

Extrusion  
Molding  
Assembly



**RAUMEDIC®**  
— Lifeline to Health —

## Pharma Solutions

High quality polymer  
products customized and  
developed for healthy  
generations

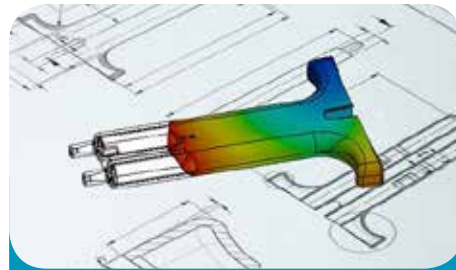


RAUMEDIC provides complete service under one roof.  
We develop your ideas into high quality products.

- Injection systems
- Drug delivery systems
- Inhalation systems
- Primary and secondary polymer packaging
- Assemblies and devices



Research and development are very important to us. In cooperation with universities and independent institutes, we create the basis for innovative product solutions.



Our experienced designers are eager to meet your challenges.

From initial concept to serial production supervision, a team of specialized engineers and technicians is at your side. Our application engineers will create a product concept for you that meets the toughest requirements in terms of function, quality, cost-effectiveness, and environmental safety.



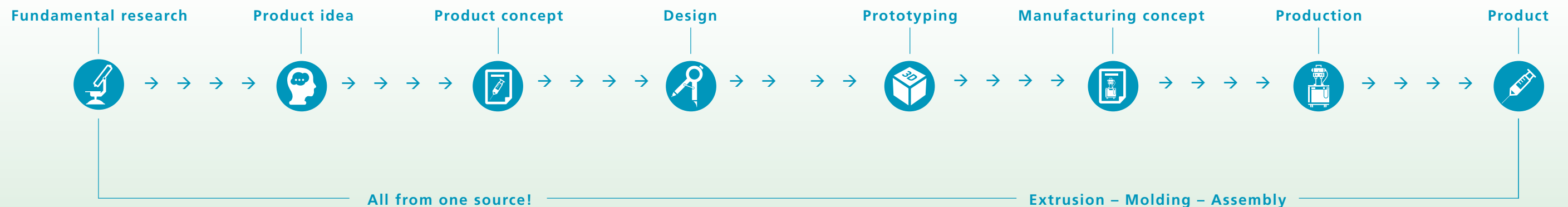
An efficient prototype construction saves time and money. With prototyping, you can have samples made quickly and economically.



Very small dimensions and tight tolerances can be implemented using the wide variety of our existing technological potential in extrusion, injection molding and assembly.



The requirements defined in the product concept determine a sophisticated production concept. Manufacturing under clean room conditions (ISO 14644, Class 7) is just as important as the criteria of cost-effectiveness, environmental soundness, quality conceptualization, and resource efficiency.



# RAUMEDIC Material expertise

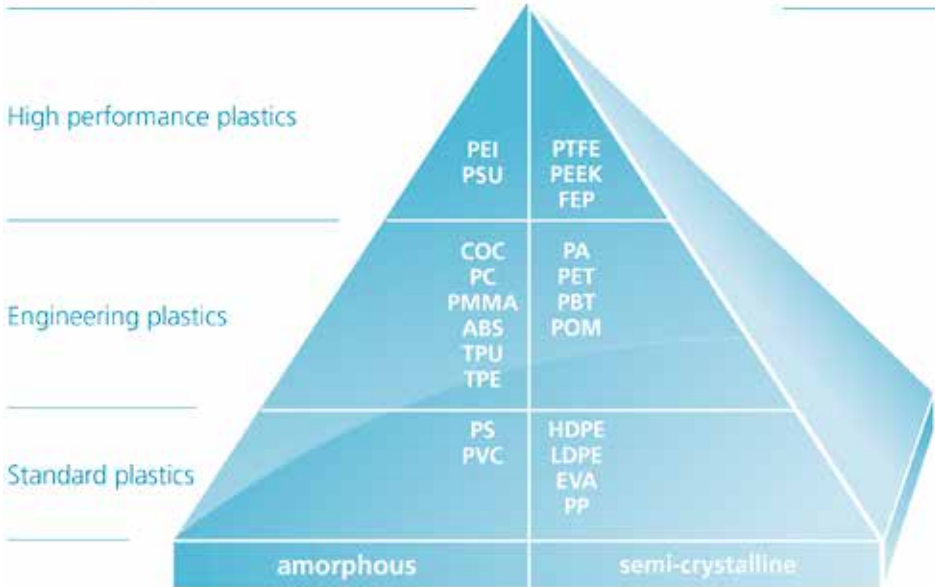
RAUMEDIC processes all types of thermoplastic polymers, through to high temperature thermoplastics, as well as silicone in extrusion, injection molding and assembly.

RAUMEDIC materials and products are approved and qualified to meet market and customer requirements, including:

- DIN EN ISO 10993
- European pharmacopeia
- US pharmacopeia
- Japanese Pharmacopeia
- FDA 21 CFR

Wide range of materials and formulations in the area of RAUMEDIC Pharma Solutions

## Thermoplastics



## Silicones



# RAUMEDIC Quality management



## Safety and quality at the highest level

RAUMEDIC focuses on customer satisfaction and compliance with all relevant legal and regulatory requirements by establishing a comprehensive quality management system:



- Certified quality management system ISO 13485
- Quality system according to 21 CFR Part 820
- Clean room manufacturing conforming ISO 14644, class 7 (=10,000)
- ISO 15378 certification for primary packaging materials (plant Helmbrechts)



# Qualification of Injection Molding Tools

The qualification process checks tools for their compliance with the specified requirements.



## Scope of Qualification

The qualification scope requested varies from customer to customer. In order to satisfy the different customer requirements, RAUMEDIC has established three different qualification levels.

The qualification proves and documents that a tool or an installation (for example an injection molding machine) is reproducible and fulfils the previously specified requirements under real-life conditions and that it is suitable for this task. ISO Standard 13485 will apply.

Design Qualification (DQ)	Definition of tool design and construction in accordance with specifications	"3" – Basic	"2" – Standard	"1" – Premium
	Review of user requirement specification for feasibility	●	●	●
	Creation of functional requirement specification	●	●	●
	Product design (drawing)	●	●	●
	Manufacturing concept	○	○	●
	Risk assessment (standard process FMEA)	○	○	○
	Risk assessment (project-specific process FMEA)			●
	Product risk analysis support		●	●
	Standard RAUMEDIC qualification plan		○	
	Project-specific qualification plan			○
	Tool specification	○	○	○
	Tool design	○	○	○
	Acceptance of tools based on tool specification	○	○	○
	DQ report			○
Installation Qualification (IQ)	Definition of process parameters for manufacturing of drawing-compliant components	"3" – Basic	"2" – Standard	"1" – Premium
	Quality planning (working and test specification)	○	○	○
	Measuring equipment analysis incl. verification of measuring equipment capability	○	○	●
	Tool optimization	○	○	○
	Definition of critical cavity (3 shots)			●
	Definition of critical process parameters	○	○	○
	Window study for a maximum of 3 process parameters (relating to critical feature)			○
	Definition of process window	○	○	
	Definition of process window according to window study			○
	Initial sample test report (Type 2 and 3 see IQ)			●
	Final product specification (TDS = Technical Delivery Specification)	●	●	●
	IQ report			○
Operational Qualification (OQ)	Proof of short-term capability	"3" – Basic	"2" – Standard	"1" – Premium
	Preliminary process transfer	○	○	○
	Customer release for serial production	●	●	●
	Initial sample test report (Type 1 see IQ)	●	●	
	Qualification feature: Shot weight + 1 test dimension (relating to critical feature)		●	
	Qualification feature: Shot weight + maximum of 3 test dimensions (relating to critical feature)			●
	Short-term capability (based on ≥ 50 parts)		●	●
	Evaluation of critical process parameters			○
Process Qualification (PQ)	OQ report			○
	Proof of process capability (specification-compliant components from first production)	"3" – Basic	"2" – Standard	"1" – Premium
	Final process transfer	○	○	○
	Start of GMP production	○	○	○
	Process monitoring according to quality plan (working and test specification)	○	○	○
	Qualification feature: Shot weight + maximum of 3 test dimensions (relating to critical feature)			●
	Evaluation of critical process parameters			○
	Long-term capability (3 production batches)			●
	PQ report			○
	Final report			○

● Customer document      ○ Internal RAUMEDIC document

## RAUMEDIC Injection systems

In collaboration with you RAUMEDIC will develop intelligent injection systems according to your requirements, for a safe handling of medication.



### Injection systems – customized syringe systems

- Fully-automated cannula processing
- Siliconization
- Direct overmolding or glueing of needles for a secure connection
- High process reliability and 100% in-process inspection for quality and cost-effectiveness
- Glass substitute (e.g. made of COC, COP)
- Specific packaging for injection systems (e.g. Tub/Nest, Trays, Blister)



*Fully-automated assembly with 100% camera inspection*

## RAUMEDIC needle safety system – RauSafe™

The new active safety system  
for your injection systems.



### Current RAUMEDIC development for your pharmaceutical products.

- Simple and intuitive handling
- Audible and tangible detent mechanism in a safe end position
- Secure and permanent enclosure of the needle
- Adaptable to a variety of injection systems
- Successfully evaluated in usability study

In 2014 the safety device with efficient protection against needle stick injuries received the coveted award in the category of medical devices and accessories.



## Greater safety for medical staff and patients

### Why do you need a safety system for your syringe?

Worldwide an estimated 3.5 million needle stick injuries occur annually in doctors' offices, hospitals and in the home care sector. Associated with this is a risk of infection with dangerous viral diseases such as HBV, HCV or HIV. The health and financial consequences resulting thereof for the patient are risk factors that have to be taken seriously.

### Legal requirements

In May 2013, the new EU Directive 2010/32/EU for the prevention of needle stick injuries came into force in all Member States of the EU. It regulates by law that employers in the medical field have to provide equipment with an integrated safety mechanism.

### RauSafe™ – The solution for protecting against needle stick injuries

RAUMEDIC has developed a new safety system for injection systems. RauSafe can be adapted to a variety of existing injection systems on the market and provides reliable protection whilst being simple and intuitive to use.



Original state



Activation



Secure end position

The RauSafe safety system can be activated after an injection by simply pushing it forward. As soon as the needle is completely enclosed, you can hear and feel the system click into the end position.



## RAUMEDIC Drug delivery systems

Medication can only be effective, if the correct doses are given. Experience shows, however, that many patients have poor medication compliance. Therefore, the market is demanding increasingly secure dosing aids. We are your partner in developing innovative and customer-specific solutions that ensure compliance to accurate doses.

### Innovative application systems for high quality medications

- Application systems for granulated medications, e.g. devices made of extruded straws and injection molded components with very tight tolerances
- Application systems for liquid medications, e.g. assembled systems consisting of matched injection molding components, including printing
- Application systems and components for dry powder medications, e.g. injection molded components, devices and thermoformed dosing tubes



## Adjustable Dosing Syringe for Oral Drug Administration

The system consists of injection molded components that are adapted to each other as well as labeled.



### Safe and Precise Dosing

We will support you in the development of innovative solutions to ensure both flexible and precise drug delivery. And all of this is customized to your requirements!

We will always ensure appropriate quality management and compliance with all regulatory requirements during the development of your drug delivery system. Your RAUMEDIC drug delivery system is designed to allow a simple dosing of dry powder, granulated or liquid drugs.

- 10 ml syringe, individually adjustable in 0.5 ml increments
- Precise dosing possible < 5% dosing error (calculated)
- Increased patient compliance: no overdosing possible
- Especially designed for pediatric and geriatric patients

### Advantages for pharmacists and fillers:

- Perfectly matched components made from polypropylene:
  - Extruded drinking straw with the tightest tolerances for smooth further processing on fully-automated filling lines of DS TECHNOLOGY
  - Injection molded cap especially adapted to the complex application system
  - Available in a virtually unlimited variety of colors for a simple labeling of drugs and doses
  - Supplied printed with brand name or dosing volume on request
- All necessary machines and tools for fully-automated production and packaging of plastic components are available at RAUMEDIC
- DS TECHNOLOGY offers a complete range of fully-automated processing equipment for filling the XStraw and the primary individual packaging units, as well as the secondary packaging units (carton)
- Patented innovation of an oral application system for medicine – ideal for lifecycle projects
- Multiparticulate dosage forms allow for modified drug release and taste masking
- Formulation of the pellets can be optimized for pediatric and geriatric use, according to target groups (e.g. sugar-free taste masking)

### Advantages for patients:

- Medicine is easier to take, especially for pediatrics and geriatrics
- High level of compliance: Patients accept this product because it is easy to use and they can choose the type and flavor of drink they like
- High convenience:
  - Exact pre-dosing by pharmacists prevents inaccurate dosage
  - Due to the airtight aluminium blister packaging no special storage conditions are required
  - Portable and easily integrated into everyday life

## Dose Sipping Technology: XStraw™

Drug Delivery System for Multiparticulate Dosage Forms.



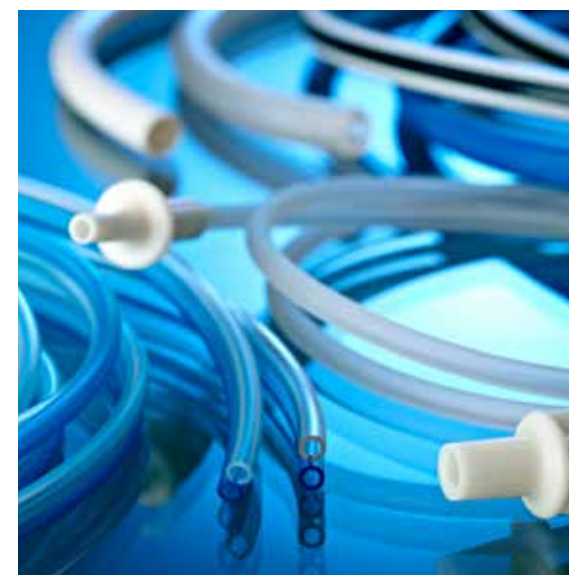


## RAUMEDIC Inhalation systems

RAUMEDIC develops inhalation systems according to your requirements. In the process we combine various production technologies such as thermoplastic and silicone injection molding, tubing extraction and installation techniques. This synergy allows us to develop complex systems and add-on components for you under GMP conditions and manufacture them in series production.

### Innovative inhalation systems for safe drug application

- From the initial idea to the finished inhalation device – all from one source
- Support in product verification and in producing devices for clinical phases
- Integration of gaskets and valves, especially through in-house silicone expertise
- Profound RAUMEDIC material know-how for increasing the efficiency of the development process



*Overmolded connector for inhalation therapy*



*Drug inhalation system*

## RAUMEDIC Primary and secondary polymer packaging

RAUMEDIC will work with you to develop polymer packaging solutions for your medication. They will be based on extrusion, injection molding and assembly, as well as blown film technologies. With this broad range of manufacturing options we are able to find innovative and customer-specific solutions. Your packaging for your pharmaceutical agent will be fully optimized.

### Customer-specific developments of pharmaceutical packaging are our speciality.

We use innovative technologies in order to make your products even safer:

#### → Barrier functions in polymer materials

Solutions for reducing vapour and oxygen permeation

- Material development:  
Development of blending systems with optimized permeation properties
- Two-component sandwich injection molding:  
Combination of properties of two different materials
- Coatings:  
Atmospheric or chemical vapor deposition as well as liquid coating

#### → Hygroscopic polymer materials

Sensitive medications require special storage conditions.

Containers made of hygroscopic polymer materials draw moisture from their environment, thus extending the shelf life of their contents.

#### → Plagiarism protection with a customer-specific fingerprint

- Use of microparticles
- UV labeling



Medication holders with integrated barrier layer



Disposable Unit for Patch-Pump



UV labeling

# Global service

## What can we do for you?

Thanks to our extensive world wide sales network, customers and interested parties can be assisted and advised personally and directly on site.



### Headquarters Europe

RAUMEDIC AG  
Hermann-Staudinger-Str. 2  
95233 Helmbrechts  
GERMANY

Tel.: +49 9252 359-0  
Fax: +49 9252 359-1000  
info@RAUMEDIC.com

### Headquarters Northern America

RAUMEDIC INC  
235 BROADPOINTE DRIVE  
MILLS RIVER, NC 28759

Tel.: +1 828 684 8870  
usa@raumedic.com



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