Because life is at stake.

ENGEL medical

ENGEL
be the first.

Excellent. Clean.
ENGEL medical.

Medical technology is an industry apart. Maximum product safety, absolute cleanliness and precision in production and complete documentation and traceability – these are the central requirements. No compromises. **After all, it's a matter of health, quality of life and life itself.**

It takes specialists to translate these special requirements into high-quality injection moulded parts. **That's why at ENGEL a separate business unit is dedicated to the needs of medical technology: ENGEL medical.** This special team combines the medical know-how within the company and merges engineering, production and sales. Worldwide. Including high clean room and automation competence.

Based on its extensive medical technology expertise, **ENGEL medical has developed a series of innovative features which respond to the special requirements of the industry.** For example, the patented barrel extraction unit makes sure that virtually no particles and very little heat escape from the machine into the clean room.

And the completely covered guides on the tie-bar-less ENGEL victory machine also contribute to achieving cleanliness. This keeps the **clamping unit totally grease free.**

Another highlight: the amazingly fast mould closing and ejector movements of the fully electric ENGEL e-motion machine. This gives you one of the most efficient and at the same time economic solutions for medical products with long cores such as syringes.

ENGEL medical.
Because life is at stake.

Diagnostics

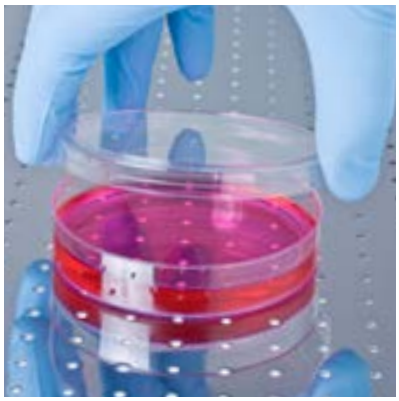
Including DNA / RNA freedom

Performance meets cleanliness

Pipette tips, cuvettes, petri dishes, etc. are mass products. The emphasis lies on maximum output. But the products place the highest demands when it comes to quality, accuracy to detail and cleanliness. And in terms of process stability, too. For if the process is stable, the machines can run at top speed. Continuously. With its high-performance electrical machines, ENGEL medical has the ideal solution for this demanding requirement profile.

Keeping a grip on energy consumption

ENGEL medical machines score points with high energy efficiency. This is particularly important in the field of diagnostics. More than in any other medical technology market, it is all about peak performance here – about the highest output rates per unit of time. And the smallest energy saving per part produced pays off a thousandfold. **In short: energy-savings mean cost-savings. With ENGEL medical.**



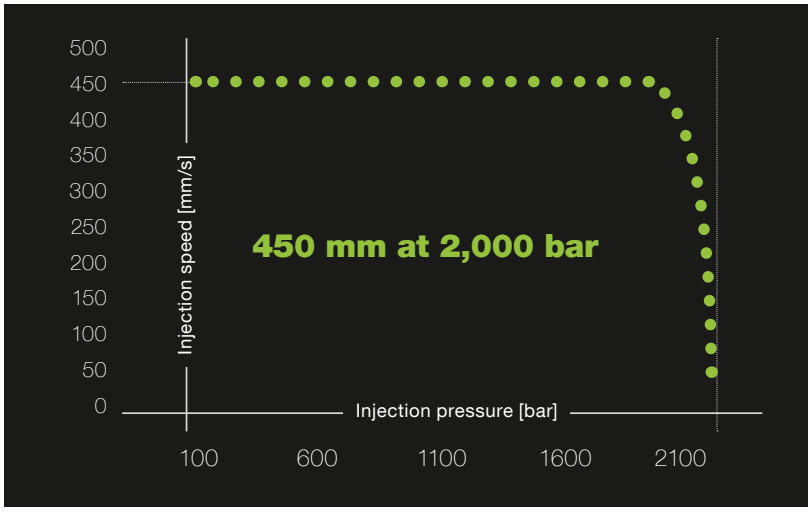
At the end of the day, **power density** counts.

All-electric. With 270 hp.

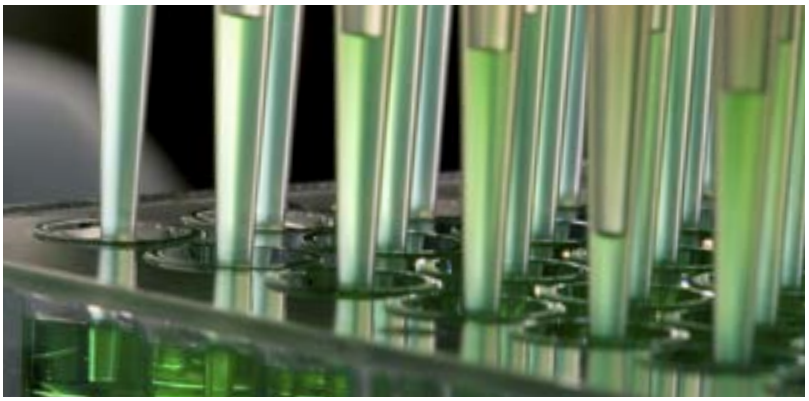
Petri dish production power

The high performance, fully-electric ENGEL e-motion T sets new standards of efficiency, for example in the production of petri dishes. The exceptionally fast toggle lever solution shares a platform with the ENGEL speed high-performance machine. And it is available as a complete series from 55 to 500 tonnes clamping force. Thanks to a host of convincing performance parameters, such as a screw speed of up to 450 millimetres per second, it secures the shortest cycle times at maximum output. The fully electric injection unit 1340 likewise is another high-performance model, achieving a maximum possible injection power of 200 kW (270 hp).

Its generous dimensions mean it has adequate power reserves to guarantee perfect product quality. In addition, it scores extra points with fully electric drive technology and high energy efficiency. As a result it generates considerable energy savings in petri dish production.



Pressure/injection speed curve of a fully electric 740 size injection unit.



Compactness is the key factor.

Because space is at a premium.

Compact top performer.

The compactly built **ENGEL e-max makes highly efficient use of your valuable floor space.** Due to the fully electric operation with screw speeds of up to 500 millimetres per second, the machine achieves impressive speed and precision. It is thus ideal for the production of pipette tips, etc. Overall the ENGEL e-max presents itself as an extremely cost-effective solution – even for the most demanding products.

Source: Schlosser Medizintechnik

Medical technology

We take cleanliness to heart.

Stay just a little bit longer…

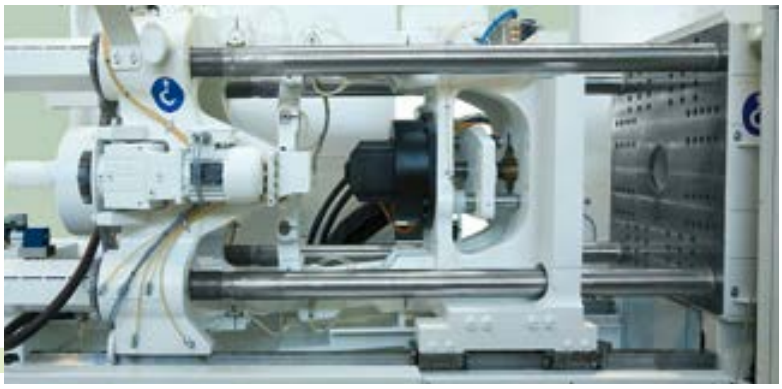
The intravenous indwelling catheter's name says it all; and the same thing applies to wide range of other medical products: **they remain in contact with human body parts or fluids – often over several hours and days.**

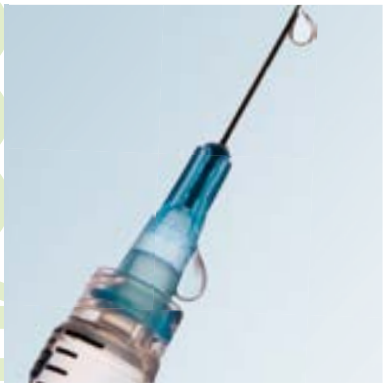
Stringent guidelines are therefore applicable to injection moulded products when it comes to cleanliness and precision. The ENGEL medical team is aware of these requirements and develops special-purpose solutions together with ENGEL engineers. For example, the completely covered guides on the tie-bar-less ENGEL victory also contribute to cleanliness. In the fully electric ENGEL e-motion the enclosed lubrication cycle ensures that the clamping unit remains completely clean.

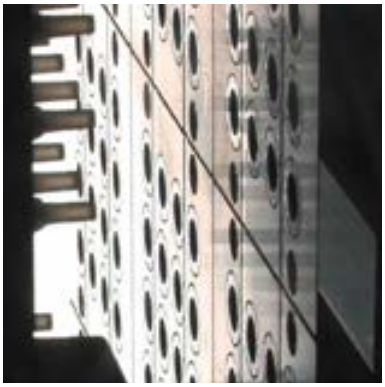
Talking of "long dwell time": this also applies to ENGEL medical machines. Thanks to the premium quality and extremely durable components, the machines deliver an extended service life. This also means you have the "life-cycle costs" under control.

Top speeds

for syringes. All-electric.







400 mm/sec.

Speed counts.

Fast closing and ejection movements are required for medical products with long, thin cores such as syringes. With **dry cycle times of less than 1 second** and an ejector speed of 400 millimetres per second, the fully electric ENGEL e-motion 100 T fulfils this task with the greatest precision.

192 cavity mould for protective caps on a fully electric ENGEL e-motion.

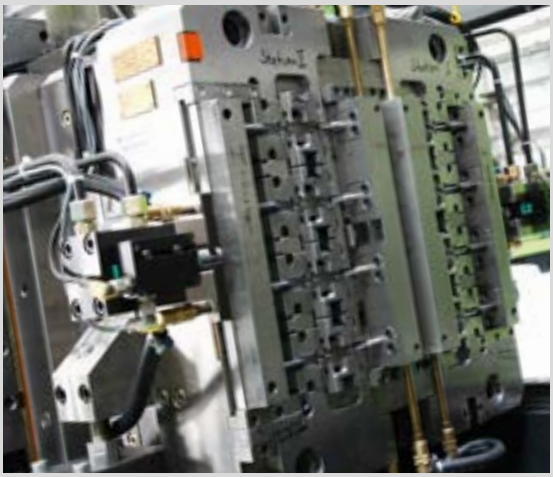
Energy saving champion ecodrive

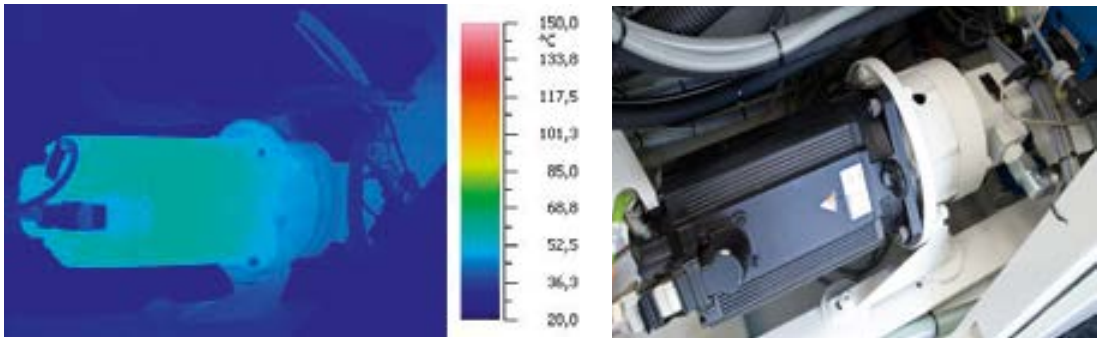
ecodrive *inside*

The servohydraulic ENGEL ecodrive economises with energy: In contrast to the standard hydraulics with asynchronous motor used previously, this system has a fixed displacement pump and servomotor. The machine's speed is directly linked to the drive's rotational speed. With ENGEL ecodrive, the machine only runs at the speed actually needed. In other words, the drive is only active during movements. The advantage: virtually no energy is consumed when idle – e.g. during the cooling time.

ecodrive: The right choice for moulds with hydraulic drives

On top of this, the machine is extremely quiet, its coolant requirements can be as low as zero and hydraulics are on board. It thus achieves energy savings comparable to those of a fully electric machine. In addition, the machine is ideally suited to energy-saving production using moulds with hydraulic components (such as core-pulls).





Due to the extremely low power loss, even the servopump assembly surface is only minimally heated up.

Pharmaceuticals

With the power of stability

Trusting in ENGEL is trusting in reliability. And continuity. This applies to the sophisticated injection moulding solutions which can still be expanded many years after acquisition and adapted to changed requirements. But in particular to ENGEL as a whole. In choosing ENGEL as a stable and financially sound family business you are opting for a reliable partner in the long term. Including a consistently high degree of supplier reliability.

Put briefly: ENGEL **– a decision with a future.**

Systematic dependability. Reliability through **integration.**

ENGEL medical takes an overall view of its specific requirements. As a whole. You receive completely integrated injection moulding system solutions which go beyond simple machine technology. We ensure a perfect interlock between the machine, automation, mould and peripheral devices including the BDE System ENGEL e-factory. **With a guarantee of reliability and delivery dependability.**

Assurance through **experience.**

Clean, precise, quiet, fast, dynamic – fully electric machines impress with a number of benefits. Including high energy efficiency. More and more production companies in the pharmaceutical industry are committed to injection moulding machines with electric drive technology.

Electrics pioneer
ENGEL recognised the sign of the times at an early stage and has been playing an active role in this sector for more than 10 years. With over 1,500 systems deployed, ENGEL has well-founded know-how in electric machines. **In short: all-round experience you can depend on.**

In short: with reliability. **ENGEL.**

Clean, tailor-made solutions

Whether it is different combinations of colour and materials which secure beneficial and functional product attributes or set appealing design accents. Or whether the emphasis is on large moulds in relation to the required clamping force: **injection moulding systems which produce health care products must exhibit above-average flexibility.**

As a **specialist for tailored solutions** and a pioneer in multi-component injection moulding, ENGEL medical implements the answer to your special requirements with a fine instinct. And the necessary experience.


Health
Care

No tie-bars. No barriers.

Freedom for multi-component applications.

Total design freedom for moulds.

The ENGEL victory machine's tie-bar-less design offers a crucial advantage: full utilisation of the mould fixing platens and thus **maximum flexibility with respect to mould dimensions.** Numerous applications, such as toothbrush manufacture with a large number of rotating parts, require elaborate moulds with the corresponding space requirements. This calls for machines that can handle larger, bulky moulds with a relatively low clamping force. The tie-bar-less ENGEL victory is the ideal machine for this purpose. It offers total design freedom for moulds. In other words: with a given clamping force there are (almost) no limits in mould size.

Freedom of placement. Maximum flexibility for mould connections.

In the case of conventional machines, mould manufacturers often find themselves severely limited by the design options. Frequently it is the tie-bars which determine where there is room for the necessary media, hot runner and core-pull connections.

From both a technical and a cost viewpoint, however, this will rarely be the ideal position. **The ENGEL victory eliminates these restrictions:** because the machine has no tie-bars, the required connections can be placed at the technically most viable location.

Total freedom of configuration for injection units

The right placement of the injection units is crucial. This is especially important in injection moulding of multi-component heath care products, such as the manufacture of 6-colour toothbrushes. Due to the ENGEL victory's tie-bar-less approach, the six injection units can be located in the rheologically optimum position.

Freedom for automation. No tie-bars. Reach the goal faster.

The ENGEL victory gives robots and handling devices fast and unimpeded access. **Advantage: the automation can be located where the process calls for it.** And not – as in conventional machines – where there happens to be space between the tie-bars.

unLIMited

Where products containing liquid silicone are concerned, such as pacifiers for babies, ENGEL can draw on abundant resources. **The LIM machine programme is extensive.** It covers everything from the tie-bar-less ENGEL victory and e-victory to the fully electric ENGEL machines – across the full range of clamping force sizes. The application technology know-how that ENGEL's staff offers you in the LIM field is also comprehensive. This means that you will always have a competent partner for all standard LSR types and multiple-component applications: ENGEL.

The right machine **for any LIM application.**

Clean.Room.Com

No two clean rooms are the same. These clean production areas must be individually tailored to the product being manufactured and the batch size. Extensive know-how and technical competence in devising technical solutions is called for. And that is exactly what ENGEL medical and its experienced clean room partners can provide.

On the basis of its in-house clean room at Schwertberg and a series of resulting machine concepts for clean room use, ENGEL has acquired extensive experience and competence with clean rooms. **Experience you can depend on.**


petence.
ENGEL medical

Clean. Length x width x height

First step: analysis

The starting point for any clean room production is a comprehensive risk analysis. Possible error sources and hotspots are systematically recorded and the necessary steps defined and implemented.

Against contamination.

The highest priority is accorded to avoiding contamination by operating materials such as grease, oil or cooling media. It is also important to minimise heat loss and particulate emissions, thus ensuring clean room suitability.

Keeping a grip on running costs

In addition, running costs must be optimised in the early planning phase. The latter amount to between 20 and 30% of investments per year and are thus a major cost factor.

A systematic analysis and optimisation of all these factors enable ENGEL medical to prepare a cost effective machine concept that is suitable for the clean room and optimally tailored to the requirements of the product.

From left to right: *Completely greaseless clamping unit due to covered guides on the ENGEL victory | encapsulated drive axes on an injection unit | encapsulated clamping unit on an ENGEL e-motion 100 T*

Source: Samaplast

Efficient injection moulding systems are developed for clean room production in the in-house clean room at the ENGEL application technology centre in Schwertberg.

ENGEL: **In-house clean room**

ENGEL medical has its own clean room. It conforms to the requirements of Class 6 (at rest) according to DIN EN ISO-14644 and is constructed and qualified according to the rules of c'GMP. In the past few years ENGEL medical has used these facilities to systematically analyse the performance of production systems in a clean environment and develop specific solutions. In addition to a large number of optimised technical solutions for medical injection moulding machines, ENGEL has acquired valuable clean room expertise.

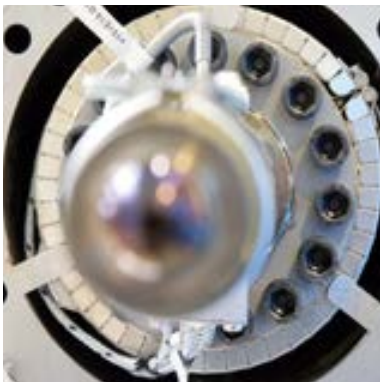
Source: starlim//sterner

*Clean room plating with **sealing plugs***

Clean room concept: Machine **in the room**

The injection moulding machine including automation is installed in the clean room

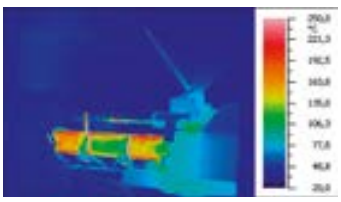
- All processes are carried out in one overall hygiene class. The staff moves around exclusively in one overall hygiene class. Particle concentration, temperature and humidity are controlled.
- With this solution, particular attention must be paid to optimising the maximum particle emission and thermal stress. At the same time, all drives and toggle lever bearings must be encapsulated.
- ENGEL medical has the right machine options: barrel extraction, clean room plating including flush-fitting plugs and the clean room basic package

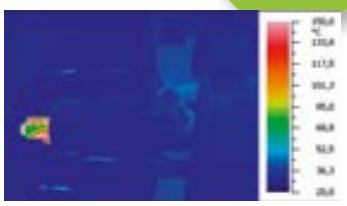

powerful.suction.
Even without smoke.

With the GMP barrel extraction unit from ENGEL

Minimisation of particulate emissions and thermal stress in the clean room. That is the task of the patented GMP barrel extraction unit by ENGEL. And it has perfected the art. The extraction unit consists of a double-walled stainless steel pipe that **prevents emissions into the clean room.** The particles and hot air are collected by the ventilation casing and fed into an exhaust system. In addition, the use of fan-less servomotors has a positive effect not only on the thermal balance but on the energy balance as a whole.



The thermal camera image shows it quite clearly: the patented GMP barrel extraction unit significantly reduces heat emission into the clean room.



Clean room concept: **Satellite**

The injection moulding machine is installed outside the clean room.

- One advantage of this solution is that the **required clean room size can be reduced** – by the footprint of the injection moulding machine. Furthermore, machine operation, maintenance, and mould changes occur outside of the clean room.
- **The following machine options are required:** clean room module (filter fan unit), parts chute, encapsulated conveyor belt, clean room basic package
- ENGEL medical machines satisfy the demanding requirement profile of the satellite concept: they are readily accessible and support fast and easy cleaning. At the same time, the production line (parts chute and conveyor belt) is fully encapsulated. Similarly, all drive units and toggle lever bearings are encapsulated.

Optimum accessibility and best in class cleaning *despite full encapsulation of the production line*

Encapsulated conveyor belt *with reject shunt*

Clean room module *(filter fan unit) fully integrated*

Satellite concept: *the injection moulding machine is installed outside the clean room.*

Source: Murrplastik Medizintechnik

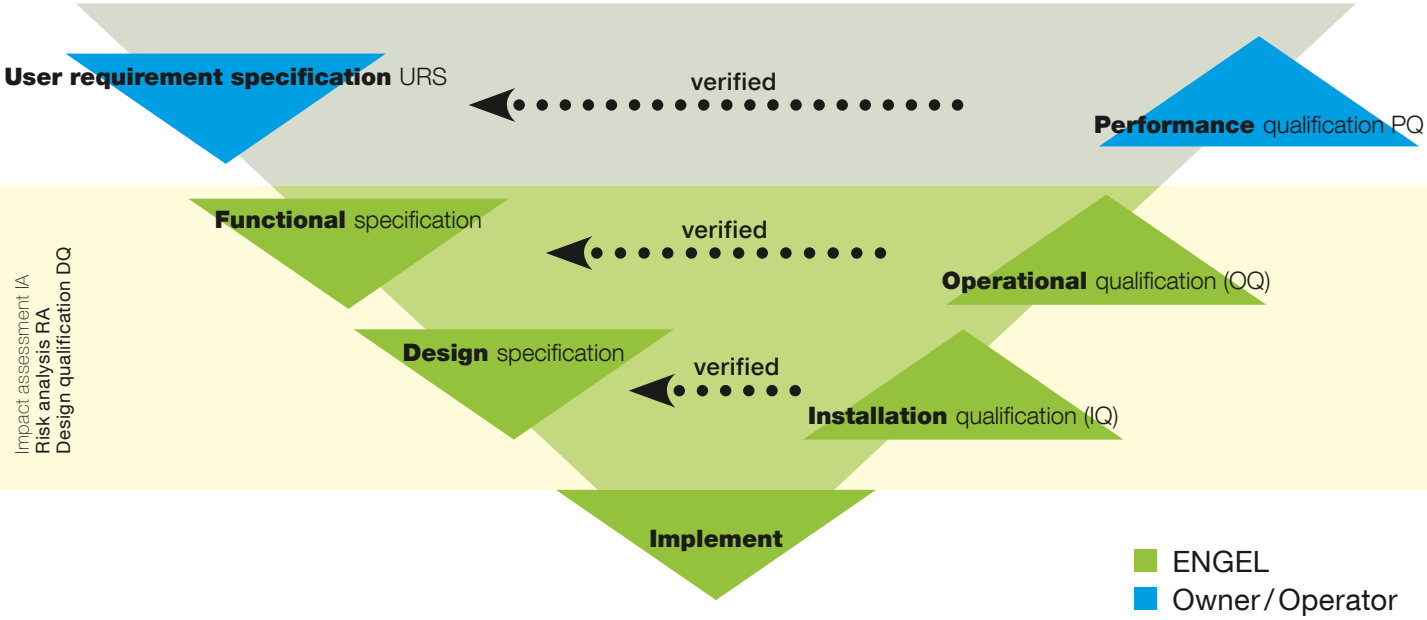
"All the details, requirements and provisions adopted by the manufacturer for his quality assurance system must be documented in a systematic and orderly manner in the form of written policies and procedures ..."

Quoted from: Medical Devices Directive MDD 93/42 EEC Annex II

Statutory **basis** for medical products

The statutory basis for medical products in the European Union (EU) is the **Medical Devices Directive** MDD 93/42 EEC, or for diagnostic products, IVD 98/79 EC. These EU directives are implemented at a national level, in the Medical Product Act, for example, in Germany. In USA they are subject to the Code of Federal Regulation Title 21 Part 820 (21 CFR 820), based on current Good Manufacturing Practise (c'GMP).

A functioning quality management system is a basic requirement for the marketing of medical products. ISO 13485 and c´GMP have become the recognised standards which, among other things, specify the qualification of operating materials as a basis for validation. Among others, Good Automated Manufacturing Practice (GAMP) is a recognised guideline for the validation of computer-aided systems.



think ahead

ENGEL medical as a machine manufacturer has established the **exactly documented process steps** within the company and applies them on a daily basis. High priority is given to thinking AHEAD in order to exactly reconcile the user's requirement specifications with ENGEL operational specifications in the project definition phase. Together with the impact assessment, risk analysis and ERES/GAMP classification, this extremely accurate and confirmed functional specification is the basis for design.

implement

These documented detailed requirements are precisely implemented by ENGEL medical in the machine and automation solution **implementation phase.**

verify

Once the system has been built, **ENGEL verifies step by step** that the physical product satisfies the requirements defined in the planning phase. In the case of deviations, a corrective measure is clearly specified and its implementation documented.

ENGEL **GMP** Documentation

In conformance with the regulatory requirements

ENGEL GMP documentation essentially comprises:

- **Scope, objective**
- **Responsibilities and organisation**
- **Definitions and system design**
- **Impact Assessment IA**
  This forms the basis for assessing the assemblies and components in terms of their relevance for qualification. The qualification scope is defined.
- **IGxP/ERES/GAMP classification**
  This serves as a basis for classifying computer-aided systems with regard to GxP relevance, classification as per GAMP5 and determining ERES relevance pursuant to 211 CFR Part 11.
- **Risk analysis RA**
  Groups and components are closely scrutinised to verify compliance with current GMP require ments. The necessary test depth for DQ, IQ und OQ is determined
- **Master Qualification Plan MQP:**
  This is a conceptual description of the qualification activities for the injection moulding machine.
- **Design Qualification DQ:**
  The DQ verifies that all specifications and standards laid down in the MQP have been satisfied, and the risk for products to be manufactured and/or the environment has been reduced to an acceptable level.
- **Installation Qualification IQ:**
  The IQ provides documented proof that all relevant assemblies or components have been mounted and installed as proposed in the final version as analysed in the DQ.
- **Operation Qualification OQ:**
  The OQ provides the proof that the whole injection moulding machine in "as built/at rest" condition conforms to the specifications laid down in the user requirement specification for normal operation. For this purpose, measurements are taken on the injection moulding machine after commissioning.
- **Factory Acceptance Test (FAT)**
  Acceptance protocol at the factory, including documentation of modifications prior to delivery.
- **Site Acceptance Test (SAT)**
  Acceptance protocol at the site of operation.
- **Requalification at the user's premises**
  Periodic verification that acceptance criteria are still met.

of FDA and EU law

Factory calibration of relevant parameters

Requalification at the user's premises

51030-0270/ENGEL medical_de/04-2012

ENGEL **medical**

ENGEL AUSTRIA GmbH | A-4311 Schwertberg | tel: +43 (0)50 620 0 | fax: +43 (0)50 620 3009
e-mail: sales@ENGEL.at | **www.ENGELglobal.com**

ENGEL
be the first.