

# POSTMARKET COMPLIANCE: FDA IS CONNECTING THE DOTS ... ARE YOU?

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**CDRH's new Medical Device Transformation Initiative was launched in January 2006**

Earlier this year, the US Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) announced a new medical device postmarket safety programme intended to increase its ability to identify, analyse and act on postmarket information. The foundation of the programme rests on CDRH's ability to effectively utilise and synergise its existing tools and resources used in its postmarket safety programmes, such as Medical Device Reporting (MDR) and postmarket clinical studies. The likely result is an enhanced scrutiny of medical device manufacturers' postmarket compliance practices to ensure that manufacturers are fulfilling their postmarket surveillance obligations and are appropriately reacting to and disclosing relevant safety information. This article summarises the FDA's Medical Device Postmarket Transformation Initiative, its likely impact on FDA enforcement efforts, and how device companies must ensure now more than ever that their quality systems, particularly their Corrective and Preventive Action (CAPA) systems, are sufficient to address potential postmarket medical device safety issues.

**Two high profile postmarket surveillance cases in drug industry have prompted actions for medical devices**

In 2004, two events involving postmarket clinical studies of high profile pharmaceuticals raised concerns about the effectiveness of the FDA's vigilance over postmarket surveillance. In the immediate wake following the global recall of Merck's VIOXX® arthritis medication and the FDA's advisory urging doctors to consider alternatives to Pfizer's Celebrex® pain medication, many projected that the enhanced public scrutiny of the FDA's postmarket pharmaceutical activities could also have significant ramifications on the device industry. On this point, Dan Schultz, Director of the CDRH stated that because medical device companies were not following up on their commitments to conduct postmarket studies, the Agency was taking proactive measures, which included reassigning the oversight of postmarket studies to different Agency staff. In the months that have passed since those two seminal postmarket events, the CDRH has conducted a comprehensive, internal inventory of the tools used to monitor the safety of medical devices after they are approved. Earlier this year, the CDRH announced a new programme to transform and strengthen medical device safety. The implications of this programme will most likely lead to enhanced scrutiny of postmarket compliance practices and decision-making of medical device manufacturers.

**Manufacturer's postmarket compliance practices and decision-making are likely to come under increased scrutiny**

## CDRH Medical Device Postmarket Transformation Initiative

On 18 January 2006, the CDRH announced the details of its Medical Device Postmarket Transformation Initiative (the Initiative) through the release of a report entitled *Ensuring the Safety of Marketed*

*Medical Devices: CDRH's Medical Device Postmarket Safety Program* (the Report)<sup>1</sup>. In this Report, the CDRH provides the details of a programme intended to increase the Center's ability to identify, analyse and act on postmarket information. To implement and oversee the Initiative, the CDRH has formed a senior level team of Agency representatives and has established relationships with outside constituencies such as consultants and industry trade associations. The Initiative focuses on three main areas:

- identification of device-related problems in the field;
- assessment of the risk of such problems; *and*
- responding to the risk through communications with the public, industry and users.

*Initiative focuses on...*

Responding to identified device problems also includes enforcement efforts. For each of the foregoing areas, the Report discusses the various tools currently used by the Center, the challenges facing the use of those tools and goals for improvement.

### **Postmarket Problem Identification**

The Report discusses the plethora of tools that the CDRH uses to identify postmarket problems and safety related issues regarding medical devices. These tools include reports of adverse events and safety related product malfunctions from medical device manufacturers and user facilities under the MDR regulations. The FDA also receives information by conducting inspections of facilities subject to its jurisdiction, including medical device manufacturers, clinical trial sites and clinical laboratories. Such inspections may be comprehensive in nature and focus on all aspects of regulatory compliance, or directed inspections that focus in detail on a specific issue. The Agency also conducts 'for cause' inspections that are focused on a specific product problem. Most inspections, however, review the company's compliance with the Quality System Regulation (QSR), discussed below. Other postmarket safety information is received by the CDRH from reports of medical device removals or corrections (e.g. recalls), device user complaints and postmarket studies required either under its statutory postmarket surveillance authority or as conditions of approval for devices approved under the Agency's premarket approval (PMA) regulations. The Agency also receives information on potential product problems from PMA annual reports and notices of device modifications from PMA supplements and new premarket notifications (510(k)s).

*CDRH receives information on postmarket problems from numerous sources*

Despite the vast number of resources currently available to the CDRH to identify potential postmarket product problems, the Report highlights several challenges that are faced by the Agency in this regard. For example, the Report notes that there is a lack of cross-Center communication and sharing of data. The Agency notes that reports of adverse events, research or other signal information are not shared between offices and programme areas. Specifically, 'information is collected for a variety of different reasons (i.e. adverse

*Poor communication and data sharing between Centers needs to be addressed*

event reports, quality inspection information) and it is reported in a variety of formats (i.e. structured questions or narrative observations) at different times (i.e. soon after the event occurs as part of an adverse event or field action report, or potentially well after the event occurs if the information is only included in a PMA annual report). In addition, the Report acknowledges that the information flows into the individual Center offices ... [and] may be adequate for a specific purpose, but [is] not always viewed in the aggregate for the purpose of postmarket problem identification<sup>1</sup>.

***Other problems include under-reporting and incomplete reports***

Other challenges identified in the Report include the under-reporting of adverse events as well as the lack of sufficient detail in the reports (e.g. reports may not specifically identify the device involved or how it was used). In addition, the Report points to an increase in 'off-label uses' of devices as well as 'in-home use' of devices by persons not properly trained to use them. In both instances, the Agency acknowledges that it is difficult for the FDA to determine whether an adverse event was attributable to the device design or to its improper use.

### **Postmarket Problem Assessment**

The Report explains that the assessment of postmarket problems is currently conducted by a variety of resources. One of the key resources currently used by the Agency with respect to postmarket problem assessment is postapproval or postmarket clinical studies. Other tools utilised by the Agency include:

***Typical methods used to assess postmarket problems are listed***

- the analysis of data provided to the Agency, such as information contained in MDRs and device recall reports filed by manufacturers;
- device and event root cause analyses conducted by both the FDA and external laboratories;
- CDRH Problem Assessment Groups; *and*
- review of external data such as Rapid Response Surveys [A Rapid Response Survey is a tool used by the CDRH when data sources fail to provide enough information to perform a risk analysis of a postmarket issue. In using this tool, the Agency contacts medical device users to enquire whether they have experienced certain or similar events regarding devices involved in a reported adverse event.].

***Information collected through the various routes is not always collated***

The Report lists several challenges that the CDRH currently faces in assessing the impact of postmarket problems. As above, data and device experience information are collected through a variety of mechanisms for specific purposes, and are not necessarily integrated, shared or capable of being utilised collaboratively to effectively assess postmarket problems. In addition, the Report notes problems with respect to the quality of data received by the Agency.

### **Postmarket Public Health Response**

According to the Report, the tools used to communicate postmarket

public health issues generally fall into two categories: risk communication tools and enforcement activities. Examples of risk communication tools include Public Health Alerts, peer review journals, technical publications, press releases and talk papers, and Patient Safety News, which can be directed to target audiences or to the general public.

Other visible ways that the CDRH can respond to public health concerns are through a multitude of enforcement tools ranging from a public warning letter to more severe sanctions such as:

- import detentions;
- injunctions;
- civil penalties;
- mandatory product recalls;
- seizure of products;
- operating restrictions;
- partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted;
- civil fines and criminal prosecution.

*Examples of CDRH's enforcement tools...*

The Report points out that the Agency faces several challenges in determining an appropriate response to an identified postmarket public health risk. Namely, the Report states that there is no link between risk communication and enforcement. The Agency also points out that there is a lack of field staff and administrative delays in processing paperwork.

*There is currently no link between risk communication and enforcement*

### **Goals and Focus of the Initiative**

In light of the foregoing challenges identified in the Report, the CDRH states that the basic goal for the Initiative is to provide mechanisms for the Agency to assess accurate and timely data about adverse events, analyse and assess this information quickly, and alert device users to signals of potential risk. Accordingly, the CDRH identifies the following goals<sup>2</sup> of the Initiative:

- assure that people in the CDRH are working collaboratively to address postmarket issues;
- build and manage effective information and knowledge systems;
- take advantage of postmarket information by cycling it into the PMA process;
- improve CDRH staff recruiting and training;
- partner with public and private enterprises to ensure regular and consistent communication;
- communicate risk more clearly and persuasively to all stakeholders.

*CDRH's new Initiative has six main aims...*

To accomplish the goals identified above, the CDRH outlines numerous steps that are being undertaken as part of the Initiative. Each step is intended to address the challenges associated with the use of the Agency's existing tools for the identification, assessment and

communication of postmarket medical device issues. Rather than create a series of new tools to accomplish these tasks, the Initiative connects the dots between the various tools, resources and opportunities that currently exist. The key steps identified in the Report are summarised below.

*Development of a 'Culture of Collaboration'*

The Report explains that the CDRH must shift to a culture that 'places more emphasis on the importance of postmarket efforts and on collaboration in identifying and solving postmarket problems, both within the Center and with outside constituencies'<sup>2</sup>. To accomplish this step, the Center has established a senior level team of CDRH representatives and outside consultants to set priorities and to oversee implementation of the Initiative. Specifically, the team is charged with identifying what factors help and which hinder collaboration between the various postmarket tools and resources throughout the CDRH. The team is also exploring areas where external expertise could be utilised for postmarket issues.

**A team of senior CDRH staff and external consultants will oversee implementation of the Initiative**

*Development of Better Data Sources and Systems*

The CDRH is also assessing its ability to identify postmarket problems and is exploring new ways to gain access to data. For example, the Center is developing a system to provide unique device identification, a standardised and globally accepted nomenclature for devices, and mechanisms and incentives for device users to include this information in healthcare records. To this end, the Center is connecting the dots to develop an electronic reporting system so that all postmarket information is available to all who need to use it. This effort includes plans to launch an electronic MDR system (eMDR) as well as to develop novel ways to routinely and systematically search healthcare literature and popular media to find reports of adverse events and then to share this information throughout the Center.

**An electronic MDR system is to be established**

The CDRH also notes that it is strengthening its PMA Conditions of Approval Requirements. As an example, the Center now has its epidemiology staff participate in PMA reviews to help design better postmarket studies. The Center has also transferred medical device tracking responsibilities and follow-up activities to postmarket staff.

*Enhancement of Risk/Benefit Communication Efforts*

The Report notes that, once timely and accurate postmarket information has been acquired by the CDRH, the Center must maximise its ability to communicate this information clearly and quickly to the public and interested stakeholders. To this end, the CDRH will assess existing tools and resources and evaluate whether they are sufficient to communicate postmarket risks or need improvement. The Center is also working with outside groups, such as trade associations, to communicate relevant and timely information. For example, the CDRH is currently working with AdvaMed and the Heart Rhythm Society to explore opportunities to improve Product Performance Reports, PMA

**Tools and resources used to communicate postmarket risks may need to be improved**

annual reports, and to develop a standardised Dear Doctor letter.

#### *Improvement of Enforcement Strategies on Postmarket Issues*

Lastly, the Report states that when product problems are discovered, the CDRH must improve the coordination, consistency, quality and timeliness of inspections, reporting and enforcement actions. Such an effort will require the cooperation of and discussion between CDRH's Office of Compliance, FDA's Office of Regulatory Affairs (ORA) headquarters and ORA staff. In addition, with respect to facility inspections, the Center has shifted its focus to a risk-based approach. Specifically, the CDRH indicates that it is focusing its limited resources on inspecting manufacturers of devices that present the greatest risk to public health.

***CDRH must also improve its inspections, reporting and enforcement actions***

## **The Potential Impact of the Initiative on the Medical Device Industry**

As the FDA is connecting its postmarket surveillance tools and resources, medical device manufacturers, particularly those that manufacture Class III (PMA) devices, can expect an enhanced scrutiny of their postmarket practices. Moreover, device manufacturers may also experience an increased scrutiny of their premarket submissions. For example, one of the goals of the Initiative is to expand the use of postmarket data, such as MDR data, across the Center. One potential result is enhanced scrutiny of a company's data during reviews of PMAs, PMA supplements and 510(k)s by the Office of Device Evaluation (ODE). If the FDA has concerns about the postmarket performance of an existing device, the Agency may raise additional questions about changes to such devices or line extensions that may have similar issues.

***Premarket submissions may also be subject to increased scrutiny under this Initiative***

With an enhanced use of postmarket data, the ODE could also scrutinise whether the manufacturer used postmarket data in the design of its device. Specifically, the ODE's review may include a detailed assessment of whether adverse events and/or product malfunctions of existing products (e.g. previous models) factored in to the company's design inputs and Failure Modes and Effects Analyses (FMEAs). Armed with an improved arsenal of postmarket data, the ODE would likely scrutinise whether certain failure modes and risks were appropriately mitigated in the new devices.

With respect to device modifications, whether reported in PMA annual reports, PMA supplements, 510(k)s and Special 510(k)s, and even change control documentation reviewed during inspections, the CDRH's use of postmarket data may allow the Agency to:

- better identify the relationship(s) between device modifications and adverse events, such as whether a device modification may have caused or contributed to an adverse event or whether an adverse event led to a device modification; *and*
- determine whether the manufacturer appropriately documented and/or reported such information and took timely corrective action to address the problem.

***Use of postmarket data could allow the CDRH to...***



**Quality systems should be comprehensive and interconnected**

Therefore, now more than ever, device manufacturers need to ensure that they have systems in place to effectively connect the dots between various quality metrics. Specifically, companies should ensure that their quality systems are comprehensive and interconnected and provide mechanisms for closing all potential loops. To this end, compliance with the QSR, particularly those facets that have postmarket implications, the MDR and the device corrections and removals regulations, is paramount. Moreover, these postmarket systems must be interconnected – each serving as a source of information and potential resolution of the other. A summary of the US regulatory requirements for each is provided below. In addition, salient linkages between each are identified followed by some suggested practices to ensure compliance.

### **Quality System Regulation**

The QSR requires that domestic and foreign manufacturers have a quality system in place for the design, manufacture, packaging, labelling, storage, installation and servicing of finished medical devices intended for commercial distribution in the USA. Specifically, the QSR requires medical device manufacturers to implement and comply with procedures covering numerous activities from the design and development of a device, to its production and processing and to recordkeeping and servicing of devices in the field<sup>3</sup>. Although the QSR requires interconnectivity between those (and other) functions, the following facets most directly involve postmarket activities:

**Primary postmarket elements of the QSR...**

- **management responsibility** – requires that company management with executive responsibility establish its policy and objectives for, and commitment to, quality, and that management with executive responsibility review the suitability and effectiveness of the quality system to ensure that the quality system satisfies the QSR requirements and the company's established quality policy and objectives<sup>4</sup>;
- **design controls** – requires that manufacturers establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met (e.g. procedures governing design and development planning; design inputs, design outputs, design reviews, design verification and validation; design transfer to production; and design changes)<sup>5</sup>;
- **CAPAs** – requires manufacturers to establish and maintain procedures for implementing corrective and preventive action, including requirements for analysing and trending processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned products, and other sources of quality data to identify existing and potential causes of non-conforming products or other quality problems<sup>6</sup>;
- **complaint handling** – requires that manufacturers establish and maintain procedures for receiving, reviewing and evaluating complaints by a formally designated unit, investigating complaints and assessing them for MDR reportability<sup>7</sup>; *and*

**Manufacturers are responsible for setting up complaint handling procedures**

- **servicing** - where servicing is a specified requirement, each manufacturer is required to establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements<sup>8</sup>, and for reviewing service records for complaint information.

### **MDR Regulations**

Under the FDA's MDR regulations, medical device manufacturers are required to report to the FDA within 30 days whenever any company employee receives or otherwise becomes aware of information, from any source, that reasonably suggests that a device marketed by the manufacturer:

- may have caused or contributed to a death or serious injury; *or*
- has malfunctioned [defined as a failure of the device to meet its performance specifications or otherwise perform as intended]<sup>9</sup> and such a device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur<sup>10</sup>.

*A 30-day timeframe exists for submitting a report on devices that...*

The regulations also include provisions for submitting five-day reports in limited circumstances<sup>11</sup>. [The reporting deadline is five days if the manufacturer becomes aware that a reportable MDR event, from any information including any trend analysis, necessitates remedial action to prevent an unreasonable risk of substantial harm to public health, or if the FDA requires such a report.] The MDR regulations further state that manufacturers must provide all information required by the MDR regulations that 'is reasonably known to them'. Moreover, according to the FDA's MDR Guidance<sup>12</sup>, information that 'reasonably suggests' that an event meets one of the criteria for MDR reportability includes 'any information, such as professional, scientific, or medical facts and observations or opinions, that would reasonably suggest that a device has caused or contributed to a reportable event'. Furthermore, manufacturers may receive complaint information that could trigger the MDR requirements from a number of sources, including 'telephone, facsimile, written correspondence [from users], sales representative report[s], services representative report[s], scientific article review, internal analyses or direct FDA contact'.

*If urgent action is required, the reporting deadline is five days*

### **Medical Device Corrections and Removals**

The FDA has the legal authority to order device manufacturers to cease distribution of devices regulated by the Agency and to notify health professionals and user facilities to cease using such devices, where it makes a finding that there is 'a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death'. More commonly, device manufacturers undertake voluntary product recalls. FDA's corrections and removals regulations require manufacturers to submit a written report to the FDA of any non-exempt product removal or correction initiated either to reduce a risk to health posed by the device or to remedy a

*FDA has the power to order removal of a device from the market in certain circumstances*



**Reports must be submitted within 10 working days and include...**

violation of the Act caused by the device which may present a risk to health, unless that information has previously been reported to the FDA under the MDR regulation<sup>13</sup>. Reports must be made within 10 working days of the initiation of the removal or correction and must describe, among other things, the event giving rise to the information reported and the corrective or removal actions that have been, and are expected to be, taken and any illness or injuries that have occurred with the use of the device (including, if applicable, the MDR numbers).

## **Connecting the Dots - Application and Linkages Between Your Postmarket Systems**

Although the regulatory requirements outlined above are addressed in separate provisions of the FDA's regulations, it is important to have an interconnected system in place that utilises and relies upon each of these important postmarket related activities. FDA inspectors are trained to connect these dots by using inspection tools such as the Quality System Inspection Technique (QSIT). The QSIT inspection technique is based on a 'top down' approach to inspecting and focuses on inspections of four subsystems<sup>14</sup>:

**QSIT focuses on inspections of four subsystems**

- management control;
- CAPAs (with satellites MDR, corrections and removals, and medical device tracking);
- design controls; *and*
- production and process controls (with links to sterilisation process controls).

The subsystem approach is designed to provide the FDA investigator with the key objectives that can help determine a company's state of compliance.

Using the QSIT approach, the relevant subsystems and linkages between them are addressed below.

### **Management Controls**

Management is fundamental to ensuring that a company is operating in such a manner that all postmarket issues are identified, analysed and, when necessary, corrected. The QSIT Manual states that '[t]he purpose of the management control subsystem is to provide adequate resources for device design, manufacturing, quality assurance, distribution, installation, and servicing activities; assure the quality system is functioning properly; monitor the quality system; and make necessary adjustments. A quality system that has been implemented effectively and is monitored to identify and address problems is more likely to produce devices that function as intended'<sup>14</sup>.

**Management is what ensures that all quality metrics are identified and addressed**

As indicated by the QSIT Manual, management is the glue that ensures that all quality metrics are identified and addressed appropriately. In accordance with the QSR, management should meet regularly to ensure that the company's quality system satisfies the requirements of the QSR as well as the manufacturer's established

quality policy and objectives<sup>15</sup>. With respect to postmarket issues, upper management should be aware of complaints and complaint trends, recent MDRs and/or MDR trends, potential device problems, CAPAs, new products, and modifications being made to existing products. In addition, management should be aware of, if not involved in, the decision-making regarding potential and existing field corrections and removals.

With respect to postmarket compliance, a device manufacturer's management controls should:

- ensure management reviews are conducted frequently enough to be (and remain) informed of ongoing quality issues and problems;
- ensure that postmarket issues, such as device problems, CAPAs, complaints, MDRs and recalls, are discussed at every management review;
- ensure that all action items, including CAPAs, which are initiated at or result from management reviews are implemented and verified for effectiveness.

***A device manufacturer's management controls should...***

### **CAPAs**

Perhaps the most comprehensive and important tool used to identify and resolve postmarket issues is the CAPA system. As described in the QSIT Manual, '[t]he purpose of the corrective and preventive action subsystem is to collect information, analyze information, identify and investigate product and quality problems, and take appropriate and effective corrective and/or preventive action to prevent their recurrence. Verifying or validating corrective and preventive actions, communicating corrective and preventive action activities to responsible people, providing relevant information for management review, and documenting these activities are essential in dealing effectively with product and quality problems, preventing their recurrence, and preventing or minimizing device failures'<sup>14</sup>.

***The purpose of the CAPA subsystem is defined***

The CAPA is the central point by which all quality data should be analysed. The inputs to the CAPA should encompass all quality metrics from design and development planning through distribution and servicing of devices in the field. Simply stated, all potential product and quality problems should be inputs to the CAPA and analysed to identify product and quality problems that may require corrective action. The QSIT Manual identifies several key sources for such data, including information from all acceptance activities, complaints, service records and returned product records. Information obtained subsequent to distribution, which includes complaints, trends, service activities and returned products, as well as information relating to concessions (quality and non-conforming products), quality records, and other sources of quality data should also be captured and analysed. Examples of other sources of quality data include quality audits, installation reports and lawsuits.

***All potential product and quality problems should be inputs to the CAPA***

Equally as important as the identification of potential postmarket problems in the CAPA system is the investigation of the issue and corresponding corrective (short term) or preventive (long

term) action taken. With respect to investigations, the CAPA system should effectively identify the failure modes, determine the significance of the failure modes (using tools such as risk analysis), state the rationale for determining if a failure analysis should be conducted as part of the investigation, and identify the depth of the failure analysis. To address such issues, the company should identify an appropriate corrective or preventive action to address the problem. In some cases, this may require a field correction or removal, or even a device modification. Lastly, any corrective or preventive action taken should include appropriate personnel and subsequently be verified for effectiveness.

Accordingly, with respect to postmarket compliance, a device manufacturer's CAPA system should:

***A device manufacturer's CAPA system should...***

- accept as inputs *all* sources of quality data, including but not limited to, complaints, MDRs, service calls, management reviews, supplier audits, external and internal audits and non-conforming products;
- ensure that appropriate personnel are apprised of and/or involved in the investigation of potential product problems, identification of appropriate corrective actions and implementation of corrective actions;
- ensure that all corrective actions are appropriately verified for effectiveness;
- ensure that all data from CAPA investigations and corrective actions are considered in future product designs.

***Customer complaints can provide the greatest source of information***

### **Complaints/ Servicing**

Perhaps the greatest source of information regarding marketed medical devices is customer complaints. Upon receipt of complaints, device manufacturers are required to review, evaluate, determine MDR reportability and, when appropriate, investigate such complaints. The Agency's QSR Manual indicates that to meet all QSR requirements, complaint investigation and identification methods should include a review and evaluation of all complaints, failed devices and service or repair requests. Complaint data, in conjunction with other quality metrics, should be used to:

- identify poor performance in the overall quality system, particularly faulty design of devices and faulty manufacturing processes;
- aid in implementing solutions to these quality problems;
- verify confidence in, and improve the performance of, the quality system;
- improve the safety and performance of devices; *and*
- reduce medical device reporting.

***Regular trending of complaint data should be undertaken***

Companies should conduct regular trending of complaint data to identify potential product problems and failure modes. Any such corrective and preventive action should also be implemented through the company's CAPA system.

Service calls and service call frequency also need to be assessed in the context of the QSR requirements regarding complaint handling, failure investigations and CAPAs, as well as reports of incidents that require analysis pursuant to FDA's MDR requirements. Specifically, finished devices that are returned to the company for service or repair may meet complaint requirements. Accordingly, all service or repair requests should be evaluated to determine if they are complaints.

***Service or repair requests may meet the complaint requirements***

Accordingly, with respect to postmarket compliance, a device manufacturer's complaint handling system should:

- consider *all* sources of potential complaint information;
- ensure that all complaints are reviewed and, where appropriate, investigated;
- serve as a key input to the CAPA system;
- include or reference the company's trending procedures;
- ensure that all service calls and products returned for servicing are evaluated for complaint information;
- serve as an input to prospective device modifications, designs and associated FMEAs.

### **MDRs**

As noted above, medical device manufacturers are required to review all complaints for potential MDR reportability. Like complaints, MDRs are an excellent indicator of safety related problems with the use, design and/or manufacture of a company's product. Accordingly, device manufacturers must establish a system that ensures the prompt identification, timely investigation, reporting, documentation and filing of device-related death, serious injury and malfunction information<sup>16</sup>. Moreover, the QSIT Manual states that 'events described in [MDRs] may require the FDA to initiate corrective actions to protect the public health. Therefore, compliance with Medical Device Reporting must be verified to ensure that CDRH's Surveillance Program receives both timely and accurate information'<sup>14</sup>.

As with complaints, MDR data should be trended. Information from individual MDRs, trends and related investigations should serve as inputs to both the CAPA system and management reviews. Moreover, MDRs may be the impetus for initiating a correction or removal from the field and/or a device modification or redesign. A device manufacturer's MDR system should:

***Trends in MDR data should also be analysed***

- ensure that all MDR reportable events are reviewed and investigated;
- serve as a key input to the CAPA system;
- include or reference the company's trending procedures;
- serve as an input to prospective device modifications, designs and associated FMEAs;
- ensure that decisions not to submit an MDR report for a device-related death, serious injury or malfunction are documented in the MDR file.

***Decisions not to report must be documented in the MDR file***

## Corrections and Removals

One potential corrective action resulting from any of the postmarket quality issues discussed above is the correction or removal of the product from the field. Such events typically result from an identified safety problem with the device, which the company became aware of through the complaint handling (including service records) and MDR systems. However, other sources of quality data may also necessitate a CAPA that may require a field correction or removal.

***Firms must use reasonable judgment when deciding whether or not to voluntarily recall a product***

As the Agency's regulations do not contain a clear definition of when a manufacturer should voluntarily recall a product, the FDA entrusts companies to use reasonable judgment in determining whether potential safety or compliance issues rise to the level of recalling a product from the field. When faced with a recall decision, the FDA expects every medical device manufacturer to make judgement calls as to whether it is appropriate to continue to ship (and not recall) devices that may be experiencing a problem. This determination should be made based on a variety of data developed and/or acquired through the company's quality system. For example, because the safety profile of such a product is not always clear, the Agency, through its regulations, policies and practices, expects manufacturers to prepare a Health Hazard Analysis or to otherwise review available quality and safety data and information to make decisions with respect to whether the continued marketing and use of the device is appropriate. Specifically, data that are collected through a complaint and/or MDR root cause investigation, or even design control information such as FMEAs, are salient to making such determinations. To connect other quality system dots, such decisions should also involve a representative from management to ensure that the management is apprised of the situation. A device manufacturer's correction and removals system should:

***A device manufacturer's correction and removals system should serve as an output from the CAPA***

- be connected with, and serve as an output from, the CAPA system;
- serve as an input to prospective device modifications, designs and associated FMEAs;
- ensure that decisions not to initiate a correction or removal are appropriately documented;
- clearly link the action to the CAPA system and the underlying event or events.

***Design controls are not just linked to premarket activities***

## Design Controls

Although design controls are most often associated with premarket activities, there are several linkages to postmarket compliance thereby making compliance with design controls as important as other postmarket quality requirements. For example, many device design inputs are derived from user experiences with existing devices. Manufacturers should feed their postmarket experience with existing devices into their design control and risk management systems. This may include, for example, revising risk analyses and making design modifications based on field experiences. A device manufacturer's design control system should:

- serve as an input from the CAPA system;
- utilise postmarket data as inputs into the company's design control and risk management systems.

## Summary

The CDRH Postmarket Transformation Initiative represents a new commitment to medical device postmarket surveillance. As the Agency connects the dots between its existing postmarket surveillance tools, the medical device industry can expect to see enhanced scrutiny of its own postmarket surveillance and compliance activities. However, like CDRH, medical device manufacturers have an opportunity and an obligation to connect the dots with respect to their own postmarket compliance. To accomplish this task, companies must ensure that their quality system is comprehensive, interconnected and includes the tools necessary to identify, assess and resolve potential postmarket problems.

**CDRH is connecting the dots between its existing postmarket surveillance tools**

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13. US Code of Federal Regulations, Title 21, Part 806 (see also US Code of Federal Regulations, Title 21, Part 7).
14. *Guide to Inspections of Quality Systems*, US FDA, August 1999, ([www.fda.gov/ora/inspect\\_ref/igs/qsit/qsitguide.htm](http://www.fda.gov/ora/inspect_ref/igs/qsit/qsitguide.htm)).
15. US Code of Federal Regulations, Title 21, Part 820.20(c).
16. US Code of Federal Regulations, Title 21, Part 803.

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