

ELECTRONIC MEDICAL DEVICE REPORTING (eMDR)

For over a decade, AssurX systems have been used in heavily regulated environments including medical device manufacturing, life sciences, energy and financial services. Our medical device industry solutions address the unique issues faced by FDA regulated businesses whose quality and compliance is not simply a goal, but a bottom line requirement.

The Industry Solution From AssurX

AssurX eMDR is designed to help medical device companies transition from cumbersome and inefficient manual MedWatch processing to electronic medical device reporting (eMDR).

By using an intuitive, tabular workflow approach, generating and submitting MedWatch 3500A reports has never been easier. AssurX eMDR is a fully functional regulatory reporting process that provides all levels of 3500A reporting, seamless direct submission to the FDA's ESG (Electronic Submissions Gateway), as well as PDF generation.

How AssurX eMDR Works WITH THE FDA'S ELECTRONIC SUBMISSIONS GATEWAY



1. The FDA ESG receives an eMDR submission from the manufacturer and sends **Acknowledgement 1** to the manufacturer/submitter confirming the submission was successfully received by the FDA ESG. (Also Contains a Message Integrity Check to validate that the submission was received intact.)
2. Submission is automatically transferred to the FDA Center and the FDA ESG sends **Acknowledgement 2** indicating the submission reached CDRH.
3. CDRH validates and processes the submission then sends **Acknowledgement 3** indicating the submission was successfully loaded into the Adverse Event database, or noting any errors that occurred during validation/loading.
4. All three Acknowledgements are attached to the MedWatch record as they are received. A dashboard provides at-a-glance Acknowledgement status from the AssurX eMDR home page.

ASSURX DELIVERS:

CONTROL OF THE ENTIRE MDR REPORTING CYCLE

BUILT-IN DASHBOARDS & DISPLAY PARTS WITH REAL-TIME TRACKING FOR ALL MDR SUBMISSIONS

COMPLETE END-TO-END SOLUTION—NO NEED FOR 3RD PARTY TOOLS OR COMPONENTS

SUBMIT 5- & 30-DAY MEDWATCH REPORTS, FOLLOW-UP REPORTS AND ATTACHMENTS

MANAGE TASKS WITH NOTIFICATIONS, ESCALATIONS, RULES AND REMINDERS

SUPPORTS US MED DEVICE BASELINE, EU VIGILANCE AND CANADIAN MED DEVICE REPORTS

Key Features—Built-in, Right Out of the Box

AUTOMATED REPORTING TO THE FDA

- Conforms to the FDA's HL7 submission schema
- Complete server-to-server solution (via the FDA's AS2 Gateway)
- Self-contained—no third party tools or EDI system to install
- Rigorously tested with the FDA
- Can be used as a standalone process or integrated with any other processes within CATSWeb (complaint handling, CAPA, NCMRs, etc.), or other vendors' complaint handling systems (e.g., Oracle/Siebel CRM)
- Automatically receives/attaches the FDA's three acknowledgements to each MedWatch record
- Easy viewing of all submitted MDR status with out of the box dashboards and display parts



PRE-CONFIGURED MEDWATCH 3500A PROCESS

- AssurX eMDR comes pre-built with the entire MedWatch 3500A process out of the box
- The only requirement during setup is entering the medical device company's manufacturing ID as well as default values such as address information
- No additional configuration is needed—users can start using the process and submitting to the FDA as-is
- File attachments can be submitted

AUDIT TRAIL, ELECTRONIC SIGNATURES

- Audit trail and electronic signature compliant to the FDA's 21 CFR Part 11, includes a secure, time-stamped archive
- Audit trail of all MedWatch 3500As submitted, as well as all follow ups, modifications and attachments
- Query on audit trail
- View edit changes on the form in the audit trail showing the before/after field values
- View changes on entire record, not just the fields
- Electronic signatures cannot be modified, copied, transferred or deleted
- Accommodates signature comments

About AssurX, Inc.

AssurX, Inc. provides highly regulated organizations with enterprise quality management and regulatory compliance solutions. With a choice of OnDemand services or OnPremise (licensed) software delivery options, AssurX offers a flexible all-in-one solution that automates quality and regulatory compliance processes so issues can be properly managed. It helps collect, organize, analyze and share information to better manage and improve quality and compliance performance everywhere in your enterprise. FDA regulated companies around the world, including Alcon Labs, Siemens Medical Systems, Genzyme, Bausch & Lomb, and Boston Scientific use AssurX.

"OTHER SYSTEMS WERE
EITHER TOO COMPLICATED
OR DIDN'T HAVE THE LEVEL
OF EXPERTISE IN THE
MEDICAL DEVICE INDUSTRY
THAT ASSURX PROVIDED."

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