

DESIGNING SUSTAINABLE DRUG DELIVERY DEVICE PACKAGING: TRENDS, CHALLENGES AND REGULATORY IMPLICATIONS

Angela Shotton and **Nic Hunt**, both of Nelipak Healthcare Packaging, look at the evolving landscape of the pharmaceutical packaging landscape and consider how the industry is meeting sustainability and regulatory requirements.

The pharmaceutical packaging landscape is changing quickly. With more drugs on the market, including a growing share of biologics and a shift towards home-based therapies, packaging demands are becoming increasingly complex. At the same time, sustainability and regulatory pressures are pushing the industry to rethink materials, formats and design approaches.

Today, packaging needs to do more than just protect a product in transit. It also has to work with automated systems, meet evolving regulatory requirements, reduce environmental impact and support patients managing their own care at home.

MARKET TRENDS DRIVING PACKAGING INNOVATION

The market for devices has grown significantly in recent years. Biologics now make up a larger proportion of prescriptions, and inhalers, autoinjectors, prefilled syringes and wearable devices are becoming more common across a variety of therapies.

This growth has increased the demand for durable transport trays, inserts and secondary packaging that can handle high-speed automation, protect sensitive components and support efficient handling in both clinical and home environments. CDMOs and pharmaceutical companies are exploring ways to optimise packaging for volume, automation and environmental performance. Initiatives such as the Pharmaceutical Supply Chain Initiative are also influencing packaging strategies, aligning pharmaceutical companies' supplier requirements to encourage a reduction in energy use and emissions.

Packaging suppliers are working closely with manufacturers to create thermoformed trays and packaging that meet these needs.

SUSTAINABILITY DRIVERS

Sustainability is no longer optional – it has become a key consideration in pharmaceutical packaging, with companies embedding packaging into their corporate decarbonisation and Scope 3 emissions strategies. Regulations such as the EU Packaging and Packaging Waste Regulation (PPWR) are reinforcing this, requiring that, by 2030, packaging not in direct contact with the pharmaceutical product contains defined quantities of post-consumer recycled (PCR) content.

Implementing sustainable packaging is a process. It starts with setting clear sustainability goals, developing design concepts and involving key stakeholders early. Rapid prototyping and proof-of-concept sampling can help to ensure that requirements are met before full production begins. Involving product stewardship helps to ensure that the benefits of sustainability are shared across the supply chain.

There are four key areas driving sustainable manufacturing in drug delivery device packaging:

1. **Material Circularity:** Choosing the right materials can make a big difference. Many companies are moving towards mono-material trays and inserts, which are easier to collect and recycle, and avoiding materials of concern. Third-party certifications can confirm recyclability readiness. Some suppliers

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are developing mono-material packaging solutions that offer sufficient strength and functionality while supporting circularity.

- 2. Recycled Content:** Compliance with PPWR requires non-contact packaging to include a minimum PCR content, with the amount varying depending on the type of materials. Manufacturers are currently reviewing material specifications to ensure reliable PCR availability and compatibility with required standards. Close collaboration across the supply chain is also key to ensuring stable supply of selected materials.
- 3. Size Optimisation:** Right-sizing trays and packs reduces material use, shipping volume, storage space and carbon footprint, while keeping contact materials unchanged. Digital simulation tools and pallet load studies can help to visualise and optimise tray density. This kind of dimensional optimisation can reduce waste by 10–15% in high-volume lines and improve distribution efficiency.
- 4. Design for Circularity:** Durable, reusable trays can replace single-use equivalents, lower carbon dioxide footprints and support circular approaches. Design considerations include durability, cleanability and traceability. Many CDMOs are exploring circular tray programmes, often in collaboration with packaging suppliers, to make sustainability practical and measurable.

DESIGN AND AUTOMATION CONSIDERATIONS

Automation plays a big role in modern packaging. High-speed assembly and filling lines all depend on trays and inserts that are dimensionally stable and compatible with robotic systems. Poorly designed trays can cause line stoppages, misalignment and extra labour.

Early collaboration between packaging engineers, automation specialists and device teams is essential. Modelling tray orientation, optimising pick points and testing prototypes can prevent costly delays. Digital simulations and pallet load studies can enable teams to understand automation efficiency and shipping density before production. It is important to use structured product requirement specification (PRS) processes to align device, automation and packaging requirements early in the design phase.

Fully integrated design services can align device protection, automation compatibility and user requirements within a single, structured process. Effective transit tray development often involves multiple stakeholders – from design authorities and consultants to pharmaceutical companies, device manufacturers and automation partners. Working with an established PRS framework can capture and reconcile all functional and technical needs before tray design begins. Designers translate the initial technical brief into detailed digital concepts that address critical considerations, such as device orientation, protection of sensitive features and handling requirements, including gripper access for automated systems. Sustainability should be embedded throughout the design lifecycle, with a team collaborating closely with stakeholders to support environmental objectives through options such as *in silico* design tools, tray take-back programmes, recycled content, recycle-ready materials and lifecycle analyses.

REGULATORY AND COMPLIANCE IMPLICATIONS

Regulations such as PPWR highlight the importance of integrating sustainability and material selection into packaging design from the start. Items that were once considered operational, such as transit trays and secondary packaging, are now classified as packaging and must meet compliance requirements. Companies need to consider material chemistries,

recycled content, supply chain resilience, sterilisation compatibility and validation requirements. Early engagement with suppliers and CDMOs is critical for regulatory and operational readiness.

HUMAN FACTORS AND PATIENT-CENTRED PACKAGING

As some therapies move from hospital to home, packaging must be intuitive, safe and easy to use. Considerations should include device removal, ergonomics for older patients or those with limited dexterity and compatibility with digital adherence tools. Packaging that is difficult to use can negatively affect adherence and therapeutic outcomes.

Many manufacturers are adopting intuitive tray designs and combination packs that guide patients through setup and administration. Packaging is increasingly a key part of the therapeutic experience. It is important that packaging suppliers work closely with manufacturers to integrate human factors into packaging early in the design process.

PRACTICAL STEPS FOR MANUFACTURERS

Pharmaceutical and device manufacturers can take several practical steps to prepare for sustainability and regulatory requirements. They can assess current packaging for material efficiency, size optimisation and recyclability. Opportunities to integrate mono-materials or PCR content should be explored. Collaborating with suppliers

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and CDMOs early can help to model tray performance, automation compatibility and lifecycle impacts. Rapid prototyping and digital simulation can validate design

choices before full production. Aligning packaging changes with sustainability goals and regulatory timelines can ensure smooth compliance.

These practices are already being adopted across the industry. Early collaboration between suppliers and CDMOs accelerates decision-making, reduces risk and supports sustainability goals.



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CONCLUSION

Sustainable packaging for devices has become a must, affecting regulatory compliance, environmental performance, manufacturing efficiency and the patient experience. By considering material circularity, recycled content, right-sizing, reusability, automation compatibility, human factors and product stewardship early in the design process, manufacturers can create packaging that meets both commercial and environmental goals.

Leading suppliers and CDMOs are adapting by exploring new materials, reusable formats and design practices in preparation and anticipation of upcoming regulations. Companies that engage early and work collaboratively will be in the best position to meet the sustainability and regulatory challenges of the next decade while delivering safe, effective and patient-friendly therapies.

ABOUT THE COMPANY

Nelipak is a global provider of healthcare packaging solutions, including rigid and flexible sterile-barrier packaging for medical device, diagnostic, pharmaceutical drug delivery and other demanding applications. To support the development of innovative sustainable packaging solutions, Nelipak offers in-house design, prototyping, tooling, simulation, validation, laboratory and other value-added services as well as a line of tray-sealing equipment.

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