

SHL GROUP

FINAL ASSEMBLY, LABELLING & PACKAGING: AN INTEGRATED SOLUTION FOR A FRUSTRATION FREE LAST MILE

For the development of combination products, pharma and biotech companies have the option to establish an assembly and packaging infrastructure internally or to outsource to a contract manufacturing organisation. In this article, one such organisation, SHL, explains what the benefits are of using a manufacturing partner and outlines what it can offer in terms of an integrated process.

For a pharma or biotech company working with a drug delivery device partner, the decision on final assembly, labelling and packaging is most often the final checkpoint in the development process for a combination product (Figure 1).

Well in advance of this checkpoint, the pharma/biotech company must make an informed decision regarding the device's final assembly: to either establish assembly and packaging infrastructure internally or partner with a contract manufacturing organisation (CMO).

Building internal infrastructure is a decision that is likely to involve input from a large cross-functional team across an organisation, with considerations such as:

- What is the overall cost of such internal infrastructure (e.g. capital expense, staffing requirements)?
- How does building this internal infrastructure align with the long-term commercial strategy of the company and the product?
- How long will this high quality and regulatory compliant infrastructure take to implement?
- What is the risk mitigation strategy if things do not go as planned?
- Are semi-automated equipment and processes acceptable or are more complex automated solutions required based on the forecasted demand?

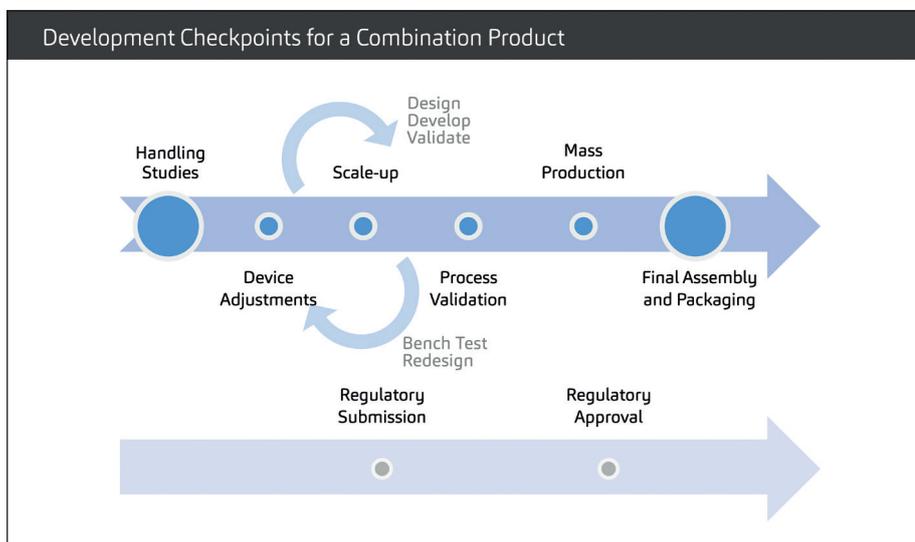


Figure 1: An overview of the stages of device development.

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Figure 2: SHL offers a range of drug delivery systems, giving customers the flexibility to accommodate changing market trends.

Lastly, it is important to consider whether the infrastructure can be leveraged across multiple products, keeping in mind that many devices differ in shape, size and industrial design. The company's infrastructure for final assembly should be future-proof: scalable to accommodate multiple products as well as changes to device volume over time – in both the best and worst case scenarios.

OUTSOURCING ASSEMBLY, LABELLING AND PACKAGING

After years of working with clients and understanding their needs, SHL Group has developed a simple solution that eliminates the frustrations commonly encountered in the final mile of the development process. SHL, a leader in device design and manufacturing, has heavily invested in recent years in establishing a contract manufacturing service offering final assembly, labelling and packaging for SHL-designed devices (Figure 2). With the addition of this business unit, SHL is able to offer a full turnkey solution that starts from device development and continues through to the commercial launch

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of a finished product, decreasing timelines to the clinic and/or commercial market for patients in need. Using our mature device platforms and infrastructure, SHL's quick-to-clinic or quick-to-market development process can take a partner from device development to clinic/commercial supply in under 15 months.

CONTRACT MANUFACTURING FACILITY

SHL's contract manufacturing facility for final assembly, labelling and packaging is based in Deerfield Beach, FL, US. This 45,000 square-foot (4,200 m²), regulatory-approved facility houses specialised equipment and processes to support both low- and high-volume production requirements. Most of its device assembly and test equipment was designed and built by SHL's in-house automation team, resulting in total integration between the device and equipment developers. Additionally, SHL has invested in universal equipment designed to be flexible, providing a wide range of capabilities that include:

- final assembly
- bulk packing
- labelling
- packaging/kitting
- serialisation.

The required specialist skills are immediately available on-site to manage, drive and complete the project in scope. SHL's engineers are hand-picked from the pharma, biotech and medical device industries, offering a unique understanding

of clients' needs. Located near multiple international airports, the world-class facility has an optimised materials flow process. Starting with the receipt of inbound goods to storage in refrigerated/ambient warehouses, the process also includes final assembly, labelling and packaging, and concludes with shipping of the finished product to our partners or a preferred distribution centre.

FROM DESIGN TO FINAL ASSEMBLY

Once a client has contracted us to design, develop and assemble its autoinjector, our final assembly team integrates with the device's project team to ensure knowledge transfer from development into commercialisation – building specific assembly equipment and processes needed per the device's characteristics. SHL's product engineers and programme managers are dedicated to creating a true supply chain alliance, providing design and tech transfer services to create a seamless commercialisation programme, while regulatory experts prepare a technical dossier that provides supporting documentation for our partners' filings. Our quality management system was specifically developed with SHL's processes, resources and needs in mind to make sure they satisfy all necessary regulatory requirements.

SHL is able to reduce lead time for equipment design and procurement by developing the client's device and the required assembly equipment in parallel. This means that in the initial stage of the device's development, SHL's in-house

design engineers are engaged with the equipment engineers to provide guidance on assembly and testing, ensuring that the final assembly process effectively aligns with the device; initiating these work streams in parallel inherently reduces lead times (Figure 3).

PROCESS DEVELOPMENT SERVICES

In addition to assembly, labelling and packaging services, SHL also offers a suite of process development services, consisting of manufacturing sciences, analytical sciences, statistics and project management.

- Manufacturing sciences are responsible for equipment commissioning and manufacturing process design. This group will partner with SHL's engineering team, automation team and the client to design an optimal and compliant manufacturing process and control strategy.
- Analytical sciences are responsible for design, development, validation and transfer of test equipment and test methods. This group is also responsible for managing a number of development studies, including syringe characterisation, feasibility testing, transportation studies and ageing studies, eliminating the need for clients to manage multiple suppliers.
- Statistical services assures optimal control strategy with high statistical confidence, eliminating waste.
- Project management provides the design and tech transfer plan, establishes and tracks completion of milestones and directly partners with clients during this process.

Given the complex regulatory requirements for stability testing of combination products, SHL conducts full stability programmes at its Deerfield Beach site for its clients. This includes creation of the compliant clinical and follow-on stability protocols, creation of stability stocks and functional testing of the devices at each stability time point. At completion of the study, a report with stability trending per FDA guidance is delivered to the client.

As the developer of the device, SHL is in the unique position to provide insight that cannot be done by outside sources. SHL performs rigorous internal analysis to determine the tests that should be performed for each process, writes the

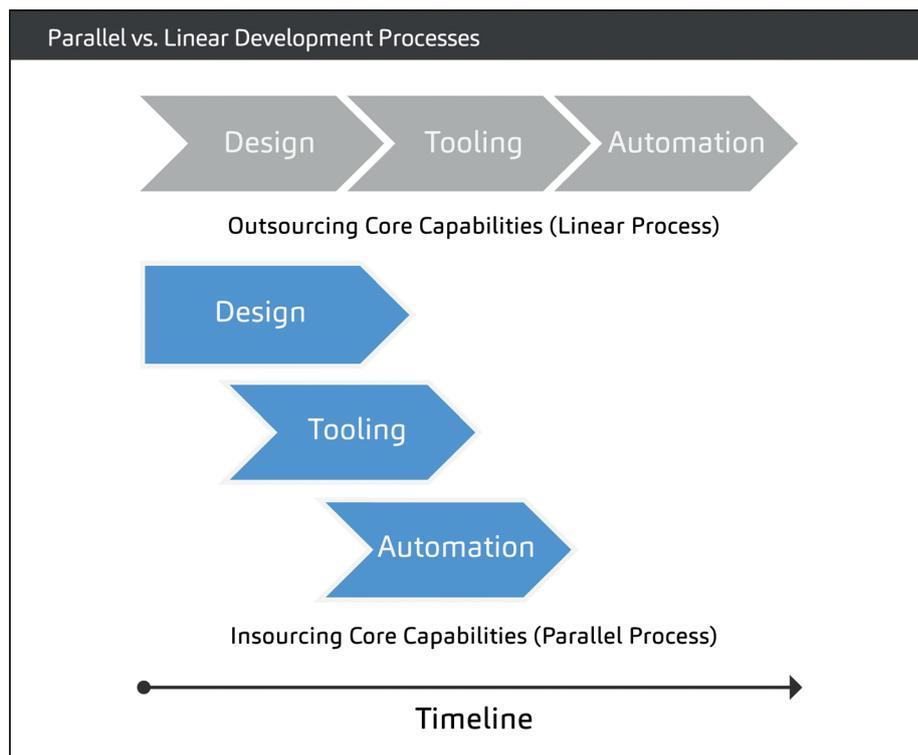


Figure 3: Running processes in parallel saves time and mitigates risk for clients.

test methods, instructions, plans, protocols and reports in-house and performs test method validation prior to design verification. This provides time savings to clients and simplifies development by keeping all operations under one roof.

SUMMARY

SHL's contract manufacturing service provides a full turnkey solution from device design to final assembly, labelling and packaging, reducing time to clinic/market and, most importantly, to those patients in need. Choosing SHL as a CMO partner provides a number of benefits, including:

- World-class assembly, labelling and packaging operations
- Programme/project management expertise with a proven tech transfer process
- Regulatory submission support
- Extensive combination product testing
- Combination product stability programmes
- Faster time to clinic, market and patients.

SHL Group's contract manufacturing services streamline our partners' operations, accelerating the commercialisation of critical medicinal products.

ABOUT THE COMPANY

SHL is a world-leading solution provider in the design, development and manufacturing of advanced drug delivery devices such as autoinjectors and pen injectors. With locations in Taiwan, Sweden and the US, experienced engineers and designers develop product enhancements and breakthrough drug delivery solutions for pharma and biotech clients globally. Significant investment in R&D has enhanced our broad pipeline of next-generation drug delivery systems. These innovative devices include a range of disposable and reusable injectors with fixed or variable dosing and the ability to accommodate high viscosities. With over 3,700 staff worldwide, the organisation consists of three distinct group companies:

- SHL Medical designs, develops and manufactures advanced drug delivery devices, as well as provides final assembly, labelling and packaging services for leading pharmaceutical and biotech companies across the globe.
- SHL Healthcare develops and manufactures equipment solutions for home, hospital and long term care use.
- SHL Technologies provides contract manufacturing and engineering services for the production of complex medtech and industrial products.



Precision Engineering Perfectly Delivered

Learn more about our world-class
final assembly, labeling and packaging services

Booth 2525 at BIO International Convention 2018



Solutions for Today on the Path to Tomorrow