Automated Integration for Organizations in the Healthcare Supply Chain

How device manufacturers, biotech organizations, and pharma companies use integration to optimize their supply chains and get life-changing products to the people who need them.
Ensure Connectivity Across an Integrated Ecosystem of Supply Chain Partners

In healthcare, it may not be an understatement to say that information literally can be a matter of life and death. The importance of reliable and secure data flows cannot be discounted, but exchanging information with various healthcare entities has traditionally been a complex process, specifically when it comes to health insurance data and patient medical records. But it can be even more complicated in other corners of the industry.

Life sciences organizations – pharmaceutical manufacturers, distributors of biologics and blood-based products, and biomedical device makers, among others – specifically face unique challenges tightening integration, optimizing business processes, and enabling dynamic data flows across multi-enterprise supply chains.

That’s because these supply chains include a mix of trading partners, government or regulatory bodies, distributed teams, and core business applications.
Such highly intricate and sprawling systems of applications, business processes, and information flows mean few organizations operating within a healthcare supply chain – and even facilities within the same organization – will necessarily have the same technologies in place that enable the fluid, reliable, and secure exchange of digital information across enterprise boundaries.

Additionally, while all healthcare organizations must adhere to HIPAA, Meaningful Use, and Final Omnibus Rule requirements, additional governance, security, and compliance affect manufacturers, distributors, and logistics providers in healthcare including, RoHS, REACH, WEEE, UDI, and more. The increasing and ever-evolving regulatory landscape complicates compliance with diverse mandates as organizations look to technology to increase automation, optimize business processes, and augment or extend business models to be more competitive.

Ensuring connectivity and an integrated ecosystem of partners is essential. Here's how to improve critical data processes through enhanced file-based integration, multi-enterprise integration, and application integration that enables the supply chain ecosystem for pharmaceutical, medical device manufactures, and biotechnical/life sciences organizations.
Hikma develops, manufactures, and markets quality branded and non-branded generic medicines. The New Jersey-based company was operating on legacy end-of-life and end-of-support systems and its business processes were not aligned, which meant challenges with SLA compliance, partner satisfaction and ecosystem growth.

Additionally, Hikma discovered a single point of failure regarding its partner interactions. Given that 90% of all its business transactions are EDI-based, Hikma needed to mitigate that risk and modernize their B2B and EDI operations.

Hikma deployed the Cleo Integration Cloud platform to support ecosystem expansion and connect business applications with other IT systems and solve important risk factors – unsupported data movement software, single-instance vulnerabilities, and key resource limitations. By moving its EDI and B2B interactions to the cloud, Hikma regained control of its important ecosystem relationships and can:

- Ensure continued uninterrupted business flows
- Maintain services levels with customers and partners
- Continue growth of its worldwide operations
The Healthcare Supply Chain Ecosystem

Drug makers, life sciences organizations, and medical device manufacturers depend on everything from research, development, and commercialization to distribution, fulfillment, and delivery to ensure doctors, hospitals, pharmacies, and patients can access their often life-changing products. Reliable data exchange and connectivity among the supply chain ecosystem, across sourcing facilities, packaging plants, group purchasing organizations (GPOs), distributors, and logistics companies, are critical.

Such increasing reliance on their supply chain means these organizations are prioritizing agility and interoperability across their trading partner ecosystem. But these organizations require more than just connectivity.

Significant challenges in recent years, from the rise of counterfeit drugs to government regulatory reform, have put added pressure on pharma, medical device, and life sciences organizations to layer their file transfer flows and supply chain interactions with enhanced governance and security protections. Such mandates require advanced data protection and flexible integration capabilities that seem to be growing by the day.

DON’T FORGET the INTERNAL SUPPLY CHAIN PROCESSES

Hospitals and clinics, dentists’ offices, labs, and so many other facilities depend on various tools and accessories for the diagnosis, prevention, and treatment of disease and injuries, but purchasing departments are fighting constant battles when it comes to ordering things like medical instruments, bandages, and machines because of an overdependence on spreadsheets and other manual processes.

According to a Cardinal Health survey of more than 300 clinicians and hospital supply chain decision-makers, the tedium of supply chain tasks is “stressing out” 20% of clinicians. So, while pharmaceutical developers, life sciences organizations, and medical device manufacturers have a clear need for external, B2B-type ecosystem integration capabilities, there’s a clear need to improve internal-facing operations across the healthcare industry through enhanced supply chain automation and optimization.

The good news is, all these use cases and processes share the same data exchange patterns and can be addressed via ecosystem integration.
Top Challenges for Life Sciences and Pharmaceutical Organizations

Life sciences and pharmaceutical organizations depend on the secure transfer of data as they go through extensive clinical testing to meet FDA and other regulatory approval. Above all else, however, they must ensure their final products get delivered, and that means seamless ecosystem integration with distributors, fulfillment operations, and GPOs to ensure patients get the products they need, when they need them.

How these businesses handle the increasing variety, volume, and complexity of supply chain and logistics data will determine their respective success, but it’s no easy feat. Here are some of the common challenges for biomedical, pharmaceutical, and health device manufacturers and distributors.
## Business Challenges

| Compliance with evolving regulations | • Exchange of data across the healthcare supply chain must adhere to stringent industry regulation  
• Proprietary sales, marketing, and R&D activity data must be kept secure |
| FDA approval/expiring patents | • Delays in approval immediately impacting revenue streams and slow down the time to market  
• Patent tweaking calls for faster R&D, where frictionless data exchange and integration are critical |
| Prove safety and efficacy during product development and fulfillment | • Transparency in operational activity  
• Tight integration with track-and-trace solutions for granular traceability  
• Mitigation of industrial-scale counterfeiting and property theft |
| Global business landscape | • Expanding operations and growing a geo-dispersed ecosystem  
• Entering new markets and developing or augmenting distribution models  
• Rapidly add new trading partners without stressing systems or burdening technical teams |

## Technical Challenges

| Connectivity | • Multi-protocol support to rapidly onboard distributors, logistics and 3PL organizations, and other trading partners  
• Extensive EDI support to automate order-to-cash and procure-to-pay processes and reduce manual file sorting |
| B2B integration | • Robust data transformation and mapping to accept, transform, route, and securely connect and integrate all data types, from any source, to any target  
• Scalable platform to create new integrations without compromising existing data flows |
| Governance | • Data traceability and non-repudiation support via message confirmations, acknowledgments, and end-to-end audit trails  
• Ensuring regulatory compliance by showing the chain of custody for EDI transaction sets |
| SLA performance | • Providing 100% uptime to reliably meet customer and partner data requirements  
• Reducing sales and distributor chargebacks stemming from EDI exception rates, late documents, and downtime |
| Visibility | • Surfacing information about EDI transactions in a real-time, contextual manner  
• Monitoring throughout the entire distribution lifecycle, including increased transparency into demand and inventory levels |
Octapharma is one of the world’s largest human protein fractionators, developing and manufacturing both recombinant and human cell line therapies. The company was plagued by a 40% exception rate for EDI transformation, and it was affecting distribution and chargebacks. When those errors occurred, Octapharma spent 20 to 30 resource hours every week manually fixing them. Additionally, a lack of visibility into its partner and customer transactions, as well as a lack of sales and distributor chargeback documentation for FDA compliance, were costly challenges.

Octapharma partnered with Cleo for its robust data transformation capabilities and vast protocol connectivity. Armed with better B2B integration via Cleo Integration Cloud, the biotherapy manufacturer:

- Reduced EDI errors hindering distribution and causing chargebacks
- Eliminated manual sorting of files downstream
- Vastly improved trading partner onboarding across its distribution network
- Ensured compliance through highly governed and auditable data communications

Octapharma can more effectively deliver critical products to the hospitals, treatment centers, doctors, pharmacies, and, most importantly, the patients who need them.
How To Improve Integration for Healthcare Supply Chain Companies

With better B2B integration capabilities, drug makers, medical device manufacturers, and other life sciences organizations will gain better insight into the demand for their products – as well as control the quality of the product at the contract manufacturing organization level – and manage their distribution more efficiently. Here’s how such companies improve how they execute their critical supply chain processes, including order-to-cash, procure-to-pay, and load-tender to-invoice:

- **Support for multiple secure protocols**, including AS2, SFTP, and FTPs, as well as APIs for back-end application integration

- **Data movement and B2B integration modernization**, to consolidate multiple file transfer and data transformation tools

- **Supply chain optimization and prioritizing connectivity**, agility, and flexibility across trading partner ecosystems

- **Enablement of seamless EDI and non-EDI data flows** to support any trading partner requirement

- **Leveraging dashboards and audit trails** that show the life cycle of every file transfer and help track key KPIs and SLAs
REQUIREMENTS FOR AN AGILE, FLEXIBLE SUPPLY CHAIN

Businesses looking to optimize their supply chain must:

SUPPORT THE EDI PROCESS

The healthcare supply chain industry has welcomed EDI data exchange with open arms because of its standardized format and data specifications, which ensures that critical order, invoicing, shipping, and acknowledgment information is quickly sent and interpreted. EDI makes document exchange between trading partners as seamless as possible and improves efficiency by eliminating manual intervention, ensuring accuracy, and harnessing automation. The secure movement of electronic transactions is mandated under HIPAA standards, and EDI is a proven vehicle for enabling such transactions.

SUPPORT NON-EDI FORMATS

But healthcare supply chain organizations also must support non-EDI data formats, which include XML, fixed-length flat files, XLS and CSV spreadsheets, as well as PDFs and other text-based documents. Transfer of these file formats typically happen outside normal integration processes when a distribution partner, for instance, sends purchase order and invoice information via fax, email, or a client web portal. Getting this info into the system often takes manual data entry, custom scripting, or some other unscalable process.

SUPPORT MULTIPLE PROTOCOLS

Digital communication with entities outside the business requires dynamic file-based integrations to connect your ecosystem trading partners and applications. The modern healthcare integration stack supports protocol depth and preconfigured connections, no matter whether the requirement is an AS2, SFTP, or HTTPS protocol, or a SOAP- and REST-enabled API. Healthcare organizations with a deep connectivity toolbox will support any communication requirement, rapidly add new connections, and ensure business continuity.
To create a safer, more transparent system for global drug manufacturing and distribution, LSPediA provides pharmaceutical serialization solutions to help manufacturers and wholesale distributors implement and meet the FDA's Drug Supply Chain Security Act (DSCSA) mandates. As LSPediA assists more manufacturers, packagers, distributors, 3PLs, and providers in deploying a comprehensive serialization process, the company must support growing data volumes and increasing file sizes while meeting stringent compliance and security standards.

LSPediA tapped Cleo to modernize its integration platform and improve data flows powering its SaaS serialization solutions. Cleo Integration Cloud enables LSPediA to secure, automate, and streamline its data exchange processes while LSPediA focuses on its core business goals: transforming the pharmaceutical supply chain and ensuring patient safety.

Cleo’s managed file transfer (MFT) and B2B integration solutions help LSPediA:

- Process of millions of serialized events and their data interactions
- Advance serialization compliance and track-and-trace mandates for its customers
- Fight prescription drug counterfeiting and compromised medications
Cleo Integration Cloud for the Healthcare Supply Chain

Secure, reliable data exchange drives modern healthcare supply chain organizations and is the foundation for improved patient outcomes. A modern B2B and ecosystem integration platform ensures healthcare supply chain companies can collaborate more freely, tap legacy or on-premise data stores and cloud application infrastructure, and leverage real-time visibility tooling across their ecosystems.

Cleo Integration Cloud is a single, hybrid ecosystem integration platform available as a service in cloud and on-premise deployments. Its flexible architecture lets healthcare supply chain organizations choose between self-service or managed service models, enabling them to connect, transform, integrate, orchestrate, and analyze end-to-end application, B2B, and data integrations for improved visibility across their healthcare networks and supply chain ecosystems.

Cleo Integration Cloud for the Healthcare Supply Chain enables organizations to make better decisions, create stronger relationships with trading partners, and accelerate growth as integration requirements change. Learn how Cleo’s ecosystem-driven approach – connecting external B2B and internal data processes for end-to-end governance and visibility – can solve your pressing healthcare supply chain data movement and integration challenges.

Cleo Integration Cloud: Driving Success for Life Sciences, Pharmaceutical, and Medical Device Companies

- Master your global supply chain
- Ensure industry compliance
- Shorten time for clinical trial submissions
- Rapidly enter new markets
- Get new medications approved faster

Want proof?

SEE CLEO INTEGRATION CLOUD IN ACTION

Schedule your live, interactive demo to learn how you can enable fluid multi-enterprise, multi-cloud, and multi-application hybrid integration flows across your ecosystem of customers and supply chain partners.

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