



Extedo integrates /n software's IP*Works! EDI / AS2 with PVC Manager providing an easy-to-use solution for AS2 connectivity and automated E2B data exchange

The Challenge

- Provide an affordable AS2-enabled solution for pharmaceutical companies to communicate securely regulatory agencies via an E2B Gateway.
- Find a communications solution that can be easily integrated and supported.
- Comply with strict regulatory requirements set forth by EMEA and FDA.

Health agency regulators worldwide have mandated the use of technology that supports the electronic submission of drug safety reports to regulatory authorities. The AS2 protocol meets FDA and EMEA requirements for the secure data transmission of adverse event reports, enabling pharmaceutical companies to automate processes while ensuring secure and accurate communications with agencies.

As a provider of e-Submission solutions for highly regulated industries, EXTEDO sought to provide a solution that would enable the secure electronic transmission of adverse event reports by pharmaceutical companies. EXTEDO developed PcVmanager to be fully compliant with regulations related to the electronic transmission of reports. The ability to automate communications with regulatory agencies via a standardized gateway supporting encryption protocols like AS2 was a requirement for EXTEDO customers.

“It was essential that we provide a standards-based E2B solution enabling pharmaceuticals to transmit reports to regulatory agencies using a secure connection with AS2 encryption,” said Oliver Bojajar, EXTEDO Product Development. “/n software’s IP*Works! EDI / AS2 allowed for the seamless integration of secure AS2 connectivity in our solution, without the development cost burden.”

The Solution

- Provide customers with the /n software IP*Works! EDI / AS2 fully integrated with the EXTEDO pharmacovigilance solution.
- Embedded solution enables regulatory-compliant AS2 communications, without internal system changes at customer site.

IP*Works! EDI / AS2 supports all major protocols for EDI INT with easy-to-use components that encapsulate the complex protocol and security logic required by the AS2 specifications. The components are fully embeddable, allowing for seamless integration with any application or solution.

Fully customizable components are designed to easily integrate with existing systems, while the unified framework with its common easy-to-learn object model and simplified interfaces allow for greater productivity during the integration process. Users of the AS2 Connector application can transition to the EDI / AS2 components if seeking a more integrated with solution. The transparent and straightforward nature of the component interfaces makes this possible with little effort.



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“We had initially planned to use /n software’s AS2 Connector to provide E2B communication, but wanted a tighter integration of the AS2 solution with our product. The EDI / AS2 components greatly simplified the process of integrating AS2 functionality into our software.”

The Result

- Offer PcVmanager with fully integrated AS2 capabilities, the standard recognized by EMEA and FDA for secure Internet EDI.
- An effective and secure solution without the astronomical annual costs of a gateway software solution.

EXTEDO customers benefit from standardized secure data transmission of adverse event reports through AS2 communication. Whether sending or receiving electronic reports, data transcription errors are eliminated, audit trail is maintained, reporting communications are expedited, and the burden and cost of paper processing is reduced.

“/n software helped us provide a regulatory-compliant solution with seamless and secure transmission capabilities, while remaining cost-effective,” concluded Bojahr.

Integrating the IP*Works! EDI / AS2 components enabled EXTEDO GmbH to offer pharmaceutical companies a cost-effective solution that includes capabilities for secure report transmission that is easy to use and maintain, requiring little or no change to the customer business infrastructure.

About EXTEDO GmbH – EXTEDO is a leader in e-Submission solutions for highly regulated industries. With more than 600 customers and over a decade of experience, EXTEDO’s customers have been able to implement a proactive regulatory process that is fast and accurate. EXTEDO solutions for life sciences are designed to achieve compliance with ICH and regulatory agency requirements for marketing authorizations and pharmacovigilance. EXTEDO enables organizations to bring new drugs to market faster with better quality submissions while proactively managing regulated content, reducing costs, and improving regulatory compliance. For more information visit www.extedo.com.

About n/software – /n software is a leading provider of software components for Internet communications, security, and e-business development. Founded in 1994, /n software (pronounced ‘n software’) is based in Research Triangle Park, North Carolina. You can reach the company via email at info@nsoftware.com, on the World Wide Web at www.nsoftware.com, or by calling (800) 225-4190 or (919) 544-7070.

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