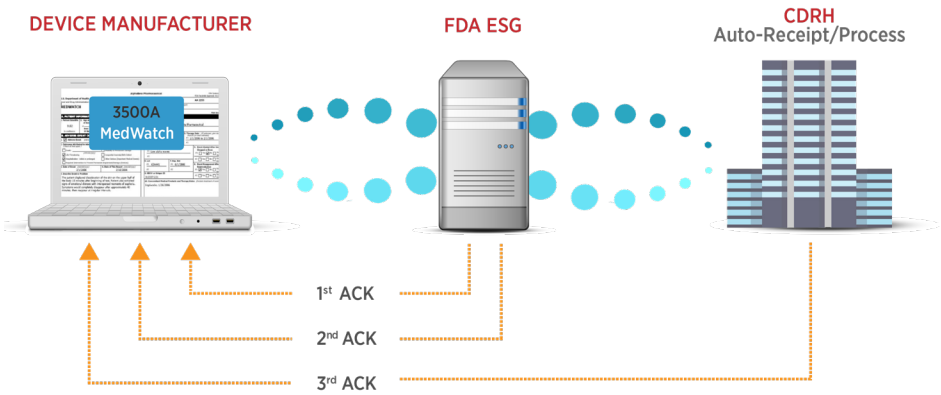
Automated Process for 3500A Submissions

AssurX eMDR is a proven solution for MedWatch (Form FDA 3500A) reporting of medical device adverse events by manufacturers, user facilities and importers. AssurX eMDR can run standalone or as an integrated process within a postmarket surveillance quality management system for unmatched visibility into the device lifecycle.

AssurX eMDR automates the generation and submission of electronic medical device reporting (eMDR) for MedWatch 3500A reports to the FDA Gateway. By using an intuitive, tabular workflow approach, AssurX provides all levels of 3500A reporting, seamless direct submission to the FDA's ESG (Electronic Submissions Gateway) via WebTrader (WT) or AS2, 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. Confirmation 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 has reached CDRH.

3. **CDRH validates and processes the submission** and 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 eMDR PROVIDES:

- Control of the entire MDR reporting cycle
- Built-in dashboards & display parts with real-time tracking for all MDR submissions
- A complete end-to-end solution—no third party tools or components required
- Automated submission of MedWatch reports, follow-up reports and attachments
- Supports US Med Device Baseline, EU Vigilance, Health Canada and Australia Med Device Reports

EXTENSIVE INTEGRATION CAPABILITIES FOR POSTMARKET QUALITY MANAGEMENT

AssurX eMDR integrates with any other AssurX process (Complaint Management, CAPA, Supplier Quality) or with other vendors' systems.

Connect complaints or adverse events to product records in external systems including, but not limited to: customer relationship management (CRM), laboratory information management systems (LIMS), and manufacturing execution systems (MES).

Integration increases the control of data throughout the enterprise and creates a quality supply chain focused on visibility, product safety/improvements and customer satisfaction.

KEY FEATURES

Automated Reporting to the FDA

- Conforms to the FDA's HL7 ICSR current standard 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
- 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
- Can be integrated with other AssurX processes or other systems

Pre-Configured MedWatch 3500A Process

- AssurX eMDR comes pre-built with the entire MedWatch 3500A process
- The only setup requirement is entering the digital certificate and default values (e.g. address information)
- No additional configuration is needed—users can start submitting to the FDA upon permission
- Minimizes the likelihood of submission errors
- File attachments can be submitted with records

Audit Trail, Electronic Signatures

- Audit trail and electronic signature compliant with 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 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

With decades of expertise built into our quality management and regulatory compliance software platform, AssurX helps companies maintain quality and compliance, streamline workflow, control risks and better manage any enterprise.

Our incredibly configurable software and deep understanding of users' needs produce a unique system that easily adapts as your business evolves. AssurX is an ideal partner for regulated companies looking for better operational control and efficiency while staying compliant.

To learn more about how AssurX can help with your quality and regulatory compliance management needs, please call 1-888-9-ASSURX.