

eSafety distribution center

The pharmaceutical industry is moving to a paperless environment. Regulatory agencies worldwide are mandating technology to electronically accept and review Individual Case Safety Reports (ICSRs). For example, the EMEA has mandated the use of the International Council of Harmonization (ICH) E2B standard for reporting of ICSRs.

The benefits of electronic submissions are comprised of:

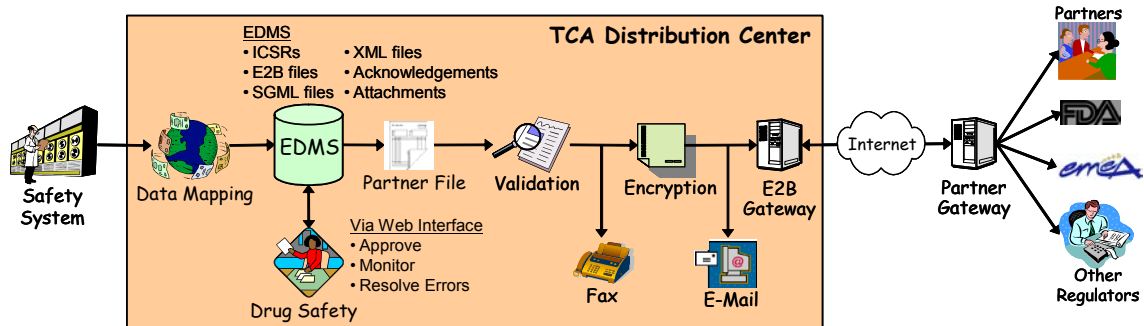
- Standardizing data transmission between regulatory agencies (FDA, EMEA, etc.) and industry
- Eliminating data transcription errors
- Reducing burden/cost on industry and regulatory agencies
- Complying with international standards and open technology solutions

The implementation challenges are:

- Existing staff may not have the appropriate skills or time to implement the E2B standard
- Packaged solutions are costly and require yearly service, support and licensing renewals
- Many of the existing solutions are tied to specific safety systems (e.g. ARISg™, ClinTrace™ and Argus PV™) and cannot be integrated with other safety systems
- Outsourcing is not a good option since outsourcing firms are not willing to accept any of the risk and overall cost of outsourcing is high
- Existing package and outsourcing options are costly and difficult to customize to support unique business requirements

vision

The eSafety Distribution Center from TCA is a comprehensive solution for distributing ICSRs to the FDA, EMEA, and licensing partners via E2B, fax, or e-mail. Our solution integrates with any safety database, and is fully compliant with ICH ESTRI technical standards. The eSafety Distribution Center does not require EDI gateway software to communicate with the FDA and EMEA, thus eliminating a lot of complexity and cost associated with other solutions.



The eSafety Distribution Center was successfully piloted with the FDA and is ready for production implementation.

Compliance with Regulatory Agencies: The solution is fully compliant with both FDA and EMEA EudraVigilance Gateway technical standards:

- Supports E2B DTD v2.1 in both SGML and XML formats
- ICH ESTRI gateway support for security envelope
- Satisfies 21 CFR Part 11 requirements

Open Solution: The solution has a robust product neutral safety system interface:

- Integrates with any safety database
- Data mapping via graphical user interface tool
- Supports multiple target formats (e.g., EMEA, FDA, and partner formats)
- Supports unique partner requirements (e.g., required fields, different field lengths, etc)
- Supports overflow logic to move truncated data into separate fields such as sender's comments

Web based user interface: The solution uses a very familiar email like "Inbox" per organization to monitor and approve submissions

- Allows each organization to review, approve, and monitor their own submissions
- Provides visual indicators for submissions that are close to the due date and/or are late
- Visually indicates if submissions have attachments that need to be sent manually
- Informs users of transmission retry attempts
- Allows users to view transmission errors
- Enables users to view the history of any submission and the associated files
- Allows users to perform searches against submissions
- Provides users with Web-based management and audit reporting tools

Reporting: The TCA solution leverages 3rd party web-based reporting software (e.g., Crystal Reports, Brio, and Business Objects)

21 CFR Part 11

- Support electronic signature on all user actions (i.e., require User ID and Password)
- Complete audit trail within EDMS
- Custom extension to EDMS to ensure full audit trail with all desired events and data
- All documents associated with submission are stored in an EDMS

Validation

- System fully validated using TCA's standard system validation procedures

Technology Consulting Associates

experience

- Documentation available upon request for review
- Validation scripts available for use by client to re-validate own implementation of TCA's solution

Ownership: The client owns the solution and source code. TCA is available for support should you need it; however, this solution is written in code that is easily supported with widely available cost effective resources.

Project Approach: TCA's solution for distributing ICSRs to regulatory agencies and trading partners:

- Enables organizations to quickly begin piloting submissions to both the FDA and EMEA
- Can be implemented in 4 to 6 weeks with minimal customizations
- Is the result of collaboration with numerous pharmaceutical companies
- Integrates with any safety database
- Supports distribution via whatever method the trading partner requires (e.g. email, web server, fax)
- Provides roundtrip capabilities for trading partners when eSafety Receipt is added

results

End-to-end fully compliant solution with streamlined processes

value

TCA's RAD methodology produces tangible results quickly; places a premium on time to market; ensures realization of measurable business benefits; and breaks down and defines projects into discrete manageable phases with predictable costs.

TCA was selected because of our unique blend of industry experience, IT knowledge, and our ability to deliver results quickly. TCA professionals:

- Have experience within Drug Safety
- Have knowledge of regulatory reporting
- Understand the FDA's 21 CFR Part 11 regulations
- Understand E2B data standards
- Are certified EDMS solution providers
- Deliver end-to-end consulting services
- Leave behind and invest their knowledge in your staff