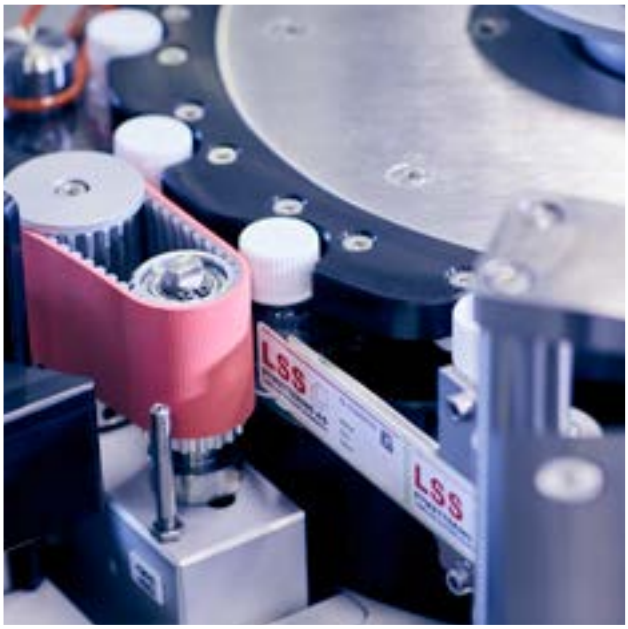
Overview Guide

More than a labelling solution: equipment, expertise and experience



LSS

Pharmaceutical labelling is central to assuring patient safety and better health outcomes and regulators increasingly demand that drug labels do more to inform and protect patients.

With a drive to deliver more product information, safety warnings, traceability and security, this is prompting drug manufacturers to explore advanced manufacturing solutions to address the complexities of vial packaging labelling, marking, inspection and quality.

Accessing labelling solutions and implementing them to meet regulatory expectations can pose challenges. To address these complexities Martin Sonne engineering lead from LSS discusses how joining man, machine and enterprise can help deliver better labelling capabilities.

01 Information complexity driving change

Pharma's manufacturers have dealt with the intricacies of labelling products for global distribution for years. But emerging global regulations to secure drug manufacturing and distribution supply chain are compounding the complexities of doing business globally.[1]

Serializing pharmaceutical packaging with an individual product identifier is now law in most established global pharma markets. This along with variables related to primary packaging, including its size, and the product's data and physical handling requirements, are making labelling and marking operations more challenging to manage effectively.

Guiding the development of all drug products is the concept of patient centricity and providing access to safer more effective drugs that deliver better results more efficiently. Labelling plays a critical role in dose compliance, a patient-centric strategy that assures accurate administration of drugs as prescribed by physicians.

Studies show that when patients take their medications as prescribed, their health outcomes are significantly better and at a lower cost to payers. Patients who can't or won't take their medications often get sicker, requiring expensive hospitalizations or surgeries.[2]

Clearly labelled parenteral drug products and devices help clinicians and patients administer treatments more accurately and comply with regulations but to accomplish this effectively vial labelling is growing more complex and technically challenging.

Package diversity and label data density

Regulations over the past 15 years have called for more information on primary package labelling, but the real estate to apply it hasn't expanded to follow. Data density on labels is a real issue and that's prompting a broad range of formatting and printing tactics on complex forms.

In the face of this regulatory complexity and data density the attitude to labelling solutions is changing fast. A robust technical and operational response is required that is well integrated to production, enterprise business and data analysis systems.

Whether introducing required capabilities to satisfy regulations or broadening capacity to meet global market demand, the labelling solution resource and expertise may not be available in-house.

Relying on expert partners

This lack of in-house function explains why pharma manufacturers and commercial packaging partners are turning to technical and system specialists to support the expansion and scope of their product labelling lines to meet their requirements.

With manufacturing excellence so closely aligned to business strategy in the pharma industry, securing a vial labelling equipment supplier that fits the product and the enterprise is a highly strategic decision.

The technologies for printing and labelling small products are well-developed – current machines from equipment vendors are offering new levels of speed and accuracy and quality control.

However, it's the people behind the labelling machines that count the most.

Engineering a better relationship

Engaging equipment and solutions partners for your vial labelling applications starts by engineering a better relationship from the outset and asking and answering some important questions about the required labelling solution.

When introducing more sophisticated labelling capabilities to the enterprise and implementing new machines, begin by painting the clearest possible picture of your labelling operations by writing up a URS (User Requirement Specification). This is a very thorough document that describes in detail what a customer needs. If the customer lacks resources to create this then the labelling solutions provider can help with its creation. The URS actually makes the basis for the equipment. The equipment will in thery never be better than specified in the URS!

The URS for a vial labeller can have hundreds of specific requirements. Some of the more important ones are:

- **Clear identification of the products to be labelled, including dimensions, weight, and surface area. Samples of filled products will be required to examine further.**
- **The specification of the label material to be used, including samples.**
- **The required variable information to be printed and in what quality.**
- **The required capacity (products per minute) and Efficiency (effective production time).**
- **Label placement accuracy – critical tolerances.**
- **Infeed / Outfeed constraints.**
- **Required controls.**
- **Communication and data exchange requirements.**

The initial URS from the customer is the basis for the first discussions with a solution provider to clarify points and potentially modify some of the requirements based on recommendations or additions. A high level of consultancy is required from the vial labeller solutions provider at this point to build trust and lay the foundation for a long term relationship with the customer.

Scope the integration with enterprise systems in mind

Every pharma manufacturing enterprise has its own unique, legacy business and manufacturing system environment. There are firewalls, unique data handling and batch recording systems. The more clarity provided regarding the scope and penetration of the integration the more likely the equipment solution can deliver business value.

Pharma companies require all processes to be validated and rely on their Quality Assurance departments to ensure compliance and current Good Manufacturing Process (cGMP) standards are met. If the machines can't generate data that QA can use, this will be addressed during the URS discussions.

Communication and partnership are key to building more capable machines and solutions. The most economical time to make changes is before machines are engineered and shipped to the site.

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Technology advances and capabilities

In a pharma setting fitting the capacity of the machine and customizing its standard features to meet production targets is a critical aspect of any vial label machine integration. For example, products intended for clinical applications may only need a stand-alone unit capable of semi-manual handling small lots of product.

Another setting might call for a more robust and automated response with throughput, data handling and inspection through a central platform. For a mid-size or larger pharma company labelling commercial volumes of vials, systems can range from a series of integrated in-line labelling solutions, to high capacity solutions capable of handling hundreds of products per minute.

The key is to find suppliers with technologies that are flexibly configurable and can scale and grow with the needs of the organization.

Reliability and user-centricity

The more user friendly and reliable labelling technologies are, the more effective they will be in delivering the desired productivity and compliance outcomes.

LSS vial labelling machine solutions are a case in point. With decades of experience in and outside of pharma, our solutions have seen continuous improvement relative to the human-machine interface (HMI) and the operator. Reliability is another engineering hallmark, with machines providing the condition and performance monitoring data that commercial operators need to stem unintentional downtime.

Beyond a one-size fits all approach

Every vial or package in pharma has to be processed with extreme care. Machine designs must be ergonomic, accessible to operators and extra sensitive at handling fragile products. Using the latest automation and control technologies helps LSS machines manage these delicate handling duties.

LSS pays particular attention to this aspect of primary packaging handling; all critical machine functions are monitored by counter-control sensors to stabilize all handling forces manipulating the vial during labelling.

Better interface, better quality

Vial labellers from LSS offer an intuitive HMI. Operators respond to color cues when perceiving and processing information and a color HMI is a proven aid to productivity and processing accuracy.

From here batches are started or stopped, and new data can be sent to the printer and vision system, messages and alarms can be read and the overall machine status can be monitored. LSS designs feature a primary HMI on the operator side of the machine and the design provides for an additional HMI to be installed in service position to support maintenance.

Inspection and control

Functionally vial labelling machines are now integrating product inspection technologies to assure quality and reliability.

A high-resolution digital capture of each product as it enters and leaves the labelling process not only assures end product or label end quality, but during manufacturing. For example, on the HMI a visualized shift register for labels and vials can be monitored.

The shift register is related to the control functions that are integrated to the machine, and generally consist of the following:

- **Vision inspection of the label after it has been printed but before vial application. Inspection of printed in-formation, label ID etc.**
- **Rejection of non-approved labels before application, which reduces the amount of rejected products.**
- **Vision inspection of the vial after the label has been applied: inspection of label presence/position, presence of cap etc.**
- **Rejection of non-approved products.**

For LSS machines only approved vials are allowed to proceed in the index wheel. Non-approved vials are rejected at the vial reject station. Lastly, the functionality of reject station is monitored by counter-control sensors for quality assurance purposes.

Line clearance and format change challenges

Line clearance before a format change and format changes may be two of the bigger challenges within vial labelling operations. Errors can be introduced and potentially lead to compliance issues beyond the processing theatre.

LSS machines are designed to make line clearance a safer process by maximizing visibility and reducing the number of cables, wires and hoses in the work area to an absolute minimum. This makes the line clearance process not only safer but also less time consuming.

A commercially viable labelling machine for pharma setting should be engineered for easy error free format changes. After selecting a predefined format on the HMI of a vial labelling machine, the replacement of a few format-specific components is all that is required.

All machine components requiring positioning are placed on motor-driven spindles and automatically adjust to the newly loaded format.

Customization opportunities

LSS vial labelling systems are ready for vials and bottles made of glass or plastic with diameters between 14 and 35 mm and a minimum height of 30 mm. However, beyond vial size, LSS machines can be configured in many different ways to accommodate specific requirements and package variation. For example, depending on the label or printing surface either thermal transfer or laser marking can be specified.

LSS integrations are open to the most commonly used suppliers of vision systems, printers, lasers and material handling solutions. Infeed of the vials and bottles can be executed from a tray via a turn table and conveyor or in-line from an upstream machine via conveyor.

Access to internal operating components, as well as line clearance, service and maintenance should also be straightforward and support, not hinder maintenance or change-over routines.

03 Tailored solutions in action

A review of two generic tailored solutions that offer great examples of custom integration and its impact on costs, ROI, quality and more.

Scenario 1 – Vial labeller for a vaccine manufacturer

Challenge: A 2-turntable solution with both in-line and off-line out feed capacity

- Specific printer and vision equipment had to be integrated
- Extensive communication setup with downstream equipment installed at the same time
- Customized batch report system

Solution

- All requirements were met by combining standard LSS modules with customized modules
- On the communication and reporting side a 100% customized solution was developed

Scenario 2 – Syringe labeller for pharmaceutical company

Challenge: Three functions in one machine

- Product inspection before labelling (looking for particle, bubbles etc.)
- High precision labelling for accurate placement of label on product (vertical and horizontal closed loop system)
- A color cap assembly process

Solution

- All requirements were met by combining standard LSS modules with customized modules and completely new modules

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Validation services

Validation is a prerequisite in all pharmaceutical manufacturing and may require the use of external consultants to ensure that it is completed correctly, and all machinery is properly validated.

To make this process more efficient LSS offers tailored validation documentation packages according to the cGMP and GAMP 5 regulations. The validation packages are composed by DS, DQ, IQ/OQ and FMEA risk analysis. This documentation certifies that the equipment has been designed, built and now operates according to your URS requirements, and that all critical functionalities has been qualified according to the risk assessment outcome.

Seek expert solution providers with flexible technology

Based on the expertise from many years of collaborating with customers in the pharmaceutical industry, we have a great deal of experience configuring and integrating vial labelling machines. From multiple successful implementations our machines have proven they fulfil the unique requirements of the pharmaceutical industry.

Each experience has been a learning opportunity and no two implementations are ever the same. But key to a successful implementation, especially to meet critical business needs and compliance goals, requires communication, understanding and insight. Technology alone is not capable of providing the robust labelling solutions pharma needs now. These solutions need to be more integrated to the enterprise than ever before, and that requires comprehensive solutions delivered by competent solutions providers.

About LSS

With more than 45 years of experience in the labelling industry, LSS Labelling Systems Scandinavia is a leading supplier of labelling solutions. The Danish company sets and meets the highest standards in developing efficient and reliable labelling solutions. They are experts in product handling and provide correct and precise label application on all sorts of products. Founded in 2001 as a continuation of the labelling machinery division of Avery Dennison, LSS was acquired by the Logopak Group in 2014 and is today benefitting from being a member of the German manufacturer's worldwide sales and service organization.

Compact stand-alone labelling unit for secure low-volume vial labelling

With a capacity up to 100 products per minute the LSS stand-alone machine offers product in-feed from trays products entering the star wheel and then back into trays.

Featuring easy in and out feed of the labelling unit, the unit is capable of printing variable and unique data for each product before label application. Further, a vision system can be integrated to control print quality and detect correct label placement.

Operator friendly, the HMI is very intuitive and gives the operator full visibility of status for the machine.

Automatic labelling of vials with vision

Our featured offering is more suited to fast-paced commercial labelling environments. With a capacity up to 250 products per minute product infeed can be served from a tray via turn table and conveyor, or in-line from upstream machines via conveyor.

This highly automated machine can be delivered both as an off-line and an in-line unit and configured with either a laser or thermal transfer printer.

Vision inspection is standard and configured so only approved vials are allowed to leave the index wheel.

Highly engineered for high throughput

Our highest throughput offering, LSS can configure vial labelling machines capable of Labelling 400 vials per minute. The system can accommodate high volume product infeed from tray via turntable, as well as conveyor or in-line from upstream machine via conveyor. Product separation is done by worm screw and product labelling occurs in roller conveyor.

Built for both off-line and in-line use, when used in-line products continue by conveyor to subsequent equipment. When used off-line, the integrated out-feed module can be used to squire vials back into trays.

Label marking is done by laser and the machine offers smart vision inspection of the labels in real time and provides label position control as well as defect rejection modes.

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References

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