

Profile

Goller Systems

**Solution partner for demanding
medical technology systems and
plastic applications**



Goller Systems

Profile

Key Facts

GOLLER Systems

Hubertus Goller GmbH
Donaustrasse 110
3400 Klosterneuburg – Austria
+43 2243 / 328 30-0
www.goller.at

- Founded in 1947
- Currently ~ 50 employees



History

- **1950s:** Development and production of diverse products made of plastic; mostly household appliances
- **1980s:** Focus on diagnostics and medical devices
- **1990s:** Start of cleanroom production; further specialization in the field of primary packaging and Medical Devices (Drug Delivery Systems)
- **2012:** Expansion of cleanroom production area
- **2013:** Registration as tissue bank acc. Austrian Tissue Safety Act
- **2014:** New filling machine and expansion of existing infrastructure
- **2018+:** Expansion continues under new owners and new managing directors

Competences

Your development partner and full-service supplier:

- of plastic components and customized system solutions made of plastic
- for the pharmaceutical, diagnostics and medical industries



Goller Systems & Renggli AG

Location

Goller Systems, located in
Klosterneuburg (Vienna region), Austria



Goller Systems

Portfolio

- **R&D Plastics Engineering**
- **Prototyping & Industrialization**
 - 3D Printing

Product- & Process-Development

- **Production**
 - Injection Molding
 - Micro-Molding
 - Printing
 - Assembly
 - Filling
 - Packaging

Clean room environment
ISO-7 (GMP C)
ISO-6 (GMP B)

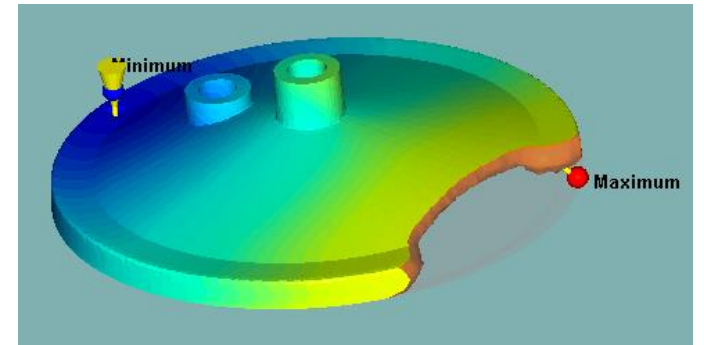
- **Sterilization (external partners)**
- **Warehousing & Logistics services**



R&D Plastics engineering, Construction & Industrialization

Tailor-made to individual requirements

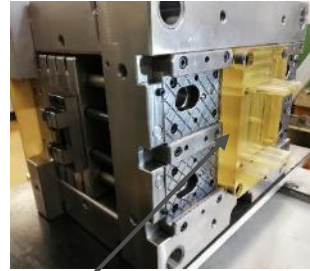
- **Goller cooperates** with customers and research institutes **in R&D projects**
- **3D CAD construction**
 - Innovative solutions (several patents!)
- **Material selection**
- **Injection molding simulation**
 - Comprehensive manufacturability check
- **Rapid Prototyping & Rapid Tooling**
 - In-house mechanical production for the manufacturing of prototypes
 - 3D Printing of prototypes and mold inserts
- **Process development**
 - tools, equipment, automation



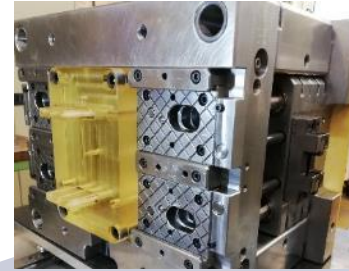
„Function, Design, Manufacturability“

Rapid Prototyping

Process flow



Injection Mold Insert made of temperature-resistant plastic (3D-Printed)



Production

- Molding of first samples (e.g. for further testing of materials or function)



Preparation

- Adjust 3D printed inserts into the modular mold



Concept

- Prepare CAD-Model for 3D-Printer → printing of mold inserts

Design

- Design idea (CAD-Model)
- Proposals for variants (CAD-Modell)



Your product



Fast proto-typing, very short processing time

Pre-condition: Geometry appropriate for 3D-print-inserts and test material available

Processing: 1-2 days

Processing: 3-4 days

Processing: 10-14 days

Processing: 2-3 days

Production

Smart processes

Injection Molding in cleanroom environment

- **Documentation** according to your requirements possible
- **Machinery**
 - Molding according to ISO 14644-1 class 7 (GMP C)
 - Clamping force from 15 to 150 tons
 - All common materials and masterbatches possible (PP, PS, ABS, PMMA, TPE, PEEK, compounds (e.g. radiopaque))
- **Scalable LOT sizes**
 - R&D trials, Pilot Runs, Product transfer
 - Flexible production areas
 - ISO-7 (GMP C) environment
- **Product versatility**
 - Regimes for different kinds of products possible



Production

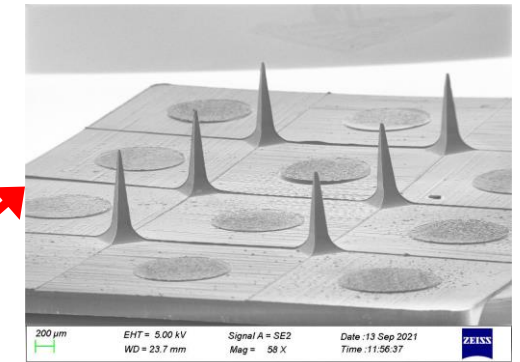
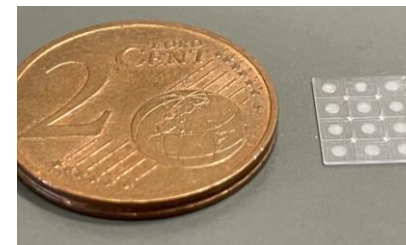
Micro-Molding Technology

Molding of parts with micro- and nanostructures

- Equipped with LF-Unit, for clean air up to class 6 acc. to ISO 14644-1
- High-precision due to separated plasticizing and injection unit
- All common materials and masterbatches possible (PP, PS, ABS, PMMA, TPE, compounds (e.g. radiopaque))
- Rotary table for insert molding (e.g. plastic/metal)
- Robot/handling unit for part removal

Advantage of using micro molding technology

- **Reliable:** High precision part geometry and improved quality
- **Shot weights:** down to 0,05 g to 4 g
- **Fast & efficient:** up to 50 % shorter cycles
- **Economical:** up to 90 % reduced material waste
- **Resource-saving:** up to 60 % reduced energy consumption



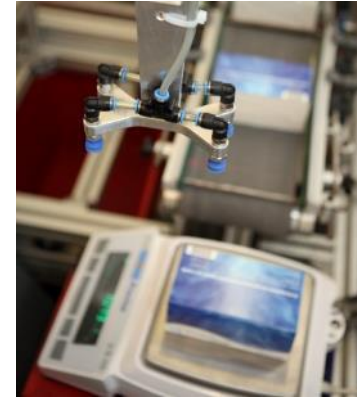
Source: Goller (PC, PMMA, Tritan, part weight 30 mg)

Production

Smart processes

Cleanroom Processes ISO-7 (GMP C) / ISO-6 (GMP B):

- **Documentation** according to your requirements possible
- **Machinery & Processes**
 - Assembling, Ultrasonic welding, Gluing, Siliconization, Printing, Labelling
 - Filling (e. g. buffer solutions, powders, liquids)
 - Blister packaging (hard-/soft blister)
- **Scalable LOT sizes**
 - R&D trials, Pilot runs, Scale-up
 - From manual to semi-automatic to automatic
- **Flexible production areas**
 - ISO-7 (GMP C) / ISO-6 (GMP B) / „A in C“ possible
- **Product versatility**
 - Regimes for different kinds of products possible
 - From metal to plastics (parts, assemblies, bags, ...) to liquids / powders to human tissue



Compliance & Quality Management

Safe & reliable processes

- Integrated **Quality Management System** Approach
 - ISO 9001 (General)
 - ISO 13485 (Medical Devices)
 - ISO 15378 (Primary Packaging)
- Development, **Design Control** and **Risk Management Processes** customizable/integrable into your Quality System according to your needs
- Comprehensive **(Design)-documentation** available to our customers
 - US: DHF, DMR, DHR
 - EU: Technical File, Design Dossier, Batch Record
- **Qualification/Validation** and Documentation activities (Equipment, Process, Method) can be aligned and highly customized according to your needs
- Reliable **Change Control** System



Goller Systems

From development to serial production – from a single source

High Performance Partner



- **Solid Enterprise:**
Successful Austrian company
- **Committed Team:**
Diverse know-how under one roof
- **Target-oriented approach:**
Hands-on, accessible, personal

CDMO & Outsourcing Partner



Manufacturing according to your specifications



Outsourcing partner for individual tasks

Your benefit:

- Focus on your competencies
- Optimization of your resources

Lean & Fast

Our corporate structure & culture:

Lean Management

- Short reaction time
- Quick decisions
- Smart processes



Fast Time to Market

Innovation Track Record



Our credo: Your Future Today

State-of-the-art is history tomorrow;
Creating the future is our mission today!



Our Approach:

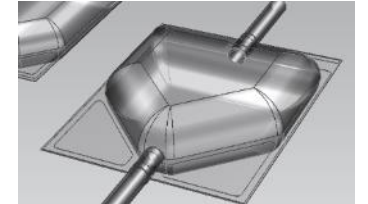
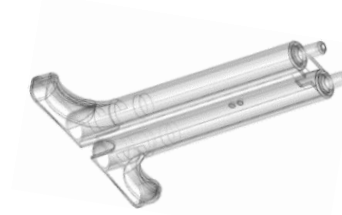
- **Visionary:** R&D projects inspired by pioneering spirit
- **Putting into practice:** Strong in delivering results – we get things done!

Goller Expertise

Medical and pharmaceutical sectors

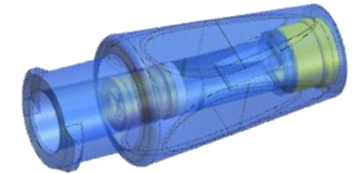
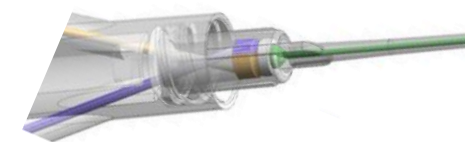
Primary Packaging

- Drug Delivery systems
- Bag Systems with connectors (filled with buffer solution)



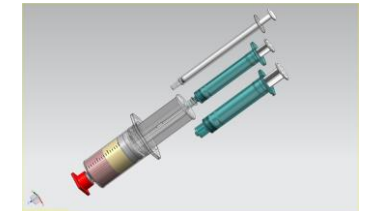
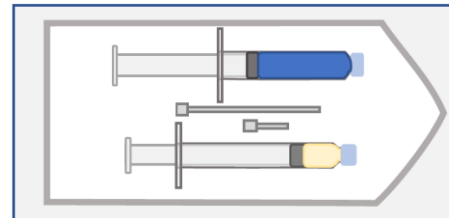
Application Systems

- Application Needles
- Spray Head Systems



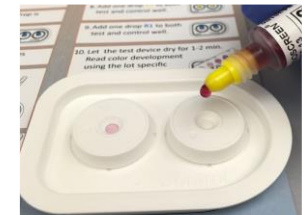
Transfer & Mixing Systems

- Fluids, Blood
- Powders



Diagnostics Test Cartridges

- Allergy-Test (300 Allergenes)
- Flow-Test (Screening)



Contact

Kurt Helletzgruber

Managing Director



Hubertus Goller GmbH
Donaustrasse 110, 3400 Klosterneuburg
Austria, www.goller.at



T +43 2243 328 30 23



Kurt.helletzgruber@goller.at

GOLLER

Systems

from vision to realisation