Tackling parenteral drug labelling's surging complexity

Pharma and biotech development is expanding following sustained growth of pharmaceutical-based healthcare around the world. To maintain health and deal with chronic disease, more people are taking prescriptions and over the counter (OTC) medications than ever before. Most of these drug products are dispensed in primary packages, including bottles and vials, and every single one requires a label application.

Although billions of doses will continue to be dispensed from basic packaging, millions more doses are being delivered to patients in new more patient-centric ways, including single-unit dose delivery and specialised functional combinations that combine the drug with the delivery device or match the patient to a personalised therapy.

Drug packaging has never been more functional or diverse, or more complex. For most drug manufacturers and packagers, complexity is surging, along with labelling requirements and the technical capabilities needed to accomplish successful drug delivery.

How can pharma tackle the surging parenteral drug labelling complexity to come? Lars Skole Managing Director for LSS discusses the emerging trends and challenges associated with growing parenteral drug packaging and labelling complexity and how pharmaceutical developers and manufacturers can meet the challenges ahead.

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.

Packaging's new role in therapeutic performance

For a time most drug labelling involved mass-scale printing and application operations and the high-speed capacity to efficiently mark the packaging of large quantities of common products. Most drugs were packaged in simple primary containers, essentially jars and bottles for oral solid dose drugs and vials for liquid or parenteral medications. Not anymore.

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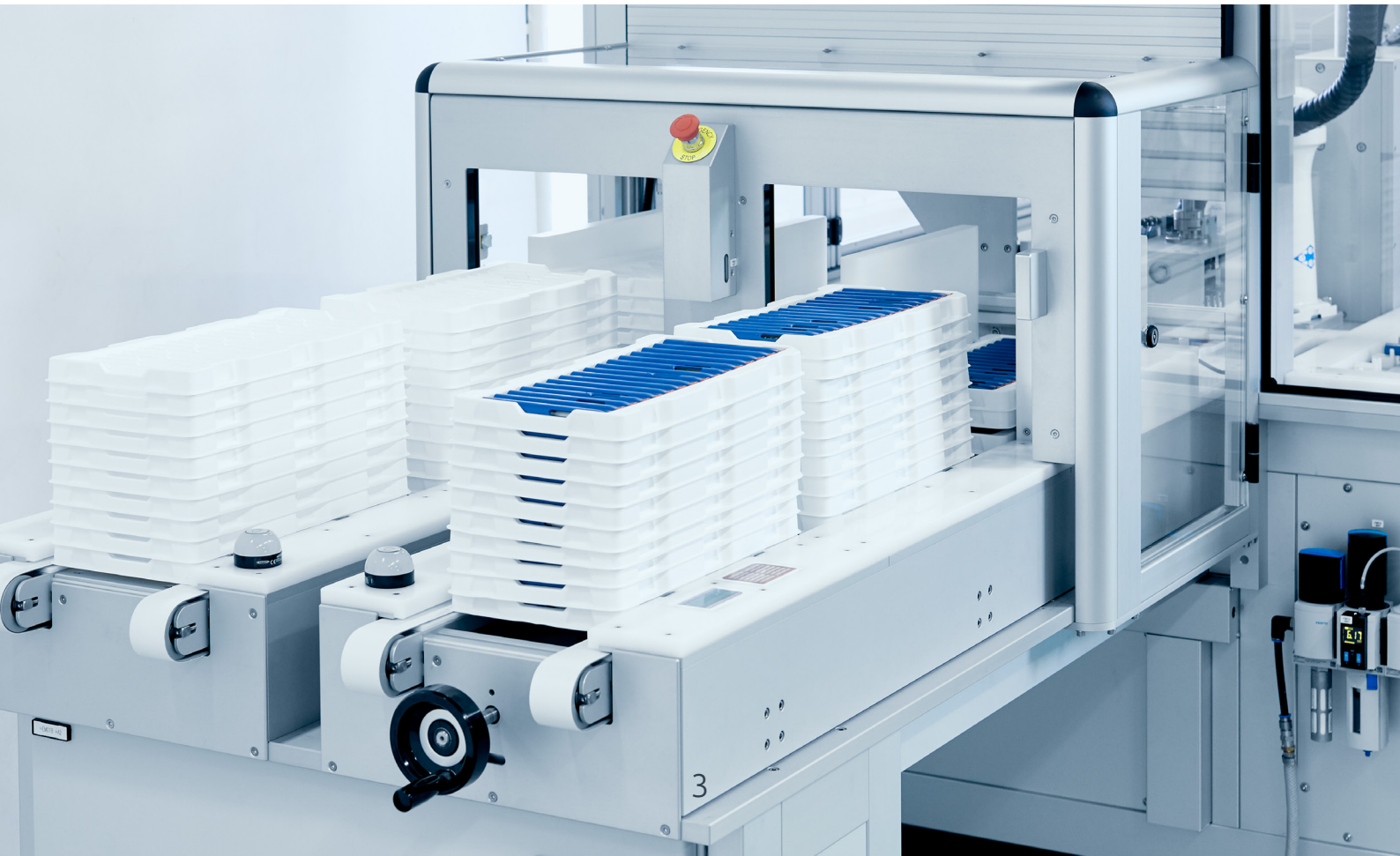
A recent pharmaceutical packaging market study by Freedonia Group, noted the increasing complexity and role of primary packaging as more sophisticated therapeutics penetrate the market.



Personally administered parenterals growing

According to Freedonia Group's market report '*Pharmaceutical Packaging - Demand and Sales Forecasts, Market Share, Market Size, Market Leaders*', parenteral containers (injectable, infusible liquid therapeutics) will post the fastest rate of growth among primary pharmaceutical packaging.[1]

Study data showed an expanding use of what they termed “high-value” containers, closures, and accessories, with the goal for drug developers to support drug delivery, supply chain security and to promote better medication adherence.

Demand for pharmaceutical packaging products in the US is forecast to grow 5.2% per year to $29.9 billion in 2024. Gains will result from:

- The expanding use of high-value containers, closures, and accessories that enhance drug delivery and security and promote better patient adherence with prescribed medication schedules
- The increasing importance of packaging as new sophisticated therapies penetrate the market

Freedonia Group

The analysts explained advances in parenteral therapies for cancer, diabetes, viral diseases, neurological disorders and similar conditions will support gains in the segment. Accordingly they note, the use of prefillable syringes, especially self-administering combinations like epipens are expected to grow the fastest. However vials will still continue to be parenteral drug’s dominant package form for the foreseeable future.

Clear labelling helps simplify drug delivery

Clearly labelled and marked primary drug packaging and devices help clinicians and patients accurately administer treatments and simplify delivery, especially for injectable and infusible therapeutics.

Many of these combination devices have limited label real estate and challenging surface characteristics and are tough to label. These circumstances explain why parenteral labelling in particular is growing more integral, complex and technically challenging.[2]

More individual product labelling requirements on the horizon

Freedonia notes trends favouring the use of smaller-sized medication containers and single unit-dosing will increase the overall number of labels pharmaceutical manufacturers will be processing for a given product. This number Freedonia noted, will also be magnified by the increases in the overall quantities of drugs produced as well.[3]

All of these development trends are pointing to one thing: higher numbers of more discrete product lines and more frequent but smaller batch sizes – all of which drive vial and parenteral drug labelling operation complexity. Regardless, there is a desire from contract packagers and pharma manufacturers to have more flexible lines.

Labelling key to patient centricity and better outcomes

Driving the development of all drug products is the concept of patient centricity. Essentially, that means providing people with affordable access to safer, more effective drugs that deliver better results more efficiently than alternatives like surgery or a hospital stay.

Requirements for labelling prescription drugs are extensive because regulators want to provide both the prescriber and user with the best information in support of administering the medication effectively.

Patients are increasingly administering their own parenteral treatments as well. To pharma and its regulators, that means clear markings, instructions and safety or administration guidance must appear on the label and be legible on the package at the point of care.

Labelling plays an even more critical role in dose compliance and is an inherently patient-centric strategy because it assures the precise prescription and dosing by physicians and accurate administration and delivery by clinicians and patients. Several studies have shown a clear correlation between dose compliance and improved health outcomes as well as lowering the overall cost of care for a given condition.

Patients who can't or won't take their medications, often get sicker, requiring expensive hospitalisations or surgeries.[4]

When patients take their medications as prescribed, they get better faster and at significantly lower cost to tax payers.

Security in the spotlight

Among other things, the COVID-19 pandemic has put the parenteral drug supply chain security in the spotlight, so expect greater attention to labelling and labelling operations in support of supply chain integrity and resiliency in this area by all players.

For example, every primary package (vial or combination device) and label now carries information that assures both source and quality to global regulators. Label technology is also offering other security functionality to help assure supply chain integrity, including heat sensitive and smart labels to thwart drug counterfeiting and diversion.

Pharmaceutical companies, noted Freedonia analyst Mike Richardson, will be increasing their purchase of label technologies featuring high visibility and tamper-evident features, because the perception of safety enhances the perception of product value.

"These value-added labels are finding increased use in the OTC drug segment, where greater competition is boosting demand for labels that enhance the perceived value of products."

Freedonia explained this trend will shift consumption towards label technologies with enhanced security features such as RFID tags, serialisation codes, holograms, color shifting inks, and other anti-piracy measures.

Industry 4.0 and data intensity

Serialising pharmaceutical packaging with an individual product identifier is now law in most established global pharma markets. This, and a number of 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.

In the face of Industry 4.0 and global serialisation compliance, companies are compelled to either develop and implement labelling operations that meet their products' packaging and labeling complexities or hire commercial partners who can. Either way, pharma and biotech manufacturers need access to sophisticated systems capable of integrating digital and information technologies currently disrupting pharma manufacturing and supporting data acquisition requirements.

Meeting requirements requires integration and expertise

Finding and integrating the capacity and capabilities to handle anticipated demand and meet emerging data requirements will likely be challenging manufacturers the most. Capable technologies are available but acquiring systems in high demand takes time, as buyers reserve their place in the production queue. Delivery time for new equipment and completing internal validation can impinge on timely access to processing and manufacturing systems.

Manufacturers are seeking faster more flexible machines with increased throughput and integrated quality assurance technologies. Because many of the new biologic drugs are parenteral, including pandemic fighting vaccines, they require processing in highly controlled cold environments (as low as -80°C in some cases). This is placing even more technical demands on labeling operations that require developed, integrated technologies to accomplish.

In the wake of the pandemic and as current trends gain momentum, specialised vial and device labeling equipment procurement will become imperative – all of which calls for defining the purchasing strategy.

When talking with suppliers, the dialogue needs to be open and forthcoming to determine optimal system specifications that create a comprehensive solution purchase and not just an equipment buy. Pharma's regulatory environment is one of the strictest there is and that increases the need to develop a robust procurement strategy.

Speed is key, accuracy and quality essential

Pharma and biotechnology developers are under pressure to respond faster to market demands. That means timing the delivery of needed capability is critical. Details of the machine, the number of systems purchased, and other variables also help set the timeline. As does the orderbook of your vendor. All of these variables can add weeks and months to delivery timing and can clash with business plans if not sorted beforehand.

Equipment purchasing strategy required

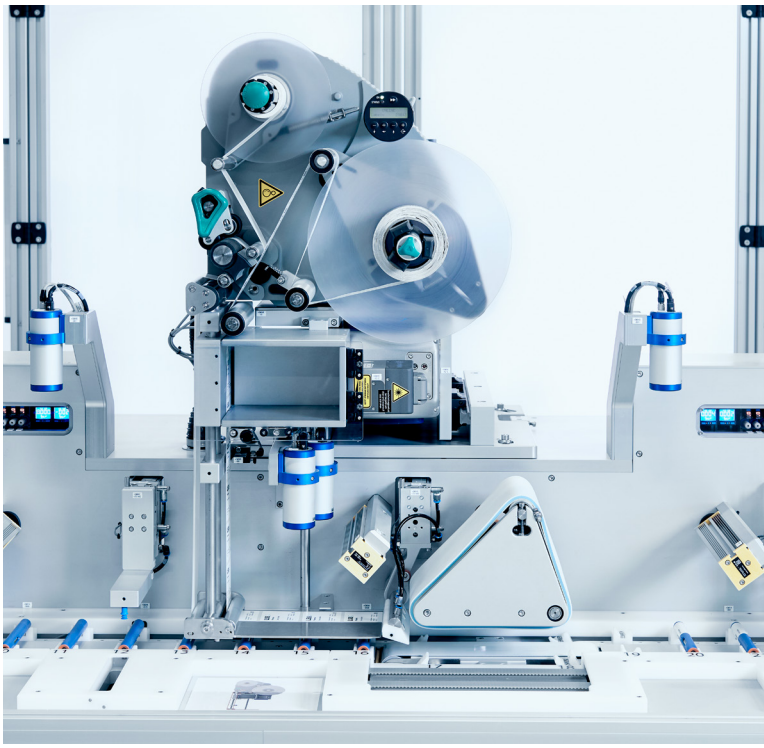
Purchasing capital equipment is a challenging process in its own right. It needs to be done with a straightforward, planned approach to ensure the investment is not wasted.

Aligning manufacturing business interests with experienced vendors who've already considered the above will yield the best machine for the investment and meet the projected demands of global markets and the needs of patients around the world.

Find expertly engineered solutions to unlock labelling complexity

If prospective vendors don't seem to understand the huge role they play in patient safety when developing labelling solutions for the pharmaceutical industry, move on and seek those that do. Finding a vendor that specialises in pharma-ready solutions for filling vials, ampoules, small bottles, syringes, auto injectors, combination devices and more will help unlock operational potential and tackle labelling complexity.

Find labelling experts with experience and know your particular labelling challenges best. They know the right questions to ask and how to leverage the system capabilities. Your labelling system partners should be well versed at delivering the integration needed to support sophisticated parenteral drug packaging operations and help make the right decisions at the right time about your future labelling project.



Click here to request a FREE consultation

Experienced equipment integrators can give you valuable insights and offer labelling solution innovations you should consider and anticipate challenges that need to be overcome before they can disrupt the project and critical timelines.

LSS Labelling Solutions delivers comprehensive labelling solutions, and with them all the documentation needed for a smooth, compliant validation and qualification process. We have the experience to know the right questions to ask and the expertise to engineer pharmaceutical-grade solutions that meet specific parenteral drug's labelling requirements, as well as all operational expectations – from its first commercial run to its last.

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**.

LSS Etikettering A/S, Normansvej 8, 8920 Randers NV, Denmark **T: +45 7020 2500**

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