FACT SHEET

IQVIA™ SmartSolve® Complaint Management

A comprehensive solution for evolving global adverse event management regulations.

Complaint handling and regulatory reporting are requirements in the life sciences industry, as well as a critical part of any quality management program. IQVIA™ SmartSolve® eQMS Complaint Management provides you with the tools you need to ensure effective, timely resolutions to customer issues and adverse events.

Effective complaint handling helps your organization improve patient safety, increase product quality and efficacy, and maintain compliance with regulatory requirements.

COMPLAINT MANAGEMENT PROVIDES USER-FRIENDLY TOOLS

- Flexible complaint intake options
- Unique device identification (UDI) capture
- Complaint evaluation decision trees
- Global regulatory reporting capabilities
- Electronic medical device reporting (eMDR) compliance

STREAMLINE COMPLAINT INTAKE

There are many potential sources of incidents, complaints, and adverse events within your demand chain. SmartSolve provides flexible complaint intake options and gives all of your stakeholders the most direct path possible from the incident to correction within your quality management system.

Complaint intake options include:

- **Web-based forms:** Complaint Management's standard intake forms give internal personnel the ability to consistently capture and submit incident information.
- **Quality intake portal:** This portal allows field personnel and extended demand chain partners (including known healthcare professionals, clinical investigators, and customers) to quickly submit incident information in a consistent format. It is a secure way

for authorized, whitelisted reporters to submit incident data without accessing your protected complaint management system and data.

- **Third-party integrations:** Incident data can also be received through integration with third-party applications, such as ERP or CRM systems, or from your organization's various web portals.

- **Integration with IQVIA's Vigilance Detect:** Vigilance Detect monitors specific social media for hidden complaints or adverse events, and automatically creates a case in Complaint Management.

CONSISTENTLY EVALUATE COMPLAINTS

Consistency in complaint and adverse event determination is an area of frequent scrutiny during regulatory audits. Complaint Management provides configurable decision trees that allow system users to accurately identify and differentiate complaints and adverse events from other customer inquiries and interactions. Your organization will be able to demonstrate that specific products and failure modes were consistently investigated and reported over time. This can shorten audit time, reduce your risk of noncompliance, and simplify processes for all personnel who interact with complaints and adverse events.

HARMONIZE COMPLAINT INVESTIGATION AND REPORTING

Life sciences products are diverse and complex. It is often challenging to capture the appropriate complaint data for devices, drugs, and combination products, and to make appropriate regulatory reporting decisions in a timely manner.

Complaint Management allows for dynamic direction of both the intake form and the complaint investigation based on product type, alleged failure, risk, or any other complaint data. The system also enables you to define the most efficient and compliance-driven resolution process based on your existing standard operating procedures, as well as data provided when a complaint is recorded. This helps you to consistently investigate complaints and ensure that adverse events are properly escalated for regulatory reporting.

SIMPLIFY GLOBAL ADVERSE EVENT REPORTING

Selling products in the global marketplace requires an understanding of reporting requirements for numerous countries. Complaint Management's finished product profiles keep you in control of regulatory reporting requirements for the various countries where your products are sold. A finished product profile captures key information including market approval dates, production classifications, unique device identification (UDI), and license numbers.

STREAMLINE POST-MARKET REGULATORY SUBMISSIONS

Complaint Management allows Regulatory Affairs to review complaints and streamline reporting submissions to the appropriate regulatory body.

Pre-configured, yet highly flexible decision trees assist in determining reportability for:

- FDA (MedWatch - eMDR)
- EU (MIR - MDR, IVDR)
- Health Canada (MDPR)
- Japan (ARR)
- Australia (MDIR)
- UK (MIR - MDR, IVDR)
- Switzerland (MIR - MDR, IVDR)

Complaint Management also maintains compliance with electronic reporting requirements for the FDA's MedWatch 3500A "eMDR" file and the EU's electronic reporting format for EU MDR. The system also supports compliance with regulatory code sets including integration to CDRH, MedDRA, and IMDRF codes.

INCREASE MANAGEMENT OVERSIGHT

Through powerful reporting, trending, and search capabilities, Complaint Management helps your team make meaningful and effective decisions.

Built-in, configurable reporting drills down into issues and offers valuable insight into the top recurring complaints, previous complaints for a product or lot, and time required to resolve issues.

SECURE COMPLAINT RECORDS AND DATA

SmartSolve allows you to automate your complaint management process with the confidence that your data is secure. The system provides role-based security, powerful password authentication, and a complete audit trail. These features help you facilitate IT and industry compliance with requirements for electronic signatures and electronic records, such as FDA 21 CFR Part 11 and EU Annex 11.

SMARTSOLVE — THE ENTERPRISE QUALITY COMPLIANCE MANAGEMENT PLATFORM

IQVIA SmartSolve eQMS is built on life sciences industry best practices. Delivered on a compliance-ready platform, SmartSolve provides closed-loop process integration unmatched in the market. Whether you are ready to automate a single process or optimize your entire quality management system, SmartSolve gives your enterprise a strategic advantage in quality leadership.

IQVIA TECHNOLOGIES

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