# EVERY DAY IS AN OPPORTUNITY

### TO DEVELOP A PARTNERSHIP.

**Don't miss our new case study: Partnerships Power New Drug Applications.** You'll discover how collaboration ensures the comprehensive logistics and new product launch process will be tailored for manufacturers' specific needs.



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## Partnerships Power New Drug Applications

When pharmaceutical manufacturers prepare new drug applications (NDA) for submission to the FDA, ICS has designed and implemented a streamlined solution integrating advanced logistics, supply chain, validated packaging and serialization solutions for the potential commercial product. Understanding the critical need for speed to market, the process can be developed and validated within 12 months.

#### **Collaboration Supports Serialization**

To support NDAs, ICS developed a strategic collaboration with two industry leaders in the serialization process, Systech<sup>®</sup> and Upak Global, the brand protection division of Ultimate Solutions Corp. The combined expertise of ICS and these complementary solutions providers streamlines the process and product movement from the drug and delivery device contract manufacturing organizations (CMO) to third-party logistics (3PL). Through the enhanced process, ICS leverages novel technologies and logistics practices that eliminate a secondary packager and Serialization Level 4 provider. Utilizing the collective, highly configurable solutions enables deployment of a full stack Level 1 through Level 4 Systech software solution — resulting in significant efficiencies and faster time to market.

Turnkey 3PL solutions, along with new product commercialization consultation from ICS include:

- Packing of product components from multiple CMO locations. For example:
  - Packaging of a glass vial containing the sterilized drug product into a tray containing sterile ancillary drug delivery components in their own Tyvek sealed compartment
  - Placing of approved package insert within carton and applying tamper evident seals

- Sourcing of all secondary cartons and tertiary master cases for proper distribution into channel
- Serialization printing and aggregation supported by Systech and Ultimate Solutions Corp.
- 3PL storage and distribution
- Title distribution





#### **Streamlining Commercialization**

In order to be ready for commercialization, manufacturers have turned to ICS to support all aspects of logistics — from kitting, labeling, packaging and serialization to sourcing materials, title model solutions, drug supply chain and FDA compliance, and other consultative support. Manufacturers have chosen ICS after rigorous RFP processes because the 3PL partner has an all-encompassing serialization and commercialization solution. With more than 20 years of experience supporting specialty and global manufacturers and emerging brands, ICS aligns supply chain strategy to pharmaceutical manufacturers' business goals.

#### Additional ICS solutions include:

#### TITLE MODEL SOLUTION

The Title Model Solution allows pharmaceutical manufacturers to focus on research and development programs and product pipelines without having to worry about setting up and maintaining State Licensure.

Clients mitigate risks while realizing speed to market and expediting cash flow. ICS takes title of the product on behalf of the manufacturer, leveraging its own licensing to handle warehousing, distribution and order-to-cash management of the product.

Emerging brands can accelerate their product launch. Pharmaceutical manufacturers will maintain the patents and control the sales, while ICS handles all other aspects of distribution. This includes orchestrating freight and quality control measures, facilitating compliance and licensing requirements, managing special product handling needs and owning and supporting the accounts receivable relationships with downstream customers.

With the Title Model Solution, ICS serves as the single point of contact and streamlined two additional steps in the commercialization process, resulting in increasing efficiencies and cost-management, while enhancing safety, integrity and the validation process.

#### ORDER-TO-CASH

Full order-to-cash services eliminate the need for pharmaceutical manufacturers investing in the build out of warehouse space, staff and manage these services on their own. ICS clients benefit from a scalable 3PL infrastructure, including superior customer service – saving costs and time.

#### LAUNCH TIMELINES

Highly customized and thorough Launch Timelines were provided during the early stages of discussions to assist the manufacturer in the validation process. Leveraging ICS expertise in partnering with 130+ manufacturers, the Launch Timelines keep implementation on track.

"Through the enhanced process, ICS leverages novel technologies and logistics practices that eliminate a secondary packager and Serialization Level 4 provider — resulting in significant efficiencies and faster time to market."



#### Additional ICS solutions (continued):

#### DQSA SUPPORT AND SERIALIZATION

The ICS system architecture is 100% compliant with serialization requirements and currently supporting all Serialization Level 4 providers.

### ICS ENHANCING EFFICIENCIES WITH SYSTECH AND ULTIMATE SOLUTIONS CORP.

In advance of the FDA's serialization requirements, ICS has partnered with Systech and Ultimate Solutions Corp. to support the manufacturers' need to uniquely identify each product. This is key in supporting the full scope of potential new product commercialization.

Systech pioneered pharmaceutical serialization and is the global technology leader in supply chain security and product authentication.

Ultimate Solutions Corp. provides the Upak serialization and aggregation equipment, a fast and cost-effective solution to support commercialization of serialized pharmaceutical products.

Collaborations between ICS, Systech and Ultimate Solutions Corp. ensures the comprehensive logistics and new product launch process will be tailored for manufacturers' specific needs. The three companies work with clients to support validation and ensure packages are sealed and serialized.

#### SERIALIZATION GENERATION AND COMMISSIONING

ICS's Upak equipment communicates with Systech's serialization and track and trace software for the generation of serial numbers. Once ICS prints and aggregates the serialized information on clients' products, the numbers are then commissioned back to the manufacturer.

#### SERIALIZATION REPOSITORY

With the Systech solution, all of the manufacturers' serialized data is stored and retained for 7+ years to meet DSCSA requirements.

#### SERIALIZATION PRINTING

ICS and Upak U-Track print serialized information directly to the clients' packaging. The packaging solutions are 100% compliant with HDA Labeling Requirements and are powered by Systech's serialization software suite.

#### SERIALIZATION AGGREGATION

Once the manufacturers' products are individually serialized, the Upak equipment then aggregates products into cases to meet supply chain aggregation needs. To complete this process, cases are then aggregated to pallets.

#### MANAGING TWO MANUFACTURING FACILITIES

The clients' potential products can be manufactured at multiple CMO locations. ICS speeds up the logistics, reduces multiple touchpoints and manages the transportation of the components by providing an inhouse, full-service transport, labeling, packaging and serialization operation.

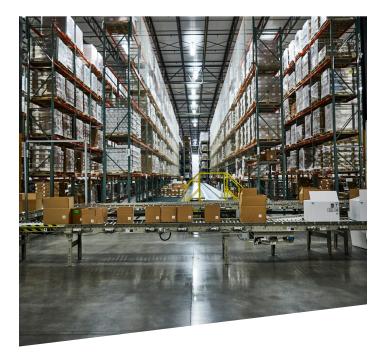
"To be ready for commercialization, manufacturers have turned to ICS to support all aspects of logistics from kitting, labeling, packaging and serialization to sourcing materials, title model solutions, drug supply chain and FDA compliance, and other consultative support."



#### **3PL Partnership Success**

By selecting ICS as its 3PL partner, the manufacturers' teams can continue to focus on research and development, without the need to hire additional supply chain, logistics, and quality control and security personnel.

The partnership of ICS, Systech and Ultimate Solutions Corp. also eliminates the need for the clients to manage separate suppliers for serialization and traceability, streamlining the commercialization process, saving time and costs.



#### ICS is the model of excellence in global healthcare logistics.

Since 1997, ICS has partnered with pharmaceutical manufacturers to deliver customized healthcare logistics solutions that improve the quality and efficiency of your supply chains. We have organically grown to become the recognized industry leader in outsourced logistics and distribution services.

With our expertise and the global capabilities of AmerisourceBergen, we bring proven and innovative solutions that deliver results. By starting with a consultative approach, we tailor your logistics strategy to your business goals and patients' needs.

#### We are more than a 3PL provider. We are your strategic partner.

As a strategic partner, we offer expanded, integrated logistics solutions designed to support pharmaceutical manufacturers regardless of size of your operation or where you are in the commercialization journey. We align supply chain strategy to your business goals and go the extra mile to deliver tailored healthcare logistics solutions that increase supply chain efficiency, maximize return on investments and enhance patient care.



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