

AdeptPackaging
PACKAGING ENGINEERS & CONSULTANTS

CMO Connectivity

Connecting to and Exchanging Data with Multiple Trading Partners

An Adept Packaging White Paper



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I. Executive Summary

For Pharmaceutical Manufacturers and Contract Manufacturing Organizations (CMO), finding a solution that makes connecting to and exchanging data with multiple trading partners is challenging. There are many factors to consider, and these factors are not always obvious.

Adept Packaging has created this white paper to shed light on this all-too-common problem and to offer strategies for solving it.

II. Challenges

Serializing products during the manufacturing process can be challenging, but innovative vendors have solutions that reduce this challenge substantially. Once products are serialized, aggregated, and packed, the challenge is sending the track-and-trace information downstream. At the start of a

serialization project, the importance of CMO integration is far too often overlooked or addressed with assumptions.

Consider the serialization challenges faced by CMOs:

- ✓ The CMO may not have the required IT Resources
- ✓ Brand owners typically do not help with B2B integration
- ✓ Trading partners have a wide variety of connection requirements
- ✓ The CMO must cross regulatory boundaries
- ✓ Various authorization and authentication methods (e.g. AS2, SSL, Dual SSL, SFTP, etc.)

The above challenges are major hurdles and deal with only with connecting; there is still the matter of sending actual data in an acceptable format.

III. Same Standards, Different Implementations

The jungle of technical details relating to data format is compounded with each trading partner. Not only are there various data standards for exchanging data (such as EPCIS, EDI, and PML), there are also many ways these standards are interpreted and implemented. Vendors who produce software to support these standards typically do so without coordinating with their competitors. Therefore, implementations will vary from one vendor to the next, some in subtle ways and others in more noticeable ways.

Whether large or small, these differences result in the same problem: a CMO with trading partners using varying vendors will have to contend with various implementations. Without the guidance and knowledge of implementers who understand these issues, an unavoidable negative impact on costs and time will occur.

IV. Global Compliance

Perhaps the most challenging of all issues is global compliance. Brand owners may ship their products to one or more global markets, and each market has different rules and regulations regarding how pharmaceutical products are received. In some instances, such as India and the European Union, it is required to connect directly to centralized endpoints to deliver. In others, like China, a more manual approach is encountered.

To add more to the global compliance problem, every regulatory market requires different data in different formats. Some regulatory markets require EPCIS or a variation of EPCIS. Some regulatory markets do not focus on the form of data but specify what data will be provided. Still other markets have a proprietary way in which they accept data. All of these exacerbate the global compliance problem.

V. Vendor Selection

All vendors are not alike. When selecting a vendor, it can be difficult to effectively sift through the sales and marketing craft to arrive at a selection that benefits you.

Vendors can be great at providing solutions for problem “A” and completely unsuited to provide equal solutions for problems “B” - “D”. Connecting a CMO to various trading partners is a problem that brings a challenge not only for you, but for the vendors as well.

To solve the multiple CMO connection problem, vendors have provided solutions from simple FTP and email services to elaborate business networks. The most effective solution to this problem is one that connects natively to any number of endpoints using any number of protocols and authentication mechanisms.

Relying on FTP/SFTP can be an option, but if it's the only option odds are the solution will not meet the needs of one or more trading partners. Proprietary networks are certainly promising but create two potentially insurmountable future problems: vendor lock-in and mandatory participation. In other words, selecting a vendor who offers a proprietary network as a solution will, most likely, require all trading partners to exist on that network and will lock you into that vendor's way of doing things.

VI. Conclusion

Adept Packaging can help you navigate to the process of selecting the right vendor for your CMO connectivity problems. If you have selected a vendor and are having issues integrating with your trading partners, Adept Packaging can help with that too.

Adept Packaging has been in the track-and-trace and serialization space since the beginning and has a staff of subject matter experts and engineers, as well as a proven methodology for implementing and solving all types of serialization problems.

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