Turning Medical Device Complaints Into Quality Management Intelligence

The Definitive Guide to Complaint Management

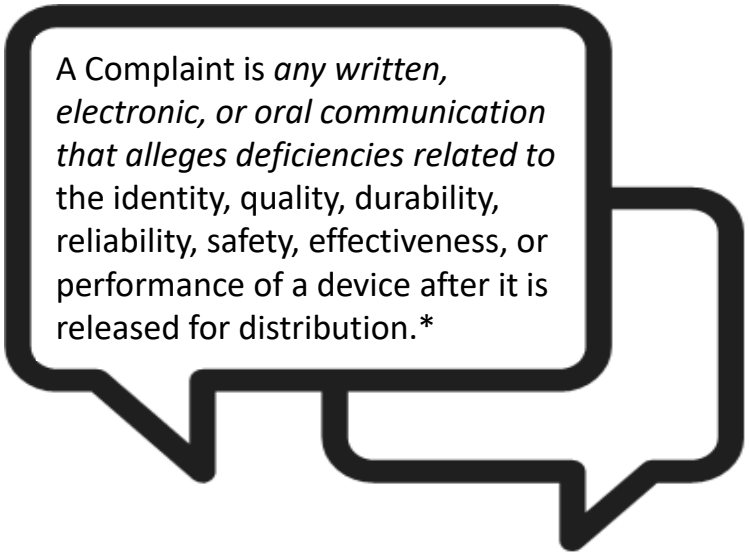
Sparta Systems

Complaints Overview – Why is it Important?

A complaint signifies dissatisfaction with device quality or performance, or the discovery of a defect after a product has been distributed to the public.

A complaint could lead to repair, servicing, and changes in a manufacturer's recommendations. An extensive complaint-related failure can lead to recalls and even product removal.

A single complaint could lead to correction action. A few complaints could lead to a trend causing the company to revise product, labeling, packaging or distribution.



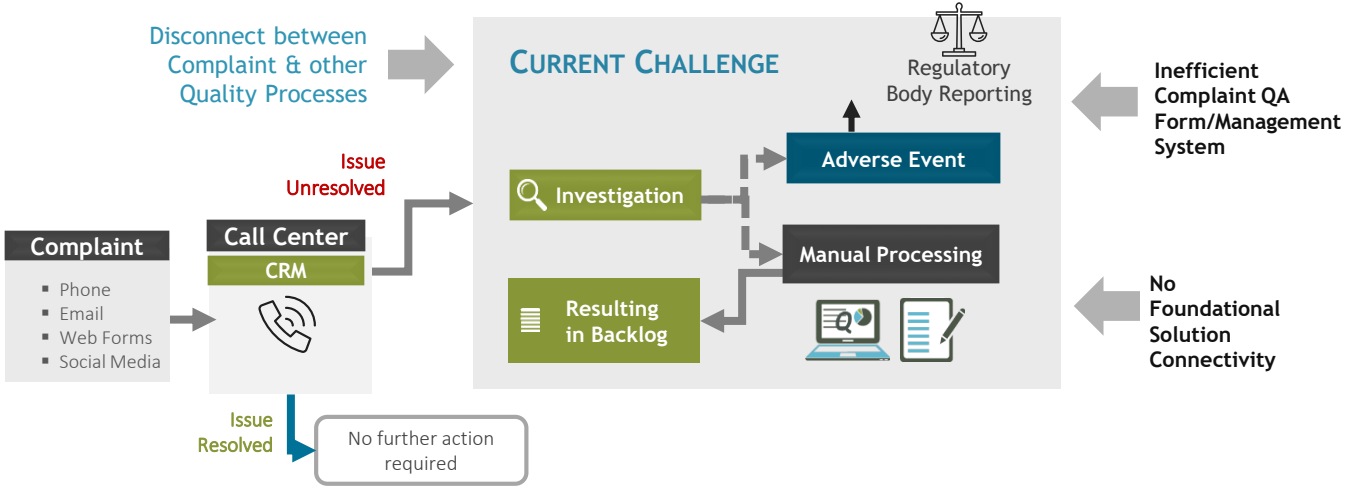
Complaints Overview – Challenges with Systems

The way in which a medical device company handles complaints is a strong indication of their manufacturing process. Having trained professionals to determine the severity of each complaint is critical to patient safety and helps establish if the issue is a malfunction within the product or if a total recall is necessary.

The most frequently cited observations on FDA-483s and warning letters for medical device companies are the need to define, document, or implement a complaint-handling system and failure to follow up on complaints.

Implementing an automated global complaints process should be part of a company's overall business strategy in order to effectively and efficiently track and monitor complaint handling performance.

Complaints Overview – Current Viewpoint



The Problem:

1. Complaints make their way in from the marketplace through a CRM solution by means of phone calls, emails, web forms, or social media.
2. They are then processed and closed or they are routed to QA for further investigation.
3. When the complaint is sent to QA through archaic means such as spreadsheets, emails, etc. it can lead to:
   - Backlogs of issues as a result of inefficient handling
   - Exposure to risk due to an inability to properly report the scope of the problem to regulatory bodies
   - Disconnect between other quality processes which leads to difficulty in trending and prevention of further issues
   - No connectivity to foundational solutions creating limitations in informing ERP, PLM, and LIMS of a broad issue

The Regulatory Landscape

The Regulatory Imperative: Complaints

One of the top 3 most frequent warning letter citations found in 2014 included complaint files, specifically establishing and maintaining procedures for receiving, reviewing and evaluating complaints (21 CFR 820.198(a))*

When medical device manufacturers receive complaints regarding products, they must adhere to reporting requirements set by the FDA. Having a integrated global complaint management system in place will allow medical device manufacturers to comply with the FDA and other regulators.

In fact, FDA 21 CFR Part 820 and GxP regulations dictate that manufacturers should maintain complaint files and establish a sustainable complaint management process. Specifically, Part 820 Section 198 requires that a formally designed complaint unit ensures complaints are processed in a timely manner, evaluated to determine the necessity of a formal medical device report or internal formal investigation.

Having reliable quality processes, systems and reporting infrastructures in place will facilitate effective and timely complaint management, especially as new legislation is created to better track and report adverse events, including the newly released UDI system rule and eMDR system mandate.

*Source: http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/UCM416501.pdf

The Regulatory Landscape

The Regulatory Imperative: eMDR

As part of complaint management, manufacturers must identify and monitor adverse events (deaths, serious injuries and malfunctions) involving medical devices and adhere to reporting requirements set by the FDA's Medical Device Reporting (MDR) regulations.

According to analytics firm DeviceMatters, the number of adverse events involving medical devices reported to the FDA in the past four years (2008-2012) has more than doubled, with 485,374 reported in 2012 compared with 194,361 in 2008.

An eMDR submission is "a file containing one or more medical device reports in an electronic format that FDA can process, review, and archive."*

* http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm175805.htm

The Regulatory Landscape

The Regulatory Imperative: eMDR

Effective August 14, 2015, electronic submission of MDRs are required to the FDA. Previously, medical device companies sent the FDA MDRs in paper format through the mail. This updated way of collecting data helps with the gathering and analyzing post market MDRs while minimizing data entry errors.

FDA Definition	FDA Regulation
Submit to the FDA reports of MDR reportable events involving medical devices	21 CFR 803.10(c) and 803.50
Develop, maintain, and implement written procedures for the identification and evaluation of all adverse medical device events to determine whether the event is an MDR reportable event	21 CFR 803.17
Establish and maintain complete documentation for all complaints concerning adverse medical device events	21 CFR 803.18*

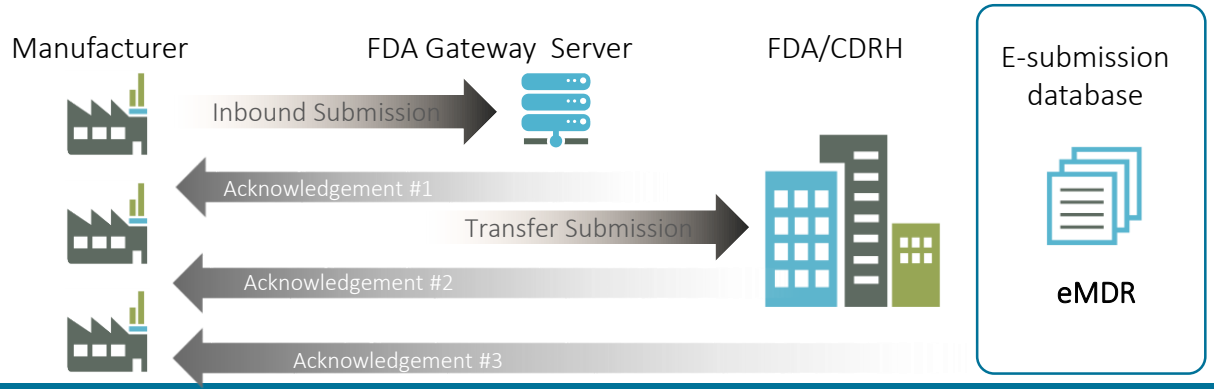
* The eMDR Final Rule permits user facilities to continue to submit MDRs on paper, user facilities may instead choose to submit MDRs in an electronic format

The Regulatory Landscape

The Regulatory Imperative: FDA Reporting Process

FDA's system will automatically route three separate electronic acknowledgments to the user's ESG account. These acknowledgements indicate the stage of processing that the eMDR has reached:

- Ack 1, or Receipt or MDN (Message Disposition Notification) acknowledgment, indicates that the ESG received the eMDR(s).
- Ack 2 indicates that CDRH received the eMDR(s).
- Ack 3 indicates the pass or failure status of the eMDR(s) into CDRH's adverse event database--that is, whether the eMDR was successfully loaded into the database.



If there are no errors, the three acknowledgement letters will be generated the same day or within 24 hours of the submission.

Steps to Compliance

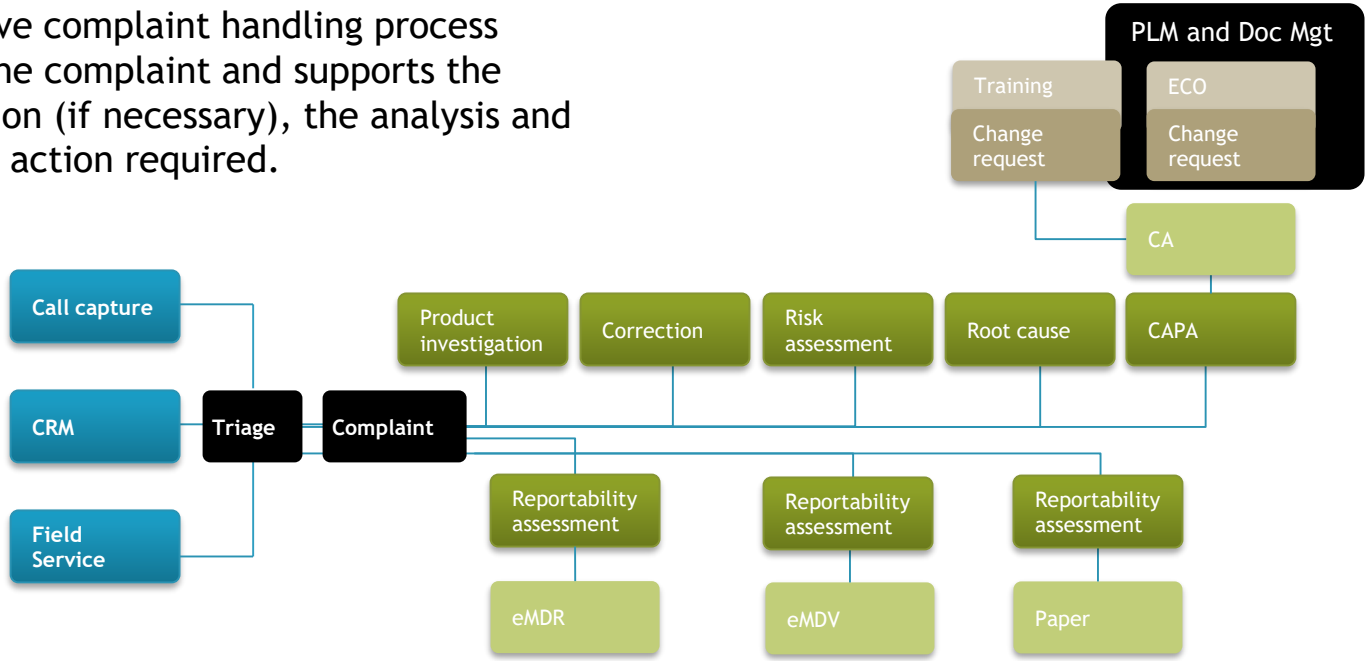
In order to achieve compliance with the FDA, manufacturers need to evaluate their current complaint management system to:

- Harmonize complaint management in a scalable, effective and efficient manner
- Drive sustainable compliance and reduce regulatory risk through simplified, standardized processes and practices
- Improve data quality and timeliness of information to empower better decision making across the entire enterprise

Steps to Compliance

Achieving Compliance through Best Practice Complaint Workflow

An effective complaint handling process receives the complaint and supports the investigation (if necessary), the analysis and corrective action required.



Steps to Compliance

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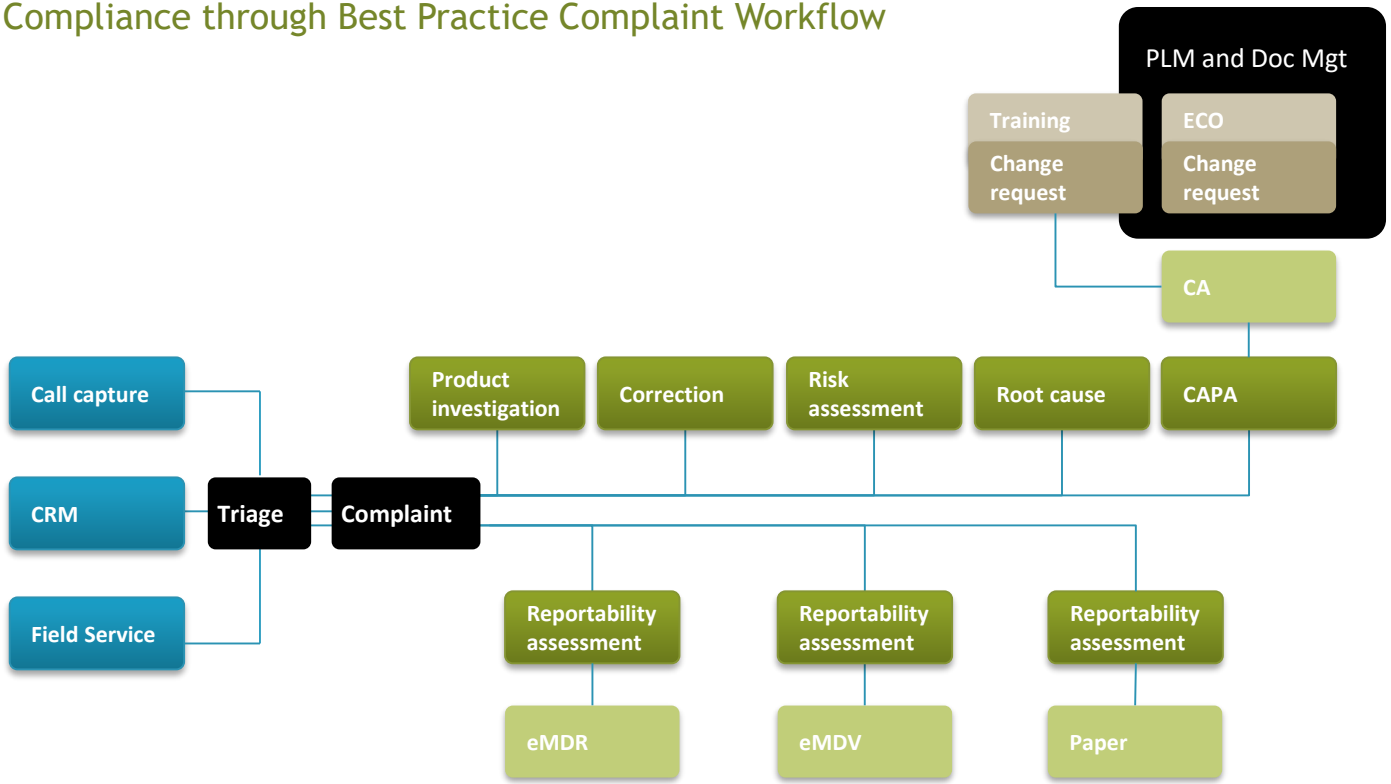
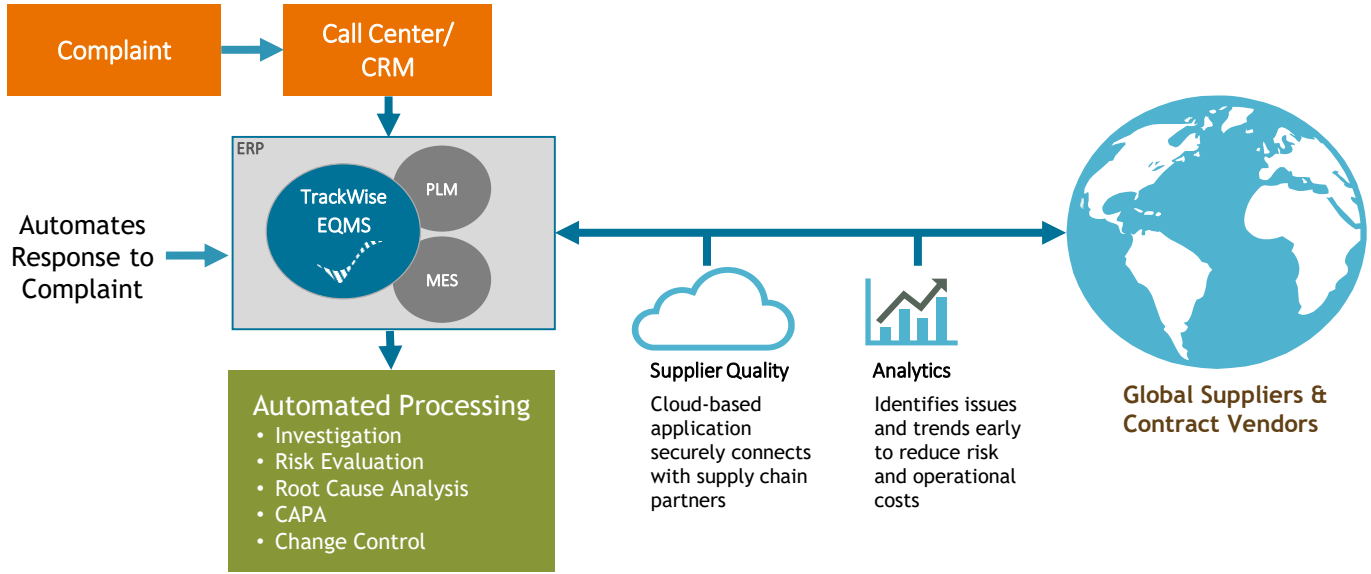


Steps to Compliance

Complaint Management Strategic Solution



An EQMS solution solves tactical challenges, and positions your organization to solve more strategic problems by:

- Connecting the complaints solution to other quality processes that can efficiently use cloud technology to inform suppliers and contract manufactures of issues
- Storing data locally in TrackWise, making it available for use with Analytics giving your organization visibility and reporting capability across the value delivery chain

Steps to Compliance

Overcoming Complaint Challenges with QMS

The challenges of complaint management include system integration, process issues, and regulatory requirement needs. A quality management system can address the pain points of medical device manufacturers.

Benefits of a Quality Management System

Challenges	Solution using QMS
Inconsistent terminology and workflows	Workflows are configured to match your business – mandatory fields
No integration between incidents, CAPA, AERS, MDR and change management	An enterprise quality management system seamlessly integrates key processes providing a closed loop
Management has no global view	Provides leadership with visibility and accessibility across the enterprise
Duplicate entry, disparate systems	Central repository for all complaint data so single source of entry
Rigid point solutions	Easy to configure based on company SOPs
Inferior Manual/Paper process	Electronic quality management system
Lack of integration to pillar systems (ERP, EDMS, LIMS…)	Integrate to and from pillar systems allows for trending across one or all sites
No ability to be proactive	Proactively monitor your data with business rules engine and allows consistent metrics of all sites

Steps to Compliance

Benefits of Sparta EQMS: Complaints Management

- Integrates complaint management globally across all sites and facilities into one system
- Allows use of harmonized categories, and processes and SOPs aligned across the company
- Lowers regulatory risk caused by maintaining different processes within the company
- Accounts for increased workload in support of investigations without additional headcount with efficiencies gained from technology

Key Benefits:

- **53%** Reduce manual work needed to ensure compliance[1].
- **48%** Reduce complaint metrics reporting cycle[1].
- Visibility into Quality processes to ensure compliance
- Increase visibility into Supplier and Partner Network
- Improve customer satisfaction.

[1]Average improvement percentage sought by companies defined in their continuous improvement plans over 2012 and 2013 timeframe.

Steps to Compliance

Improved Intelligence

- The data that companies capture as a result of complaint reporting and processing can be used to gain insight into production and quality. An effective complaint management system enables manufacturers to access a variety of data reports and trends which are very useful in determining the difference between random errors and critical production issues.
- Once a manufacturer has processed the complaints and trended the complaint data, they can analyze and discuss the data. Cross-functional quality teams can be utilized to provide solutions to reoccurring complaints or issues as provided by the data reports. This group can be responsible for discussing newly reported failure modes, trends, and/or the effectiveness of corrective actions.

Case Study

ACIST, A Bracco Group

Industry:
Medical System Manufacturer

Profile:
220+ employees, with US Operations and global service and distribution sites.

NEED:
Rapid worldwide growth made managing quality inefficient and unreliable using Microsoft Access, Excel and paper forms, particularly for complaints.

- Centralized system for real-time communication of issues between US, Europe and Japan offices.
- Transparency and visibility of product quality across enterprise
- Reliable data integrity
- Regulatory compliance with 21 CFR Part 11

The Solution

- ACIST required the complaint solution to enable accurate, secure, compliant and timely exchange of information
- The quality system needed to expand with the company's growth as future needs for additional quality applications emerged.
- Initial goal was improvement of complaint handling and investigation process, with capability to streamline a QMS that would be easy to implement, require little maintenance effort and able to meet additional quality initiatives.
- Due to successful rollout of complaints system, ACIST deployed TrackWise for managing failure investigations, material review board (MRB) issues and CAPA.

Project Detail	Benefit
Better visibility across the global enterprise	▪ All sites use a consistent data model and process ▪ Standardized reporting and metrics universally available
Improved efficiencies in automatic notification, distribution and records assignment	▪ Complaints and investigations closure goal of 30 days ▪ 50% reduction in closure time in a six month period
Integrated reporting capabilities	▪ Monthly report consolidation reduced four to six hours per week
Future implementation for Global Change Control system	▪ Integrate with other quality processes for visibility and transparency across the enterprise

Conclusion

- Having a global complaint management system in place is critical to medical device companies to understand if there is a problem with a product and how/where it needs to be fixed.
- The ability for a company to recognize if a product issue is widespread to the manufacturing operation or equipment can speed up process improvements to stop the recurrence of an issue. Being able to identify and address life threatening complaints can prevent other injuries or even deaths.
- The ability for a complaint handling system to communicate with a quality management system is essential for identifying if other facilities are having issues, communicating to leadership for continuous improvement and trending to prevent additional problems from occurring in the future.

Founded in 1994, Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the solutions, analytics, and expertise that speed up quality and compliance. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta.

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