Staying ahead: Innovations in parenteral drug labelling

The pharma and biotech industries are in a state of constant evolution, expanding at an unprecedented pace and paving the way for groundbreaking medications and therapies. From rare diseases to personalised medicines, companies are increasingly tasked with providing treatments that meet patients' needs.

As the pharma and biotech sectors flourish, so does the demand for parenteral medicines. The increased demand is reflected in the global parenteral drugs market, which is expected to rise from an estimated $451 billion in 2019 to a value of $802 billion by the end of 2029 [1]. The efficacy and precision of parenteral delivery methods make them indispensable in the treatment of complex medical conditions.

These crucial parenteral medicines now account for around 40% of new molecular entities approved by the U.S. Food and Drug Administration each year [1]. Amid this dynamic environment lie both opportunities and unique challenges that demand production expertise to deliver accurate, clear and secure labelling. The production of parenteral medicines is becoming more challenging as the industry adapts to trends that are reshaping the landscape.

In this eBook, Lars Skole, Managing Director for LSS (Labelling Systems Scandinavia), explores the trends and challenges of parenteral packaging and labelling and outlines how innovative labelling solutions address them. From the rising demand for biotech solutions and small batch demands to the integration of digitalisation and advanced technologies like Pharma 4.0, he examines the forces propelling this industry forward.

With more than 15 years leading manufacturing technology companies and over 12 years devoted to the packaging industry, Lars Skole, managing director of LSS (Labelling Systems Scandinavia) has extensive experience of integrating labelling technologies and systems to create high-performance packaging operations.

Efficiency for cost-effective and streamlined production

As the demand for complex labelling solutions continues, efficiency becomes a necessity. This need for efficiency is confounded by governmental pressures to keep costs down so that medicines can be accessible to the increasingly ageing global population. The industry must therefore embrace technological advancements to revolutionise production efficiencies.

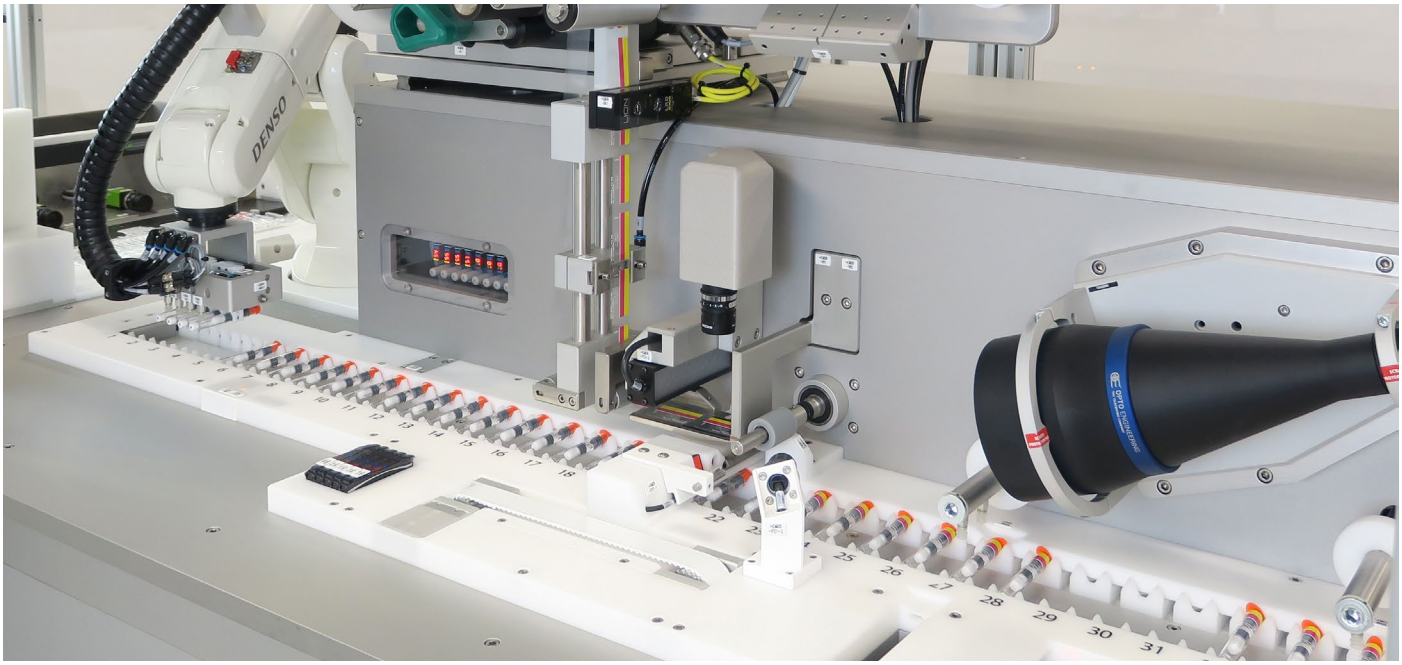
> The global pharmaceutical packaging market is thriving and is estimated to rise from $105.01 billion in 2023 to $156.12 billion by 2030 [2] -Fortune Business insights

This growth exemplifies how packaging and labelling are developing in tandem with the rapidly transforming pharma landscape. Labelling solutions play a crucial role in conveying vital information, which is essential for maintaining product integrity, ensuring compliance and safeguarding patient safety.

For example, the adoption of Pharma 4.0 represents a paradigm shift in pharmaceutical manufacturing. It embodies the convergence of data analytics, robotics and artificial intelligence (AI). These elements are formidable tools that are redefining the way drugs and medical devices are produced.

Embracing Pharma 4.0: A technological leap

Pharma 4.0 is transforming the industry by enabling real-time monitoring of processes, predictive maintenance and data-driven decision-making through data analytics. Additionally, robotics introduce precision and consistency, while AI enhances adaptability and problem-solving.



To understand the evolving technological landscape of packaging and labelling, it's essential to recognise Pharma 4.0's integral role in the industry's pursuit of efficient production and cost-effectiveness. These solutions pave the way to enhanced precision, traceability and flexibility in packaging and labelling, with digitalisation allowing for a "batch of one" to be ascribed to every individual unit, with impending impacts on standards and regulations. These advancements are vital to safeguarding both quality assurance and regulatory compliance, along with facilitating patient needs as technologies progress.

Attaining a “batch of one”: Precision and digital twins

Traditionally, pharmaceutical production has centred around the concept of batches. Multiple units of a medication or medical device were manufactured together and each batch was labelled accordingly. However, the “batch of one” concept represents a seismic shift from this approach. This innovative approach proposes that each unit - whether it is a syringe, vial, cartridge or pen device should be traceable and identifiable as a standalone entity.

Part of what makes the “batch of one” truly transformative is the potential integration of a digital twin, which is a virtual replica of a physical product or system. In the context of pharmaceutical packaging, it represents an exact digital counterpart of each labelled product. This digital twin can mirror every aspect of the physical product, from labelling specifications to manufacturing data.

The benefits of incorporating a digital twin into the “batch of one” paradigm are profound. It enhances traceability to an unprecedented level, allowing real-time monitoring and verification of every product’s label and status. Quality control becomes exceptionally precise, reducing the risk of labelling errors and ensuring compliance with stringent regulatory standards.

Moreover, a digital twin opens the door to predictive analytics. By analysing data from the digital twin, manufacturers can anticipate potential issues, implement preventive measures and optimise labelling processes in real time. This proactive approach minimises downtime, maximises efficiency and ultimately reduces production costs.

The integration of a digital twin within the “batch of one” framework aligns perfectly with the industry’s shift toward digitalisation. It’s a testament to the pharmaceutical packaging and labelling sector’s commitment to harnessing technology for unparalleled accuracy, compliance and operational excellence.

Technology to facilitate changing patient needs

Technologies that are being explored and implemented include radio-frequency identification (RFID), which is a well-established technology primarily used for tracking, and near-field communication (NFC) tags have emerged as a promising addition to our toolkit. These tiny yet powerful tags hold the potential to revolutionise how users interact with pharmaceutical products.

NFC tags are garnering attention for their ability to provide users with real-time product information directly on their mobile devices. Imagine a patient using an auto-injector or a pen device. With a simple tap of their smartphone, they can access detailed information about the medication, usage instructions and more. It's a game-changer in terms of patient centricity and empowerment.

The response to advancements: Changing standards

As technologies within the pharma industry advance, the standards that govern them also progress. In Q1 2024, the International Society for Pharmaceutical Engineering (ISPE) is set to recommend a significant shift - the move from batch-level traceability to product-level traceability. For syringes, RFID will be the chosen technology while vials, cartridges and pen devices will adopt Datamatrix. Unlike traditional barcodes, Datamatrix can store a significant amount of information within a compact area, including product identification, expiration dates, batch numbers and manufacturing details, in a format that is easily scannable and traceable.

This shift underscores the industry's growing emphasis on digitalisation and traceability. It's about ensuring that every product can be tracked, monitored and identified at a granular level, adding further precision and accountability to product logistics.

Governmental pressures for innovation

Beyond technological advancements, governmental pressures to lower drug prices have instigated a profound reevaluation of production efficiency and labelling processes. Cost containment has become a driving force, compelling manufacturers to explore new strategies and technologies.

The stringent regulatory landscape and governmental pressures are catalysts for innovation.

There is a clear change in the pharma industry, where companies are now less conservative and are embracing novel technologies more than before while striving to reduce the number of people on production lines as much as possible.

This shift to applying technologies, such as IT and automation, is in recognition that efficiency is not just a matter of choice but a survival imperative.

"The strategic decision to adopt technological solutions can ensure not only compliance but also cost-efficiency and streamlined operations. It is a commitment to meeting the dual challenge of maintaining product quality and reducing production costs."

— Lars Skole, Managing Director for LSS.

The LSS comprehensive approach to cost-efficiency

As a company dedicated to excellence in labelling solutions, LSS actively contributes to cost-efficiency through automation, data collection and validation services. We provide the tools and expertise necessary for our clients to thrive in this dynamic landscape. To achieve cost-efficient production, we use technology-driven innovation to provide labelling solutions through the following means:

Increased automation through robots Automation is the cornerstone of efficiency in modern pharmaceutical production. By incorporating cutting-edge technology and robotics, we reduce the need for manual labour on the production line. Our tray handling modules, in particular, utilise robots for in-feed and out-feed operations. This not only streamlines processes but also minimises the risk of errors.

Optimising the labelling line output
Avoidable rejects can be a significant bottleneck in the production process, leading to a waste of resources and time. We address this issue comprehensively:

Closed-loop controls: Our solutions incorporate closed-loop controls, which means that drifting parameters are corrected on the fly. This real-time adjustment minimises avoidable rejects, ensuring that production remains smooth and efficient.

Consulting on existing lines: We understand that not every production line can be overhauled entirely. That's why our consulting services are designed to optimise existing lines, identifying areas for improvement and efficiency gains. We work closely with companies to ensure that their current setup operates at its full potential.

Data collection for future optimisation

Data is the currency of efficiency, allowing us to collect actionable insights. Our solutions are equipped with data collection capabilities, allowing us to gather vital information about the labelling process. This data serves as a foundation for future optimisation efforts, helping companies make informed decisions to enhance efficiency. For example, our practice of tracking and sharing machine data with clients empowers them with valuable insights through data analysis and gives them transparency into the production process. By analysing this data, clients can pinpoint areas for operational improvement, optimise workflows and reduce downtime, while data transparency enables clients to closely monitor labelling accuracy, ensuring that their products meet quality standards.

Clean design for swift batch changes

Efficiency comes from flexibility and agility as well as speed, and our solutions are designed with efficiency in mind, featuring a clean and intuitive design. This design not only facilitates faster batch changes but also expedites line clearances. Less time spent on these tasks means more time dedicated to actual production.

Small batches, major impact: The cutting edge of labelling strategies

The emergence of biotechs has ushered in a new era of innovation that caters to people with rare diseases and those with small patient populations. Biotechs have assumed a pivotal role in developing medications for diseases that were once considered too rare to warrant extensive research. Today, these advancements offer life-changing solutions to patients who would otherwise have limited treatment options.

Parenteral products have emerged as critical medicines for these applications, with administration through injection or infusion often being the most effective and reliable method for patients with complex medical conditions. However, the very effectiveness of parenteral products introduces unique challenges, particularly in packaging and labelling.

Small batch production, often a necessity for rare diseases, requires precision and agility to address the distinctive and exacting specifications of these specialised medications.

Labelling solutions optimised for frequent changeovers in smaller batch production

The industry trend toward smaller batches and increased changeovers necessitates careful consideration of equipment efficiency. The layout and design of machinery play a pivotal role in streamlining the production process and ensuring minimal downtime during labelling.

Small batch efficiency isn't just about speed; it's about maintaining high productivity levels while keeping downtime to a minimum. Our machinery is engineered to facilitate swift line clearances and batch changes, allowing for a seamless transition between different product proportions and types.

Small batches may present unique challenges, but they are challenges we are well-equipped to handle. Our expertise and commitment to excellence empower our customers to navigate the complex terrain of small-batch labelling with confidence.

3D printed trays:
Ensuring flexibility without compromising quality

We understand the unique challenges our customers face when it comes to efficiency with small batches and handling devices in our machines. Recognising the specialised needs of biotech companies, LSS offers labelling solutions to cater for adapting to all shapes, sizes and types of products offering versatile versions of tray handling designed to address these specific needs:

Customised tray solutions

In our first approach, we customise the solution to precisely match the tray provided by the customer. This tailored approach ensures that all trays seamlessly integrate with our labelling solution, providing a smooth and efficient process.

3D printed tray innovation

In addition to customisation, we also offer a cutting-edge solution using 3D printed trays. This innovative approach provides flexibility and adaptability, allowing us to create trays that perfectly accommodate all variations of devices.

Solving customer challenges

Our tray handling solutions often resolve a common issue among customers. While we are known for our labelling expertise, we recognise the importance of seamlessly integrating different trays into our machines. Our expertise extends beyond labelling to include efficient product and tray handling, both in in-feed and out-feed modules. These solutions not only streamline the process but also enhance overall efficiency.

LSS tray handling modules excel in delivering flexibility in labelling. They enable the seamless handling of various products and sizes within a single labelling unit, providing the agility and efficiency required for small-batch labelling and allowing clients to excel in the pharma landscape.

Documentation and validation excellence

Integrity and compliance are embedded in our process from the outset — we provide comprehensive documentation and support to ensure client peace of mind regarding the integrity and compliance of the labelling process.

Our validation documentation process is entirely customer-centric and driven by our expertise in navigating the complex landscape of regulatory compliance. We start by closely collaborating with the client to understand the unique User Requirement Specifications (URS). This dual focus forms the foundation of our documentation and validation efforts to ensure that client and legislative needs are met.

We follow a meticulous URS Design Specification (URS-DS) cross-reference list to ensure that every requirement is met. Our factory acceptance testing (FAT), site acceptance testing (SAT) and Installation Qualification/Operational Qualification (IQ-OQ) test protocols and reports are conducted rigorously to exceed expectations.

Our team possesses an in-depth understanding of our equipment, enabling us to streamline the validation process. While external consultants are often brought in for validation, our in-house expertise ensures an efficient and effective validation process that seamlessly meets requirements. This allows us to provide a documentation and validation process that is tailored, thorough, risk based (FMEA) and customer-focused.

Flexibility in packaging for CMOs and CDMOs

Contract manufacturing organisations (CMOs) and contract development and manufacturing organisations (CDMOs) continue to be pivotal players in the pharmaceutical industry. They provide pharma and biotech companies with the versatility required to navigate the complexities of a dynamic market. Their ability to offer end-to-end solutions, from development to manufacturing and packaging, has made them indispensable partners in the production chain.

The success of CMOs and CDMOs hinges on their ability to cater to a diverse array of parenteral packaging requirements. This multifaceted demand necessitates flexible packaging lines that can swiftly adapt to varying specifications, ensuring that each product is handled with precision and care.

Adapting to the challenge of changing labelling requirements

In this environment of constant change and diverse needs, labelling solutions become vital to success. These solutions must seamlessly integrate with flexible packaging lines, automating processes to ensure accuracy, compliance and efficiency. Navigating the intricate web of global regulatory standards and swiftly adapting to changing requirements is paramount in this context. These challenges underscore the critical role of labelling solutions in not only meeting regulatory demands but also in maintaining accuracy and efficiency throughout the production process.

"The relationship between pharma companies and packaging partners is evolving.
It is no longer a transactional exchange but a strategic collaboration. A collaborative packaging partner understands the nuances of the industry, anticipates challenges and works in tandem to find innovative solutions."
— Lars Skole, Managing Director for LSS.

The landscape shift to patient centricity and self-medication

Healthcare is undergoing a transformation that places patients at the forefront of pharmaceutical decisions. The shift to patient centricity is driving patient empowerment and a movement towards self-medication.

The rise of self-medication is allowing patients to increasingly take charge of their health, seeking convenient and accessible ways to manage their well-being. This shift represents a seismic change in the pharmaceutical landscape.

In meeting the demands of patient centricity, parenteral delivery methods, particularly auto-injectors, have emerged as champions. They provide patients with the power to self-administer medications, offering independence and control over their treatment.

However, this newfound independence comes with unique challenges, particularly in the realm of labelling, with country-specific legislation further complicating matters. Auto-injector pen devices demand precision and clarity in labelling to ensure patients receive the right instructions to deliver their medication in the right way. These challenges are where innovation finds its purpose.

Effective labelling is vital to enhance the user experience and ensure accurate labels for patient safety when administering parenteral medicines. For specialised medications designed for small or rare diseases, or when country-specific compliance regulations apply, precise labelling solutions become even more critical. These solutions go beyond the conventional and cater to the unique demands of these scenarios. The result is a seamless process that empowers patients while maintaining safety.

The LSS commitment to customers

As a company committed to excellence in labelling solutions, we are dedicated to ensuring that our customers, the dedicated medical manufacturers, receive products with confidence. We recognise the immense responsibility that rests on our shoulders, knowing that our solutions have a profound impact on the health and well-being of individuals worldwide. These solutions ensure our customers have peace of mind knowing that every patient can trust that they are receiving the correct medication in the right dosage.

The LSS solution to packaging and labelling needs

A specialist and collaborative packaging and labelling partner is a necessity in the intricate pharma world. Finding the right partner, particularly for parenteral medicines, is critical.

Parenteral medicines demand a level of precision and expertise that can only be achieved through collaboration with a specialist. The intricacies of labelling, compliance with regulations and the need for customisation all underscore the need for a partner who understands the unique challenges of this sector.

The LSS solution to packaging and labelling needs

LSS allows collaborators to benefit from a combination of strengths to address client labelling challenges.

Small batch proficiency and consultancy expertise

Our proficiency in handling small batches is a testament to our commitment to adaptability. We understand that each batch is unique and our consultancy strengths ensure that labelling needs are not just met but exceeded.

Reducing rejects

Rejects can be a costly and time-consuming issue. We offer solutions that not only minimise rejects but also automate inspections that were traditionally done manually in up- or downstream processing. This proactive approach streamlines the production process, making it more efficient and cost-effective.

Our inspection functions cover a wide spectrum of quality checks ensuring label correctness, readability and precision. Before the label is applied, we verify whether it's the correct product according to the batch. We check if the device has been activated, examine the dosing wheel and perform colour cap control, among other checks.

Some medical products, especially those for rare diseases, can be expensive. That's why our reject functions are designed for precision. Depending on the cause of the rejection, the product can be directed to a rework station. Here, an operator manually inspects the product, ensuring that only genuinely faulty items are rejected. This approach not only saves time but also minimises waste and cost. Reject handling goes beyond efficiency to preserving the value of each product, especially when they play a vital role in addressing rare and critical medical conditions.

Flexibility and customisation at the heart of LSS solutions

Flexibility is vital to success in the pharma industry. Our labelling solutions are designed to be adaptable and customisable, providing elements of a platform solution. We understand that your needs are unique and our solutions are tailored to meet those specific requirements, from label placement to other critical details.

Digitalisation and labelling of the "batch of one"

Exploring new frontiers in identification technology is key to enhancing the user experience and adapting to evolving industry standards. As traceability becomes a priority, there is a need for labelling technologies that allow companies to attain "batch of one" product identification.

In a world driven by data and automation, digitalisation is imperative. The LSS vision-based solutions provide closed-loop precision, ensuring that every label is placed with accuracy and consistency, which is particularly challenging in the realm of parenteral products. This digital transformation is at the core of our commitment to excellence.

Innovative solutions for an evolving industry

The pharma packaging and labelling industry is undergoing a profound transformation. Smaller batches, the increasing reliance on CMOs and CDMOs, the focus on parenteral product innovation and the growing prevalence of self-administered medicines have become defining trends, and LSS is at the forefront of these changes.

Our commitment to adapting to industry trends is not just a promise; it's a mission. We have showcased our proficiency in handling smaller batches and parenteral products, emphasised our strengths in collaborating with CMOs and CDMOs and underlined our dedication to empowering patients through self-administered medicines.

LSS has labelling solutions that align with the industry's ever-evolving needs, from precision and accuracy to adaptability and customisation. As digitalisation transforms labelling into a seamless, data-driven process, we are committed to embracing new technologies and driving our customers, and the wider industry, forward.

About LSS

For more than 40 years LSS has delivered automatic labelling solutions around the world and for all kinds of pharmaceutical products. Our individually designed and customised labelling solutions meet the unique requirements of the pharmaceutical industry. With decades of experience in developing, designing, manufacturing and installing pharmaceutical labelling machines our versatile solutions range from simple offline systems and automatic label dispensers, to integrated labelling systems that interface with other equipment and software. We have standard solutions for vials, ampoules, small bottles, syringes, auto injectors, pens and boxes. To find out more about LSS pharmaceutical labeling solutions click **here**.

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