



SOVRIN

Medical Device Manufacturer

About us

Sovrin Plastics provides injection moulding and contract manufacturing services for the supply of precision plastic components and assemblies to the medical, electronics and engineering industries.

- Engineering based company led by engineers with a lean 6 sigma culture
- Established over 45 years as mould makers & precision injection moulders
- Turnkey contract manufacturing, from concept to completion
- 140 personnel, 52 moulding machines, site 7500 sq. metres
- 30 years manufacturing for the healthcare sector
 - Drug delivery systems
 - Diagnostics & Patient Monitoring
 - Ophthalmic devices
 - Surgical instruments
 - Implantable medical devices
- Suite of Class 7 Cleanrooms, GMP areas & Customer specific manufacturing cells
- 'Can do' approach to complex moulding & assembly projects

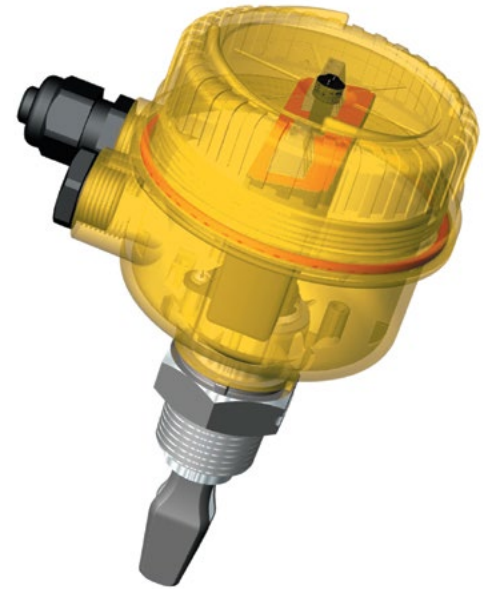


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Design to Industrialisation

Sovrin provides development & manufacturing services from product concept, through prototyping, mouldmaking, validation and into high volume production. Dedicated project teams ensure contribution from all areas of expertise throughout each stage of product development ensuring smooth transition from design to industrialisation.

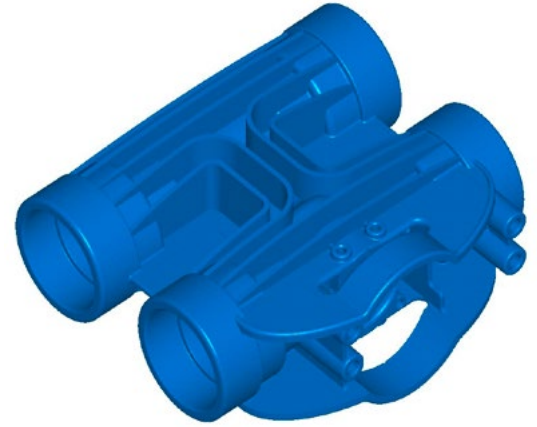


- Product design review & development utilising CAD
- Moldflow analysis to support product design & material selection
- Design for manufacture and assembly, maximising output, minimising cost.
- Comprehensive knowledge of engineering plastics & processes
- Rapid Prototyping
- Optimisation of processes and equipment
- FMEA, Capability studies and DOE
- Validation and Qualification

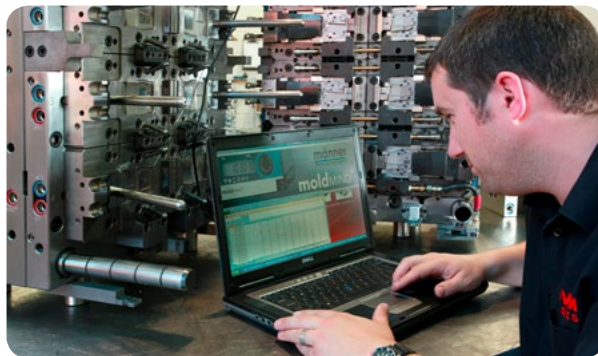


Mould Making

Precision toolmaking is crucial to the efficient production of quality injection moulded components. In-house design and manufacture of injection mould tools ensures that every detail of the component design is precisely reproduced whilst incorporating the specific needs of the selected polymer.



- Design, manufacture and development of precision mould tools
- CAD/CAM integrated design facility
- Moldflow analysis to support product design-for-manufacture & material selection
- CNC machining facilities
- Toolroom accredited to ISO 9001 & ISO 13485
- Validation of new and transferred mould tools
- Project management of larger suites of tools during manufacture by approved sub-contractors
- Modifications & planned preventative maintenance of mould tools



Injection Moulding

Plastic injection moulding of precision components is our core business and one at which we have excelled for over forty years.

- Precision injection moulding of all thermoplastic materials
- 52 moulding machines (5T – 350T)
- Cleanroom moulding – Class 7 & GMP
- Customer specific injection moulding & assembly cells
- Multi-material injection moulding
- Insert & outsert moulding
- Micromoulding & small component production
- Optically critical moulding
- Volume production and small batch quantities
- Robotic handling systems and automated assembly



Micromoulding

Sovrin plastics micromoulding manufacturing cells are the innovative answer to the growing demands from the medical, pharmaceutical, engineering and electronics industries for micro-precision components in thermoplastics

- Micromoulding of precision components down to a few milligrams
- Micromoulding, robotic handling and packaging cells
- Inline optical comparison system for 100% product quality assurance
- Cleanroom micromoulding
- Bio-absorbable polymers for medical implants.
- Conductive polymers for electronic applications
- Optically critical micromoulding
- Specialised micro mould tools



Medical Device Manufacture

Sovrin specialises in the development and manufacture of mould tools, plastic injection moulded components and the assembly of complex devices for the pharmaceutical, drug delivery, medical, and healthcare industries. Our engineering expertise developed over thirty years serving these markets and the latest technology ensure consistent and superior quality is invested in all we produce.

- Contract manufacturers of plastic medical devices
- Precision injection moulding
- Class 7 cleanrooms & GMP areas
- Automated & hand assembly and value added operations
- Customer specific medical device manufacturing cells
- Validation & qualification
- ISO9001, ISO13485, FDA compliant
- Regulatory affairs management
- Bioburden management



Assembly & Services

Our plastic injection moulding facilities are complemented by assembly rooms providing automated and manual completion of products in Class 7 cleanrooms.

- Manual & automated assembly
- Four colour pad printing
- Ultrasonic welding
- Laser marking, drilling, cutting & welding
- Gamma & ETO sterilisation
- RFI shielding
- Custom packaging
- In-mould labelling
- Function testing
- Customer specific injection moulding & assembly cells



Quality Assurance

Our quality management system encompasses ISO 13485:2003 and ISO 9001:2008 and supports everything we do for our customers. Quality laboratories, fully equipped with the latest technical innovations, provide comprehensive support to the process management systems ensuring consistent product quality.

- ISO9001:2008, ISO13485:2003, FDA compliant
- FMEA/Risk Analysis/Risk Benefit Analysis
- Advanced product quality planning (APQP)
- Production Planning Approval Process (PPAP)
- Regulatory Affairs Management
- Support in the preparation of Design & Drug Master Files
- Metrology Laboratories incorporating optical and contact CMMs
- Bespoke test equipment
- Bioburden monitoring of product and production environment
- Validation and qualification



Validation

Sovrin are committed to meeting customer specifications in relation to design, manufacture and qualification of all processes, facilities and equipment. Design, installation, operational and performance qualification ensure complete and seamless validation.

- Full validation of mould tools, processes and equipment
- Creation of Validation Master Plans covering all aspects of:

Design Qualification

- Component DFM, Mould tool design, URS, Risk Assessment, FAT

Installation Qualification

- R & R, MSA, SAT, Equipment Environment Facility

Operational Qualification

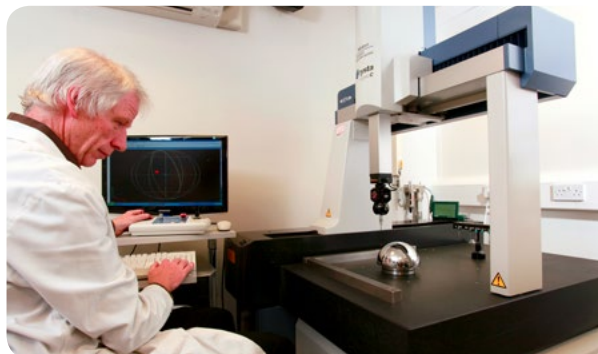
- Process optimisation, Process capability analysis, Functional & dimensional assessment

Performance Qualification

- In-process testing, Product training, Batch traceability, Production control

Final Summary Report

- IQ/OQ/PQ Checklists, FAT & SAT Reports, FOIRs/ISIRs, MSA/R & R Studies, Capability Studies, Interchangeability Studies



Case Studies

Drug Delivery Device Production Cell

In response to an urgent demand for additional capacity for the production of a drug delivery device to combat a predicted pandemic, Sovrin embarked on a challenging programme to design, build from scratch, commission and validate a dedicated cleanroom production cell.

Project:

- Design & build a new cleanroom production cell (150 sq. m.) utilising lean & 6 Sigma techniques.
- Project manage construction and sub-contractors
- Specified and sourced plant – five moulding machines, 6 axis automation, conveyors & assembly machine
- Project manage mould tool manufacture
- Validation – mould tools, process, facilities

Outcome:

- From concept through validation and into high volume production in less than 5 months
- Rate of output – 24/7 365 days – number of devices manufactured – 6,500,000 in year 1
- Reliability of plant, tools and process. Uninterrupted output to date exceeds 33 million
- Optimisation of process increased projected output by 16%



Wound Closure Device

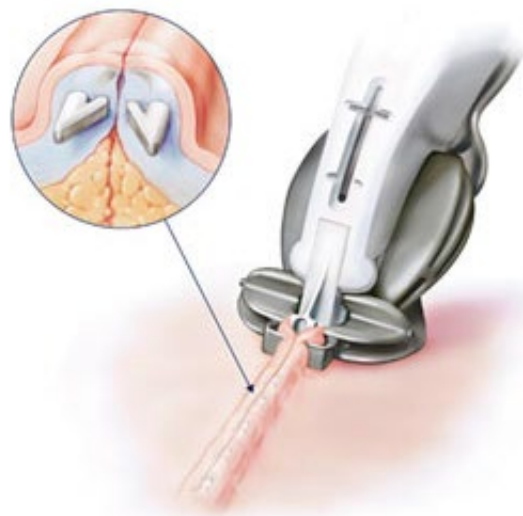
A US based high technology company sought micromoulding expertise in the development of a device to replace use of metal staples and sutures following major invasive surgery.

Project:

- Micromoulding mould tools for MKI & MKII versions designed and manufactured at Sovrin
- Bioabsorbable polylactide/polyglycolide copolymer @ \$1,500/kg
- DoE (Design of Experiments) to determine optimum process settings and product performance
- Product and delivery device validated
- Support of clinical trials

Outcome:

- Turnkey project development successfully completed on time and within budget
- Clinical trials succeeded
- Regulatory approval achieved
- Enthusiastic reception to the product from a highly selective market
- Production unit established and validated on schedule



Ophthalmics Packaging

Sovrin were asked to adopt an existing mould tool to deliver improved product quality. The superior service and quality provided persuaded the customer to place a suite of new mould tools with increased cavitation.

Project:

- Provide dedicated production cell
- Establish capable in-process quality monitoring
- Meet the technical challenges of post-moulding product handling
- Prevent the attraction of particulate due to high static charge emanating from PP components

Outcome:

- Purchased new 350 Tonne Fanuc moulding machine with robotic handling
- Completed validation of new 32 cavity hot-runner valve-gated mould tools
- Resolved previous quality problems and reduced cycle time on existing mould tool.
- Installation of over-clamp cooling conveyor – improvement in product precision achieved
- Install end-of-line automated packaging
- Designed and manufactured 32 station metrology fixtures



Medical Gas Delivery Device

A company specialising in medical gas solutions and their means of delivery approached Sovrin to develop and manufacture a novel device for the administration of a special mixture of medical grade helium and oxygen.

Project:

- Design and development support for moulding, assembly and testing
- Consideration of critical failsafe features
- Support of polymer selection with Moldflow
- Integration of crucial bought-in components
- Validation of mould tooling, components and device assembly
- 100% Functional Testing

Outcome:

- Protocols for mould tool validation compiled and objectives achieved
- Tooling validated by use of IQ, OQ, & PQ.
- FDA compliant Drug Master Files prepared
- Product taken to clinical and user trials as programmed



Speciality Orthopaedic Syringe

A company with a requirement for a unique design of syringe for delivery of their novel product asked Sovrin to conduct a DFM, manufacture mould tools and provide volume injection moulding and assembly.

Project:

- Specialised design called for more challenging polymers and tool design
- Capability for sterilisation by ETo
- Total oxygen barrier required for drug compatibility
- Tight tolerances including zero draft in syringe bore
- Flow patterns studied by Moldflow to overcome difficulties created by product design
- Soft-touch and functional seal feature, both overmolded

Outcome:

- Suitable specialist polymer identified and successfully tested
- Tool design proved by capability studies, verification protocols and Moldflow analysis
- Elastomers compatible with overmoulding identified and successfully tested
- Product developed to clinical trial readiness



Syringe Extension

A company using an expensive two stage assembly for a cartridge used to contain their drug compound asked Sovrin to devise a one piece answer to improve the storage life of the product whilst offering a cost reduction.

Project:

- Inherent technical problems with the existing design
- Problems in dosing the adhesive used in the original assembly
- Shut-off on substrate part with dimensional variation was critical
- Polymer selection dictated by the need for a strong bond with substrate
- Very high pull force testing requirement

Outcome:

- One-piece component design developed
- Use of adhesive eliminated
- Tool design developed to cope with inconsistent substrate
- Suitable polymer identified and successfully tested



Bath Overflow Prevention Device

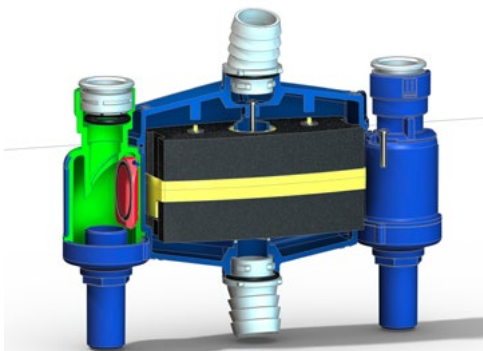
Following a successful presentation on the BBC's Dragons' Den programme, the inventor of a device to prevent baths from overflowing approached Sovrin to assist in the development and industrialisation required to bring the product to market.

Project:

- Selection of polymers to meet the stringent requirements of several regulatory bodies e.g. WRAS & IAPMO
- Conduct design for manufacture review
- Consult with industry experts on the technical requirements of each specific market
- Design and manufacture mould tools capable of processing demanding engineering polymers
- Conduct capability studies of the device assembly in the polymers specified by European & US markets
- Develop in-line equipment for function testing
- Label and package each assembly ready for point-of-sale

Outcome:

- The product designed, developed and in production on time and within budget
- Product approved by regulatory bodies
- Successful product launch on both sides of the Atlantic



Contact

Sovrin's sales team would welcome enquiries on any of our Plastic Injection Moulding, Micromoulding or Tooling services and would be delighted to discuss your requirements.

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Fax: +44 (0)1753 694923

Web:

Address:

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