



H&T PRESSPART

Impacting Tomorrow. Together.

# Multi-Component Drug Delivery Devices



At H&T Presspart we are committed to long-term partnerships with both our customers and suppliers. We have been supporting the growth of global pharmaceutical companies across different markets for 50 years. We partner with our customers to provide dedicated single-source supply and contingency concepts.

We deliver long-term value through continuous improvement and nurture partnerships through dedicated customer care.

# Working Together

## 1.4bn

MDI cans, actuators, assembled devices and plastic components produced

## 60+

Injection molding machines with up to 64 cavities and 25+ automatic assembly lines

## 50+

Years experience in manufacturing components and devices for the healthcare market

## 750+

Employees across our 4 sites and global functions

## 7200

Sqm of ISO 7, ISO 8 and ISO 8 equivalent cleanroom space





We are a world leader and specialist in manufacturing drug delivery devices and pharmaceutical components. Our extensive skills and experience cover drug delivery device development and Industrialization. With 50 years' experience in partnering with the world's leading pharma companies, we have developed a strong reputation for precision and reliability – critically important when patients' quality of life depends on our products.

### Bringing your product to market

As a partner at every step of the development process, we tailor our services to meet your individual requirements of each project.

From idea generation stage to product design and manufacturing process definition through to validation we take your drug delivery device ideas or concepts to commercial supply.

From low volume manual or semi-automatic solutions for concept devices or clinical batches through to automated commercial production, we can support you.

Working with clearly defined development, risk management and regulatory processes our close knit teams ensure a seamless transition from design to manufacturing.



Discover how we can bring your product to market

[www.presspart.com](http://www.presspart.com)

# Services and Capabilities

Whether you are looking for standard inhalation components or a bespoke device, H&T Presspart offers a wide range of services to support your developments. From the idea generation stage to product design and manufacturing process definition onward to validation, we take your drug delivery device ideas or concepts to commercial reality and supply.



## Concept and Feasibility

Realising user-friendly and sustainable drug delivery devices and solutions from your ideas and concepts

Optimisation of your design assuring the functionality and manufacturability of the device

Simulations on computerised fluid dynamics (CFD) or Finite Element Method (FEM) analyses on mechanical stresses

Support in the material selection, assessing the product requirements and their processability

Moldflow simulations to eliminate material accumulations and determine best tool layout

## Small Series & Pilot Phase

Validated small batch production cell is set up

Development of low cavitation tooling, semi-automatic assembly concepts and metrology plans

Small scale manufacturing of low volume samples for clinical trials and low volume production units

## Prototyping & Testing

Samples throughout all project phases deliver valuable information for concept evaluation

Samples are manufactured in original materials by representative production processes

Tests to ensure desired functionality of the product for data-driven design freeze

Design Verification Testing to demonstrate compliance with the Design Input Requirements and applicable regulatory standards

## Industrialization

Development of high-cavitation injection mold tooling and automation concepts for serial production

Value Stream Designs to ensure the most lean and efficient processes

Our teams set up the final supply chain and develop business continuity plans before manufacturing begins

## Design for Manufacturing

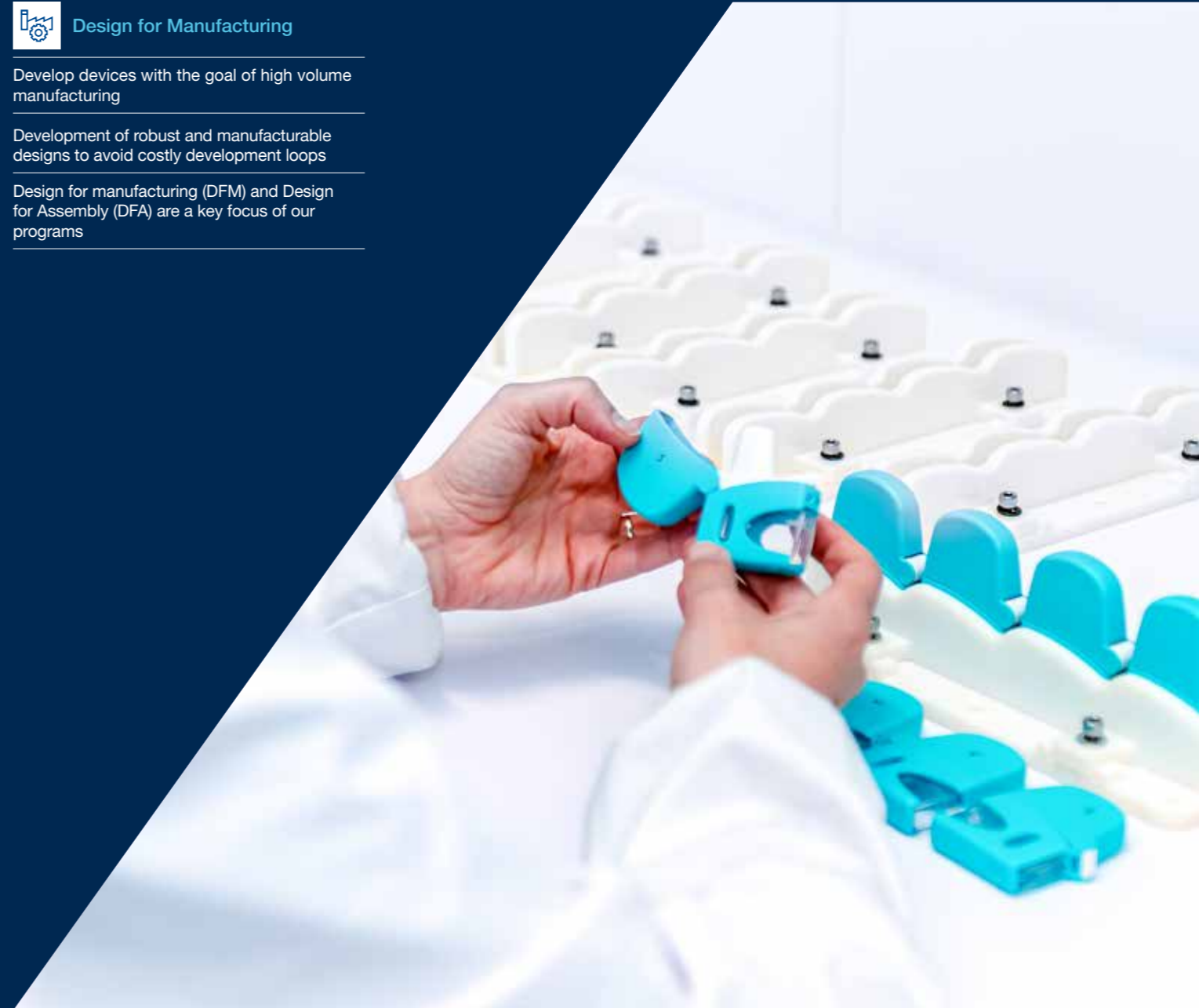
Develop devices with the goal of high volume manufacturing

Development of robust and manufacturable designs to avoid costly development loops

Design for manufacturing (DFM) and Design for Assembly (DFA) are a key focus of our programs

# 30+

Engineers and scientists to support device developments



# Services and Capabilities



## Analytical Services

Support our development services with end-to-end analytical services to optimise in-vitro performance of MDIs and DPIS

Our team has many years of experience of bringing highly complex inhalers to market

We can help accelerate customer product programs and minimise development cycles

## Program Management

Dedicated project managers to support our customers and ensure we achieve the best result together

We manage every aspect of our projects according to our stage gate process

Develop risk management plans and perform design reviews

## Smart Solutions

Development of integrated connected technologies to track adherence to therapies and correct use of the device in clinical or commercial setting

## Regulatory Support

Full regulatory service for dossiers in all major global markets

Drug Master Files (DMFs) for our standard product portfolio

# Technologies

**Cutting edge devices require cutting edge technologies. Our state-of-the-art manufacturing technologies ensure that we are able to manufacture some of the most innovative & reliable drug delivery devices on the market.**

Whether it is manufacturing low volume requirements for concept devices or clinical batches through to large volume Industrialization, we can support you with a wide range of innovative and flexible manufacturing technologies to meet your needs



## Injection Molding

H&T Presspart offers customers high precision injection moulding for drug delivery devices, sub-assemblies and components. We use high-cavitation tooling on state-of-the-art hydraulic and electric injection moulding machines to achieve highest precision on low weight components.

Our teams support during development and Industrialization to ensure robust manufacturing processes for efficiency, repeatability and quality.

## Multi-Component Assembly

Using robotic part handling and high-speed fully automated assembly, we manufacture multi-component drug delivery devices in ISO 7 and ISO 8 clean rooms. Our automated assembly systems are designed to meet all international manufacturing and regulatory standards and ensure precise, consistent, and repeatable processes.

As part of the development and validation processes our teams support customers to find the most suitable assembly solutions for their products from pilot to serial manufacturing and from standard solutions to highly customised processes.

## Tool Design

H&T Presspart has dedicated in-house precision tool design and manufacturing to ensure the highest standards of deep drawn components. Our experienced engineers and tool makers and state-of-the-art technology and equipment allow us to produce and maintain precision tooling that is cost-effective is optimised to the requirements of each individual component.



# Technologies



## Deep Drawing

H&T Presspart is a specialist in deep drawing precision metal components for the pharmaceutical industry. Whether it is one of the 650 million MDI cans we manufacture each year, or a customised component for a medical device, we partner with our customers to meet their needs.

With an emphasis on impeccable quality, reliability, flexibility and fast turnaround, we've become the world's leading manufacturer of deep-drawn pharmaceutical components.



## Surface Treatments

H&T Presspart offers a variety of innovative surface treatments to optimise the performance of drug delivery devices. Our Plasma treatment technology is fully industrialised and provides a unique solution to prevent drug degradation and drug adhesion in aluminium MDI cans.

The Plasma technology has the potential to be used on other metal and plastic components to modify a surface's adhesive or hydrophobic properties. Contact us to discuss your needs in surface treatment.



## Quality and Regulatory

Our manufacturing sites comply with all necessary international quality and regulatory requirements. We are ISO 9001, ISO 15378, ISO 13485, ISO 14001 certified and follow EU/FDA Good Manufacturing Practices (cGMP) ensuring the highest standards across the business.

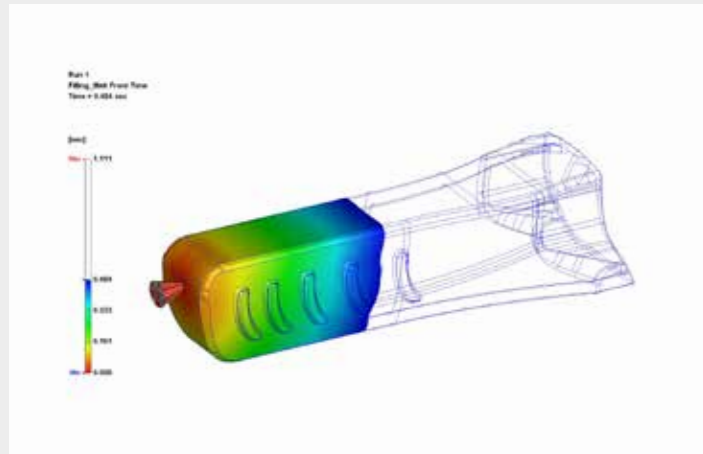
Our in-house metrology laboratories are equipped with high-performance measurement machines to carry out detailed inspection of components with repeatable processes.

Product and process developments and validations, production and maintenance processes are all carried out according to applicable quality and regulatory standards. Lean and Excellence programs and methods are embedded in our culture and drive continuous improvement across the business.

# Success Stories

Since the launch of our inhalation component portfolio more than 30 years ago, our long-term partnerships with customers and industry players have resulted in a number of successful drug delivery devices being approved and launched in the global market. We have shaped the drug delivery device industry and led the way to improve patient outcomes in inhalation, injectable drug delivery and diagnostics. We are proud to share a selection of our successes.

Parenteral Device Development



Reconstitution Device Development



Automation for Diagnostics



Sunriser High Performance DPI Technology



In-vitro Equivalent Generics



In-Vitro Diagnostics



Dispensing Actuators for CBD



Discover more about our success stories on the website





# Let's work together

## Manufacturing

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