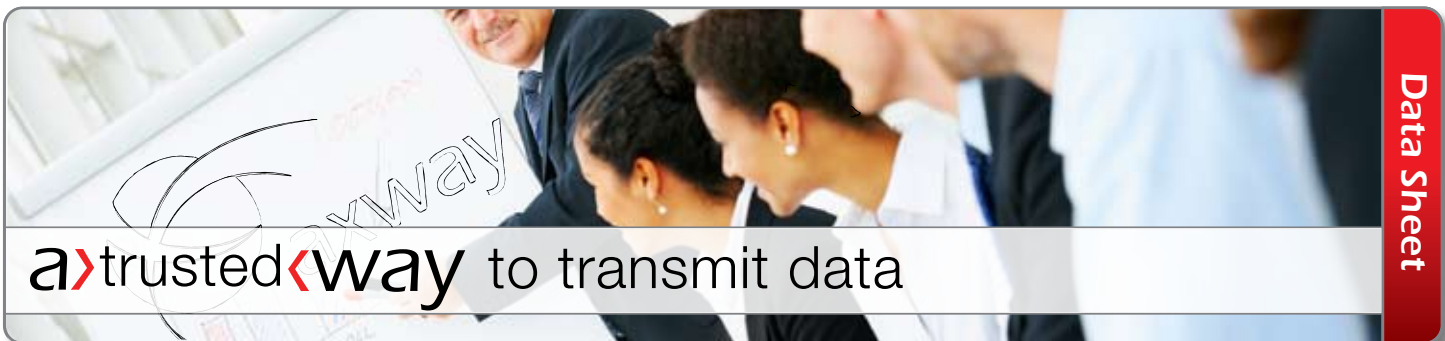




Synchrony™ eSubmissions

Pharmaceutical enterprises are required to provide copious manual reports to regulators that are time consuming and can hinder production. With Synchrony™ eSubmissions, you can quickly and efficiently create collaborative connections that improve the efficiency of transmitting reports to both industry partners and regulatory authorities.



- Ensure regulatory compliance
- Support eCTD format
- Eliminate paper and manual transaction errors
- Reduce paper and processing costs
- Increase visibility into the submissions process
- Standardize and automate data transmissions

Axway is the leading global provider of collaborative business solutions.

Defying boundaries, Axway accelerates and optimizes cross-business processes within and among enterprises. We establish the connections that make companies easier to do business with — improving value-chain efficiency, regulatory compliance, and quality of service.

That's business in motion. That's Axway.

Challenges

Industry regulators across the globe are responsible for protecting consumers and public health by assuring the safety and effectiveness of drug products. Companies that develop, test, and manufacture these products are required to provide copious reports to regulators for everything from new drug applications to adverse events.

Lack of a consistent electronic submissions format has necessitated the use of paper, CDs, tapes, diskettes, and e-mail. Inefficiencies and latencies in the conventional submissions process delay the introduction of new, life-saving drugs into the market, adversely affecting public health. For pharmaceutical and medical/surgical manufacturers, contract research organizations (CROs), and biotech companies, the impact can be:

- Increased costs for submitting regulated data
- Lack of visibility into the submissions process
- Lost revenue from latency in the submittal process

Solutions

Axway is the gold standard for eSubmissions. Synchrony eSubmissions powers communications hubs for the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Japanese Ministry of Health, Labor, and Welfare (MHLW). Synchrony eSubmissions dramatically improves the submissions process for regulatory documentation. The non-intrusive, standards-based software:

- Enables, tracks, monitors, and reports on submissions activity
- Ensures privacy and security of your electronic submissions



- Provides additional compliance assistance with data retention and archiving for auditing purposes

Synchrony eSubmissions integrates seamlessly into your existing infrastructure, enabling you to send and receive regulatory documents via any industry-standard protocol and document type. The platform-independent solution uses adaptive agents and a highly scalable, robust server to securely track and locate each regulatory submission through your communication gateways, translators, and back-end systems—in real time. This visibility helps you better manage the submissions process.

Benefits

Regulators in the United States, Europe, and Japan are driving change in the submissions process by automating connectivity to suppliers of regulated data. The FDA, EMEA, and MHLW have all standardized on Synchrony eSubmissions to submit regulatory documentation. Benefits of electronic submissions include:

- Standardizing data transmission between industry and regulatory authorities
- Eliminating data transcription errors and manual interaction
- Increasing visibility into the submissions process
- Reducing paper processing costs for industry and regulatory authorities
- Reducing latency time in the submissions process

With Synchrony eSubmissions, you can quickly and efficiently create collaborative connections that improve the efficiency of transmitting reports to both industry partners and regulatory authorities. The results are:

- Improved accuracy and timeliness of information
- Increased process visibility
- Reduced submissions costs
- Enhanced revenue

Synchrony eSubmissions is available as a tiered solution to meet your specific needs:

- Synchrony eSubmissions Express: For quick, validated connectivity to FDA, EMEA, MHLW, CROs, and industry partners
- Synchrony eSubmissions Standard: For quick, validated connectivity to FDA, EMEA, MHLW, CROs, and industry partners, and visibility into the submissions process
- Synchrony eSubmissions Enterprise: For quick, validated connectivity to FDA, EMEA, MHLW, CROs, and industry partners, plus complete, end-to-end visibility into the submissions process and multiple data exchange options

For more information on how you can benefit from the power of Synchrony eSubmissions, call your Axway sales representative today. Visit www.axway.com.

business. in motion.



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About Axway

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Axway is a leading global provider of collaborative business solutions. Axway establishes the dynamic connections—within and among enterprises—that make companies easier to do business with. Spanning all industries, over 8,400 organizations in more than 100 countries depend on Axway to manage and control their business-critical information in motion—improving value chain efficiency, regulatory compliance, and quality of service. Built on a service-oriented architecture (SOA), Axway's Synchrony™ solutions feature a highly flexible integration and B2B framework, business and technical analytics, and professional services. Axway also offers customized solutions for the financial services, life sciences, and automotive industries. Many of Axway's solutions are available in a software-as-a-service (SaaS) model. A subsidiary of Sopra Group, SA, Axway is headquartered in Scottsdale, Arizona.

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