



PACKAGING FOR INJECTABLE DRUG DELIVERY DEVICES

In this piece, Seán Egan, Group Marketing Manager, and Angela Shotton, Business Development Manager, both of Nelipak Healthcare Packaging, describe how Nelipak's transit tray solutions are comfortably keeping pace with current and future trends in the pharma and biopharma industry, from greater use of robots and pick-and-place, to transportation requirements and stresses, clean-room and sterilisation specifications right through to the emergence of smart packaging and connected delivery devices that can increase adherence.

The past few years has seen the growth of injectable drug delivery in the pharmaceutical market with biologics now representing five out of the top ten drugs globally. Currently biologics sales account for approximately 20% of market share with high-single-digit growth expected through 2020.¹

Growth in generics and biologics has resulted in the increased use of injectable drug device components including syringes, autoinjectors, insulin pens and wearable devices, with an estimated 30 billion units used annually.² This in turn has led to significant growth in the manufacturing of injection moulded drug delivery devices.

"Greater use of robots and pick-and-place systems in manufacturing has led to a need for dimensionally stable transit trays to meet the demands posed by process optimisation."

While some pharmaceutical companies develop devices in-house, there is a trend toward specialist third-party contract manufacturers to meet increasing volumes and speed to market. Greater use of robots and pick-and-place systems in manufacturing has led to a need for dimensionally stable

transit trays (Figure 1) to meet the demands posed by process optimisation. Empty trays that do not separate properly in the automation process and require manual intervention can result in extra costs, causing downtime and reduced run rates. Too much tolerance from tray to tray may lead to product misalignment causing potential product damage and disruption on the machine. As a result, there is greater risk involved if the tray is not properly designed due to a lack of understanding of the specific processes and how products interface with the equipment involved.

Additionally, components shipped between manufacturing locations for different assembly and fitting operations place transportation and storage demands on the part and the tray. Poor packaging density can reduce the autonomy of the machines, increasing both manual loading requirements and transportation and storage costs between the contract manufacturer and the filler. During transportation the tray must ensure those devices must be protected and remain correctly positioned in the tray. Functional features ensure product protection in transit. At the same time, trays are designed to nest inside each other reducing storage, space, labour and transport costs.

Nelipak Healthcare Packaging understands that it is crucial to develop the right transit tray solution that fits the device as well as the automation, transportation and user requirements identified in the overall



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Figure 1: Transit tray for automation line.

process. However, developing a solution often involves multiple parties – design authority, consultants, pharmaceutical company, device manufacturer and automation partners. In response, Nelipak has developed its Design Requirement Specification (DRS) process (Figure 2) to capture the requirements of the injection moulder, the automation provider, the packaging supplier and, if involved, the contract manufacturer, to specify the needs for both the process and the device before it is decided how the trays should be designed. This program draws on the company’s unique project management experience gained from working with pharmaceutical and medical device OEMs on packaging, transit trays and automation systems across Europe and the Americas.

Starting with the initial technical project brief, Nelipak designers deliver digital sketches (Figures 3 & 4) to clarify aspects that are critical for the packaging, such as device orientation in the tray, critical areas of the device which require extra protection, or how the device will be handled. If, for

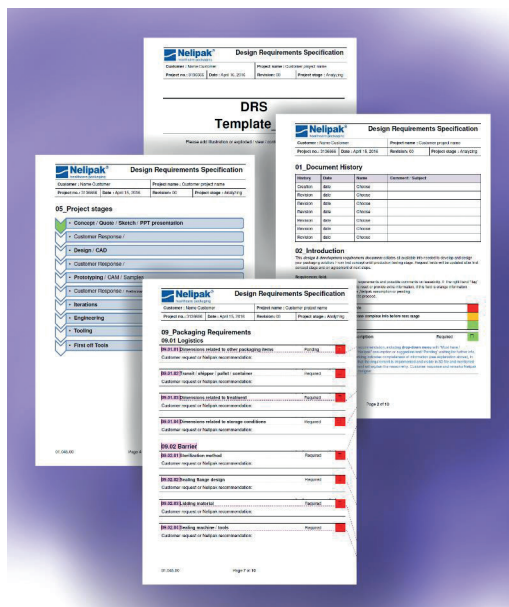


Figure 2: Nelipak design requirement specification.

example, the device will be picked up by grippers, the next question would be where and how much gripper access is required; this can result in an appropriate feature being built into the tray.

Agreement on design concept allows development of orientation and pallet load studies (Figure 5) to visualise quantities per tray, box and pallet to predict overall storage and shipping volumes. For example, a device placed upright in a tray may result in high density per tray during automation but a lower density per pallet in shipping. This analysis tool gives the wider project team the ability to review potential issues or concerns early on in the supply chain and make informed choices

Dedicated design and project management teams work closely with automation and filling companies to provide technical drawings, consultation on material specifications, tray tolerances and deliver prototype samples to support machine development, trials and ultimately supply. Through this process, Nelipak has developed an understanding of what works on their equipment to deliver greater autonomy and shorter lead times and, as a result, has become the solution partner of choice for many leading automation companies to deliver successful transit tray projects on time.

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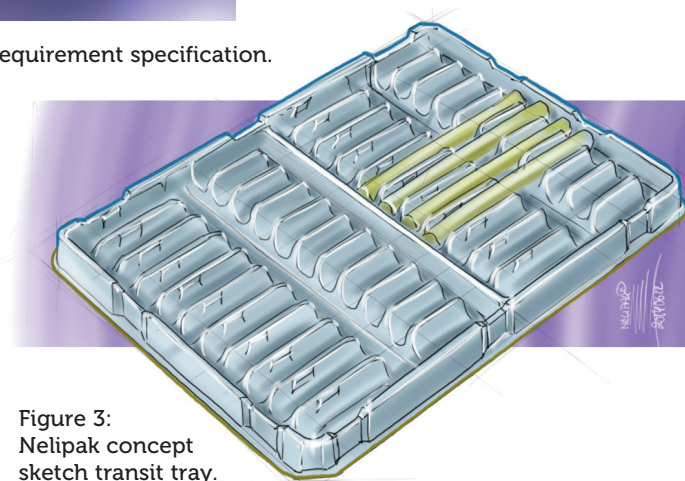


Figure 3: Nelipak concept sketch transit tray.

With the growth of the injectables market, a critical factor in the supply chain is the capacity to deliver an uninterrupted supply of components. Pharmaceutical companies build contingency into their processes to ensure they can continue to deliver product to market should one location go off-line and they expect the same back-up and support from their key suppliers. Nelipak is one of the few thermoform packaging providers that has both the capacity and footprint to support global pharmaceutical manufacturing. Five facilities in the Americas and Europe provide design, development and manufacturing in a variety of materials.

FROM PRODUCTION TO PATIENT

Biologics, for instance, not only continue to disrupt the traditional drug market through platforms with better efficacy, but also with more effective delivery through new devices, enabling patients to manage their own treatment regimes. In

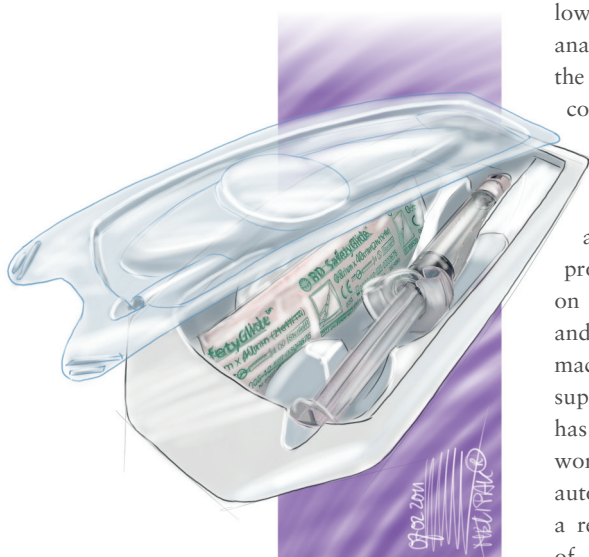


Figure 4: Nelipak concept sketch of a patient pack with syringe.

turn, this has allowed healthcare providers to move treatment from clinical settings to the home environment in order to reduce in-patient costs on hospital systems. While this move is welcomed by both clinicians and patients alike, it can provide

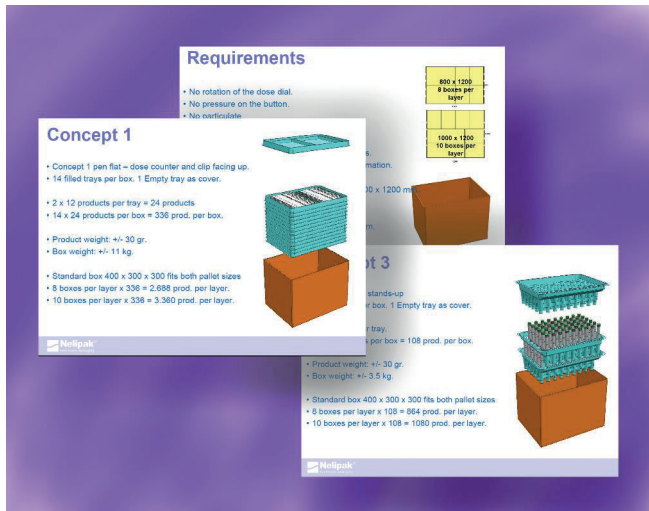


Figure 5: Nelipak part orientation packaging study.

a new set of challenges for pharmaceutical companies such as patient adherence / compliance. Medication non-adherence drives unnecessary medical spending when chronic conditions spiral out of control. The US healthcare system spends an estimated \$290 billion (£199 billion) annually on “otherwise avoidable medical spending” related to non-adherence.³

Pharmaceutical companies are looking to address this through development of smart devices that can instruct proper use, report patient uptake, prompt reminders and monitor the patient’s condition. Device developers also focus on human factors engineering in the development of devices to insure ease of handling and intuitive use by the patient – consider the elderly patient using an auto injector to treat their arthritic condition. This approach is more frequently being extended to final packaging. If the device is difficult to remove from the packaging it may affect the patient’s ability to use the device and possibly their perception or acceptance of it.

Once the device has been filled, assembled and labelled, shipping packaging is required. This may simply consist of a shipper carton, clamshell, blister, thermoformed tray insert, pouch or a combination of any of the aforementioned. While some devices are hand-filled into packs, volumes generally dictate semi-automated or fully-automated processes in conjunction with automatic cartoning / IFU lines. As with transit tray

automation, tolerances are critical for the smooth operation of high volume lines. In this instance, Nelipak employs the same DRS process in the development of thermoformed tray inserts used for transit trays to deliver solutions that work.

Material choice for packaging will depend on a number of factors such as barrier requirements, protection during transportation, storage requirements and how the packaging is to be accessed to use the device inside. For thermoformed tray inserts a variety of materials such as APET, PETG, High Impact Styrene (HIPS), Aclar® (Honeywell) and Eastalite™ (Eastman) are available for use. While most shipping packaging

is considered secondary and therefore not required to be sterilised, these materials are cleanroom-compatible making them ideal for aseptic sealed packaging for drug products used within sterile clinical fields. When matched with Nelipak’s automated tray heat sealers and lidding solutions, pharmaceutical companies have an end-to-end recyclable solution custom designed by a global provider around their delivery device needs and manufactured to ISO standards.

turn, apply this knowledge to optimised packaging solutions. These can include intuitive packaging, which guides the user through the set up process, combination packs with all components required for administration or senior- friendly access.

PACKAGING DEVELOPMENTS

As patients live with their medical conditions and self-administer medications, they demand more from their devices in keeping with their lifestyle. Increasingly, patients are also expecting more from the packaging their device comes in.

Packaging is evolving to meet the next generation challenges of drug delivery devices and user needs. From simply transporting and protecting to point of use, to being part of the procedure or home therapy, packaging continues to be an integral part of the solutions to address adherence and compliance issues.

Smart pill packs already monitor usage while packaging combined with new technology platforms inform patients when their next dosage is due and are capable of sending out reminders to the patient and/or caregivers if need be. Drugs sensitive to temperature and humidity can be monitored by smart sensors built into the packaging with data tracking. This intelligent packaging, such as SensePak, being developed by Nelipak and SHL Group (Figure 6), can also report on how the packaging and device were handled in

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Nelipak has a track record in designing medical device packaging that protects product up to the point of use, is ergonomic and intuitive, and can be part of the procedure delivering benefits to the surgical team. This experience has been supplemented through studies carried out with healthcare professionals to understand their requirements and challenges. Building on its heritage of developing award-winning packaging for medical device OEMs, Nelipak is working with pharmaceutical industry partners to learn more about the diversity of the end user, the environment the packaging is used in and then, in

transport, and when it was activated.

While many autoinjectors discreetly fit in a jacket pocket or purse, devices with refill vials / ampoules require a number of components to be carried about. Packaging manufacturers need to take a variety of challenges in to account and develop solutions to meet these needs in order to deliver an overall better customer experience. For pharmaceutical companies, this also presents opportunities to use packaging that differentiates themselves to gain market share and build brand loyalty.

In the future, drug/device combinations may present new challenges in terms of



Figure 6: SensePak smart packaging under development with SHL Group. (Image courtesy SHL Group)

packaging such as material selection for drugs requiring additional barrier properties in order to maintain a controlled atmosphere within the package.

For instance, in oncology procedures patients undergoing surgery may receive drug therapy while in theatre. While the primary container – the syringe with the drug – is considered a sterile unit internally, the outer portion of the device is not. In this situation the drug delivery device needs to be packed in a secondary package which can be sealed and sterilised, maintaining a sterile device to the point of use when it is presented to the surgeon in the sterile surgical field. This places greater emphasis on the need for certified cleanroom-manufactured trays and lidding material used to seal the primary device. Nelipak meets this need through cleanroom-produced thermoformed packaging operating to ISO standards. In addition, the company has developed and supplies cleanroom-compatible heat tray sealers with the ability to log critical parameters during operation.

With the development of newer and smarter drug delivery devices, packaging manufacturers will face many challenges to reduce costs, improve compliance, provide tamper evidence, educate users and be sustainable. Nelipak, a leading provider of medical device and pharmaceutical packaging solutions, brings a deep technical understanding of supply chain requirements, particularly in regard to high speed automation for manufacturing and pack out operations for transit tray and patient packaging solutions to address these market needs.

PACKAGING DEVELOPMENTS

1. “The Global Use of Medicines: Outlook through 2017”. Report by IMS Institute for Healthcare Informatics.
2. IMS and Tech Group Estimates from “Building for the Future”. West Pharmaceutical Services Investor Day, March 10, 2016
3. “Estimated Annual Pharmaceutical Revenue Loss Due to Medication Non-Adherence.” Capgemini Consulting and HealthPrize Report, 2012.

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