

LPS INDUSTRIES, EARLY ADOPTOR OF END-TO-END MATERIAL SUPPLY CHAIN TRACKING

An Established and Thorough Approach to Quality ensures Compliance and Traceability Every Step of the Way for Leading Global Medical Packaging Suppliers

(Moonachie, NJ – April 2016) By every account, the medical packaging industry will continue to experience considerable worldwide growth in the coming years. This expansion is being fueled in part by the needs of an aging population, and more specifically, the growing acceptance and use of point-of-care testing. The global market for point-of-care diagnostics is projected to reach \$16.5 billion in 2016 according to BBC Research, a leading market research company. As this acceptance continues to increase, medical test and device companies, as well as their suppliers, will be required to comply with evolving industry standards and more stringent government regulations.

LPS Industries, a leader in the high-barrier flexible packaging industry, supports the quality control programs of its medical test and device manufacturing clients with a proprietary inventory tracking and management system that delivers the highest level of transparency, accountability and responsiveness. For more than eight years, the core of the LPS system has been barcode tracking, from raw materials to delivered product.

“As an ISO certified manufacturing organization since 2003, LPS has been committed to the highest level of quality control and standards compliance. We continue to evolve our processes to support our customers’ supply chain accountability requirements,” explained Charles Ardman, LPS Industries’ Vice President of Marketing. “The barcode tracking solution is an integral component of our ability to readily and accurately provide total supply chain traceability.”

Although FDA and EU regulations apply to a device and not to its packaging, the LPS tracking solution is based on “device-level” track and trace requirements. Medical device manufacturers require their vendors to have traceability from raw materials all the way to the finished goods. While suppliers to the healthcare industry all typically have some degree

of tracking capability, LPS was early to implement a comprehensive, end-to-end system designed to respond to end chain inquiries promptly and with pinpoint accuracy. The goal of delivering consistent, high quality compliant product drives the process, and an experienced quality assurance team makes it happen.

The LPS tracking protocol starts well before manufacturing begins, with each shipment of raw materials receiving a barcode as soon as it arrives on-site. As materials move through each successive manufacturing stage, the LPS system builds and maintains a comprehensive production history that can be easily accessed. In the end, the tracking system documents each step along with the source and composition of each component through the manufacturing process while optimizing the quality of the finished product.

Using the creation of a three layer high barrier flexible packaging material as an example, the process begins by assigning each of the three layers of raw materials an individual ‘part’ number. At any point when the original state of a raw material is changed, e.g., a film is printed, it receives a new part number. As the components move through subsequent production stages to become the finished product, each variant receives its own, unique identifier. This enables LPS to determine not only the raw materials used for a particular order, but also creates the ability to identify the exact stage/part that may be related to a quality control inquiry from the customer. Simply stated, this system enables LPS to readily “deconstruct” a finished good to its components at each stage of the manufacturing process.

Ardman acknowledges, “Whenever there are increasing regulations in a growing industry, the critical importance of track and trace accountability escalates in a commensurate manner. The LPS barcode tracking system, an integral component of our quality program, also supports our customers in the event they become subject to an audit or recall. In these instances, an immediate and accurate response is of paramount importance.” Should a pharmaceutical, biotech or medical customer request an audit of a supplier, complete traceability is expected. During on-site audits, LPS readily demonstrates track and



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About LPS Industries

John M. Robinson founded LPS Industries in 1959 primarily as a converter of military specification barrier materials. Today, under the direction of Madeleine D. Robinson, CEO, LPS Industries is a diversified manufacturer and leader in the flexible packaging industry, providing packaging solutions for a diverse range of markets, including medical, food, transportation, electronics and agricultural. LPS Industries is an ISO 9001:2008 certified company offering three separate product groups: flexible packaging, coated products and general packaging systems and accessories. Modern production facilities and state-of-the-art equipment assure all products are manufactured to the highest quality standards. Research and development are also an LPS priority – a modern R&D laboratory is dedicated to product innovation and quality assurance. LPS is a woman owned and operated company.

For more information on LPS Industries and its packaging products and services, please visit: www.lpsind.com.

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trace capabilities for materials throughout the process and is routinely complemented on the scope and effectiveness of their quality control processes.

Regulators also expect medical companies to perform “mock” recalls, which may include prompt reporting of data related to the construction of a product. Suppliers may also be contacted as part of the investigative process including those that manufactured the primary packaging materials. In the event of an actual recall, the serial numbers on the end units trace back to the precise device, and LPS in turn would be required to trace back to the material through the manufacturing process. LPS can then pinpoint the exact raw materials, in-stage product, even the exact shift and operator responsible for a processing stage. “Our system is both highly accurate and intuitive to manage, which gives our pharma, biotech and medical customers an added level of confidence in working with us,” Ardman added.

The barcode traceability system also means LPS can be responsive to new FDA and EU regulations that may surface in the future. If a new standard directly or indirectly impacts a medical device company’s supply chain, the foundation LPS has built positions them to deliver timely, 360 degree information.

As the medical device industry continues to grow, and the complexity of products grows, LPS’ forward-looking barcode tracking system will continue to play a key role in not only ensuring the highest quality end product, but also providing customer support in the event of an audit or recall.

Ardman concludes, “This is one of the many reasons leading pharmaceutical, biotechnology and medical test and device companies align with LPS. We are not just a supplier, but a trusted partner that has committed to supporting our customers’ obligations with respect to supply chain traceability.”



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