FDA held regulatory meetings via telephone with the following device user facilities to address significant deviations from the Medical Device Reporting Regulation (21 CFR Part 803) for which we determined the facility had not provided an adequate response.

User Facility	Inspection Completed	Form FDA 483 Observations[1,2]	Form FDA 483
Advocate Lutheran General Hospital Park Ridge, IL	01/11/2016	1. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to death of a patient of the facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer with 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. An MDR adverse event report was submitted on a form other than FDA Form 3500A (MEDWATCH form) or an approved electronic equivalent. 4. MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable. 5. The user facility report submitted on FDA Form 3500A did not include all information reasonably known. 6. The written MDR procedure does not include documentation and recordkeeping requirements for all Medical Device Reports and information submitted to FDA and device manufacturers. 7. Written MDR procedures have not been developed.	[link]

1 Form FDA 483, Inspectional Observations lists observations made by the FDA representative(s) during the inspection of a facility. They are inspectional observations and do not represent a final Agency determination regarding the facility's compliance.

2 MedSun hospitals are asked to submit all mandatory and voluntary reports to FDA though the MedSun reporting system. FDA sends a copy of reports received through MedSun to the appropriate device manufacturer on behalf of the hospital, which fulfills any applicable requirement for hospitals to submit medical device reports for those events to the manufacturers.

User Facility	Inspection Completed	Form FDA 483 Observations[1,2]	Form FDA 483
Cedars-Sinai Medical Center **Los Angeles, CA**	12/07/2015	1. Written MDR procedures have not been developed. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient in the facility.	[link]
Huntington Memorial Hospital **Pasadena, CA**	12/11/2015	1. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. Written MDR procedures have not been implemented.	[link]
Indiana University Hospital **Indianapolis, IN**	02/03/2016	1. The written MDR Procedure does not include an internal system which provides for the timely and effective identification, communication and evaluation of events that may be subject to medical device reporting requirements. 2. MDR event files have not been established and maintained.	[link]
New York Presbyterian Hospital **New York, NY**	12/10/2015	1. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 2. Written MDR procedures have not been developed, maintained, and implemented.	[link]

User Facility	Inspection Completed	Form FDA 483 Observations[1,2]	Form FDA 483
Reading Hospital and Medical Center West Reading, PA	12/16/2015	1. The user facility did not submit FDA Form 3500A or electronic equivalent to within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. The written MDR procedure does not include an internal system which provides for a standardized review process/procedure for determining when an event meets the criteria for reporting. 4. The written MDR procedure does not include documentation and recordkeeping requirements for all information that was evaluated to determine if an event was reportable. 5. MDR event files have not been established and maintained.	[link]
Rochester General Hospital Rochester, NY	12/09/2015	1. Written MDR procedures have not been implemented.	[link]
University of Rochester Medical Center Rochester, NY	01/29/2016	1. The written MDR procedure does not include documentation and recordkeeping requirements for systems that ensure access to information that facilitates timely follow-up and inspection by FDA.	[link]

For the following inspected device user facilities, FDA determined there were no significant deviations from the Medical Device Reporting Regulation (21 CFR Part 803) or that the response the facility provided was adequate.

User Facility	Inspection Completed	Form FDA 483 Observations[3,4]	Form FDA 483
Allegheny General Hospital Pittsburgh, PA	12/17/2015	1. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA and the device manufacturer within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. Written MDR procedures have not been implemented. 4. MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable. 5. The user facility report submitted on FDA form 3500A did not include all information reasonably known. 6. The written MDR procedure does not include an internal system which provides for timely transmission of complete medical device reports to FDA and manufacturers.	[link]

3 Form FDA 483, Inspectional Observations lists observations made by the FDA representative(s) during the inspection of a facility. They are inspectional observations and do not represent a final Agency determination regarding the facility's compliance.

4 MedSun hospitals are asked to submit all mandatory and voluntary reports to FDA though the MedSun reporting system. FDA sends a copy of reports received through MedSun to the appropriate device manufacturer on behalf of the hospital, which fulfills any applicable requirement for hospitals to submit medical device reports for those events to the manufacturers.

User Facility	Inspection Completed	Form FDA 483 Observations[3,4]	Form FDA 483
Brigham and Women's Hospital Boston, MA	12/10/2015	1. The user facility did not submit FDA Form 3500A or electronic equivalent to within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. Written MDR procedures have not been developed and maintained and implemented. 4. MDR event files have not been established and maintained.	[link]
Carolinas Medical Center Charlotte, NC	12/11/2015	No 483 Issued	N/A
Dartmouth-Hitchcock Medical Center Lebanon, NH	12/17/2015	1. Written MDR procedures have not been developed and maintained and implemented. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. MDR event files have not been established and maintained.	[link]
Froedtert Hospital Milwaukee, WI	12/16/2015	No 483 Issued	N/A

User Facility	Inspection Completed	Form FDA 483 Observations[3,4]	Form FDA 483
General Hospital Corporation **Boston, MA**	12/18/2015	1. Written MDR procedures have not been developed and maintained and implemented. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to FDA within ten working days after becoming aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient of the facility. 3. The user facility did not submit FDA Form 3500A or electronic equivalent to the FDA, because the device manufacturer was unknown, within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 4. MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable.	[link]
UCLA Ronald Reagan Medical Center **Los Angeles, CA**	12/18/2015	1. The user facility failed to provide all information concerning individual adverse event reports that is reasonably known to them, including information found in documents in possession of the user facility. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility.	[link]
UMass Memorial Medical Center **Worcester, MA**	12/11/2015	1. The written MDR Procedure does not include an internal system which provides for the timely and effective identification and communication and evaluation of events that may be subject to medical device reporting requirements. 2. MDR event files have not been established and maintained. 3. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility.	[link]

User Facility	Inspection Completed	Form FDA 483 Observations[3,4]	Form FDA 483
Virginia Mason Medical Center Seattle, WA	04/15/2016	1. MDR event files do not contain or reference all adverse event information in the possession of the reporting entity, including documentation of the deliberations and decision making process used to determine if an event was or was not reportable. 2. The user facility did not submit FDA Form 3500A or electronic equivalent to the known device manufacturer within 10 working days of becoming aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury to a patient of the facility. 3. An authorized FDA employee was not permitted to copy MDR required records during reasonable times. 4. Written MDR procedures have not been implemented.	[link]