## Grssbus

## Highlights:

- RSSBus AS2 Connector provides PhACT a way to securely send their customers' applications for drug approvals
- The AS2 Solution is met the strict submission requirements of the electronic submissions gateway used by the European Medicines Agency
- The reasonably priced, feature-rich AS2 solution saved PhACT thousands of dollars they would have spent on other less effective solutions

The robust RSSBus AS2 Connector meets PhACT's strict security and electronic submission requirements, while keeping their costs low—without sacrificing performance or reliability.

PhACT approached RSSBus with a crucial need to their consultancy service: create and submit marketing authorization applications for drug approvals via a Drummond Certified AS2 solution.

A Swiss-based Drug Regulatory Affairs consultancy services company, PhACT focuses on creating and submitting electronic submissions in eCTD-format for marketing authorization application for medicinal drug products. PhACT required AS2 messaging because their organization needed to meet submission requirements of the eSUB gateway used by the European Medicines Agency (EMA).

PhACT needed a tried-and-true AS2 solution for creating and submitting electronic submissions in an XML-based format. With customers in the pharmaceutical industry located across the globe and specific gateway requirements, PhACT needed a solution that was customizable, easy to implement and cost-effective.

"Everywhere we turned we saw exorbitant prices for AS2 solutions," Barbara Jentges, PhACT CEO, said. "We were almost at the point of way over paying for an inferior product, when I came across the RSSBus AS2 Connector."

The RSSBus AS2 Connector is a Drummond-certified, eBusinessReady<sup>™</sup> application for sending and receiving files between trading partners through AS2, the leading standard for secure Internet EDI communications. With a full range of features including cross-platform support, integrated 'AS2 restart', and advanced firewall options, the AS2 Connector includes messaging features unavailable in solutions costing ten times as much. Thousands of users of the AS2 Connector have utilized the extreme flexibility in integration with other systems, applications, and platforms through the unique Service-Enabled<sup>™</sup> features of the RSSBus AppServer framework.

"The solution works perfectly! It is a great relief to know that I don't need to worry about whether my EMA submissions are being properly and securely handled. Not only is this a great product, but the support is fantastic."

— Barbara Jentges, CEO, PhACT Corporation



## **B**rssbus

PhACT used the AS2 Connector to securely create and send eCTD-formatted submissions to the European Medicines agency through the electronic submission gateway required by the drug approval agency. Since the connector is service enabled, PhACT was able to access the solution from any remote location, seamlessly integrate it within their organization, and customize the application to fit their industry-specific needs.

With the RSSBus AS2 Connector at their disposal, PhACT was able to rapidly implement the secure AS2 solution. From the initial planning stages to implementation, the entire project was up-and-running in less than two months.

"The solution works perfectly! It is a great relief to know that I don't need to worry about whether my EMA submissions are being properly and securely handled. Not only is this a great product, but the support is fantastic. They were fast in reaction time and professional in outcome," Jentges said.

About PhACT – PhACT, a Swiss-based company, was founded in November 2006. Together with associated partners and regulatory affairs professionals, PhACT aims to support pharmaceutical companies, manufacturers of active pharmaceutical ingredients, biotech companies, contract manufacturers and contract laboratories—as well as traders in major fields of the Regulatory Affairs business.

About RSSBus – RSSBus is a spin-off of /n software inc. (www.nsoftware.com). RSSBus provides high-performance, reliable, and fully-extensible products that simplify the process of producing, consuming, and integrating data. The RSSBus products enable a simple yet effective layer of middleware that helps users drive information flow without the added complexity that is common across other integration solutions. You can reach RSSBus via email at info@rssbus.com, at www.rssbus.com, or by calling (800) 235-7250 or (919) 928-5214.

