across product families. For example you had 339 (b) (4) failures from 01/01/2009 to 01/30/13 which did not include an investigation after the component was replaced.

**** This is a repeat observation from the last inspection conducted 6/19/2012 - 7/13/2012****

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,

According to the "Medical Device Post-Production Risk Management Procedure," Risk is acceptable with adequate justification (AWJ) shall require investigation and include the rationale why the risk is acceptable using Severity and Likelihood of harm while developing the rationale for acceptability. The following risk assessments have calculations within the level of "AWJ" but fail to provide adequate risk assessment:

a) The risk assessment (359998797551) dated 2/4/2013 for Gemstar Backward Motor Movement [Rollback] Issue for Overdose includes evaluation of 34 complaints; *27 of which it states are MDR reportable.* The risk assessment is inadequate as:

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i. The risk level is calculated as "AWJ" (Acceptable with Justification) but the "Conclusion" does not state if the risk is acceptable or unacceptable even though there are no risk measures in place to mitigate the hazard of "overdosing." The Conclusion only states "It is recommended that this issue be escalated through a Notification to Management" with no date of when this event would occur.

ii. On 2/6/2013, I (JAV) discovered that the number "27" is incorrect and the actual number of MDR reportable events is "19."

b) The risk assessment (505430404190) dated 12/13-14/2012 for Gemstar Backward Motor Rollback (Hazard: "Infusion is stopped" in Gemstar Pumps related to CAPA ER-DVC/MH-001441 opened July 1, 2010 documents) evaluates 448 related complaints from November 1, 2010 to October 31, 2012; *4 of which it states are MDR reportable complaints*. The risk assessment is inadequate as:

i. The risk assessment does not include analysis/investigation of the previous risk assessment conducted on 7/1/2010 which documents 232 related complaints from June 1, 2008 to June 1, 2010

ii. The risk assessment documents the conclusion as "Risk is deemed Acceptable per analysis above" without including analysis of the previous 232 complaints and without providing adequate justification/rationale for the acceptability of the hazard, "Infusion is stopped" (i.e using Severity and Likelihood of harm to develop rationale)

iii. On 2/6/2013, I (JAV) discovered that the number "4" is incorrect and the actual number of MDR reportable events is "1."

*** ***This is a repeat observation from the last inspection conducted 6/19/2012 - 7/13/2012***

OBSERVATION 8

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

Specifically,

According to the your Supplier Evaluations Procedure (QSM.10.007, Section titled, "Corrective Action Follow-up Activities and Audit Closure), "Critical and Major observations will be tracked for proper closure based on supplier CAPA plan." The following were not adequately tracked for closure:

a) You receive the following Batteries from (b) (4)
   i. (b) (4) - Plum A+
   ii. - PCA Lifecare and Plum XLD

On 3/18/2011, the audit for this supplier found three (3) Major observations. On 1/31/2013, I (JAV) found that these observations had not been adequately addressed by the supplier and you failed to actively monitor these

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observations for closure.

b) You receive the components for the Part (b) (4) (camshaft) for the Symbiq Infusion Pumps from (b) (4) in (b) (4) On 8/11/2011, an audit found three (3) major observations. On 2/4/2013, I (JAV) found that you did not have evidence that (b) (4) had corrected all the major observations and that you were not actively monitoring these observations for closure.

**** This is a repeat observation from the last inspection conducted 6/19/2012 - 7/13/2012****

OBSERVATION 9

Procedures for training and identifying training needs have not been adequately established.

Specifically,

a) You failed to adequately train four Hospira Global Product Safety and Complaint employees. On 2/5/2013, I (JAV) found that four employees [(2) Global Product Team Managers and (2) Regulatory Reporting Specialists] who are designated to monitor teams complaints to ensure complaint handling and medical investigations are being conducted properly; and to coordinate data for US FDA {respectively} are not trained to the "Medical Device Complaint Investigations Procedure" LC-QA-QCP.05.017 procedure.

b) You failed to train your firm's Lead Director of Customer and Supplier Quality to the firm's current LC-QA-QS.05 "Exception Report ER and CAPA Management Policy." According to the director's position description (Director Quality - Supplier Quality, TPM Quality and One2One Quality dated March 2012), the director is responsible for the continuous improvement of Hospira's global Third Party Manufacturing Quality program. On 2/5/2013, the employee and her team were found to be conducting corrective and preventive actions for the previous FDA inspection conducted 6/19/2012 - 7/13/2012 (FDA 483 observation # 5 regarding supplier controls) and had not placed all of these corrective and preventive actions in Hospira's CAPA system.

OBSERVATION 10

Document control procedures have not been established.

Specifically,

You have conflicting information in your Plum A+ complaints, for example in the designated root cause field you state "not applicable" however in the "investigation summary" you state a root cause. The investigative summary information is not tracked and trended into your CAPA system.

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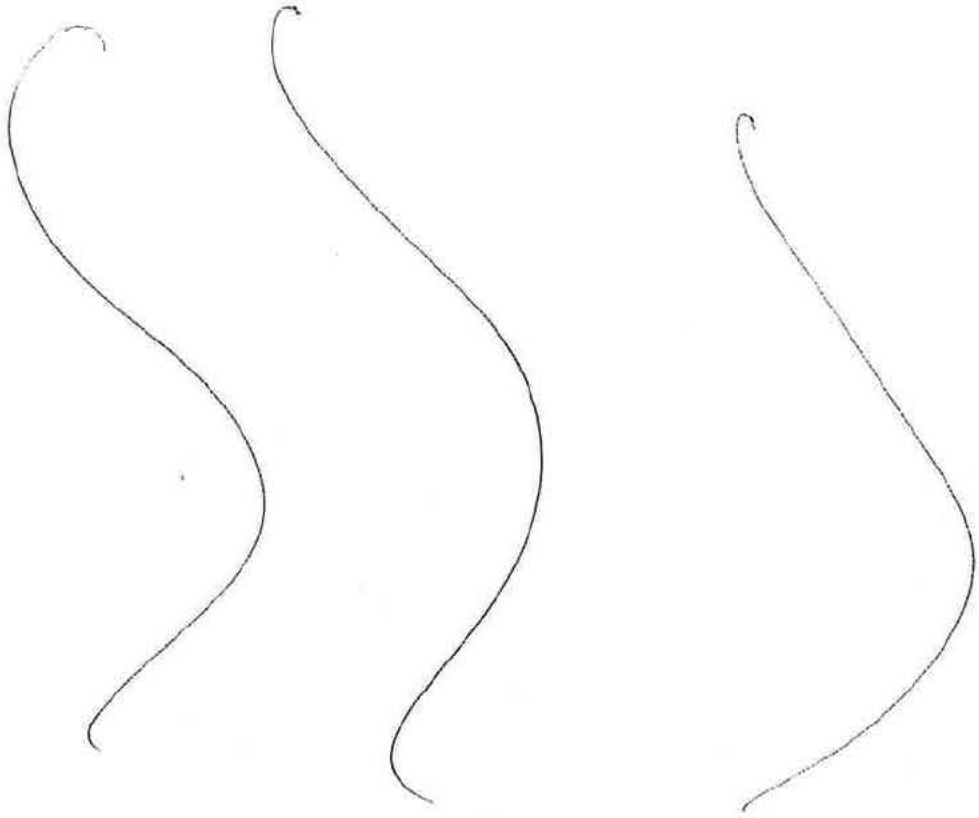
Observation Annotations

Observation 1:	Promised to correct.	Observation 2:	Promised to correct.
Observation 3:	Promised to correct.	Observation 4:	Promised to correct.
Observation 5:	Promised to correct.	Observation 6:	Under consideration.
Observation 7:	Promised to correct.	Observation 8:	Promised to correct.
Observation 9:	Promised to correct.	Observation 10:	Promised to correct.



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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."