Integrate intelligent assistance systems into validation strategy for medical products

Compliant dynamic processes

Injection moulding machines with assistance systems open up new possibilities for even higher process accuracy and product quality. Such intelligent software solutions adjust the process parameters cycle by cycle based on current conditions. One example is iQ weight control by ENGEL, which automatically compensates for external influences such as fluctuations in the raw material. The challenge for medical technology, however, is to integrate this dynamic process control into the validation process. Different approaches were examined and a procedure designed which makes it possible to validate processes with iQ weight control in compliance with both EN-ISO and FDA.

For medical products, the regulating groups (also known as Notified Bodies) of the EU and the USA require detailed documentation during the entire product development, process planning and manufacturing process. The requirements can be found in the European standard "EN ISO 13485:2016 – Quality management systems for medical devices" and in the American FDA regulation "21 CFR Part 820 – Quality Systems Regulations". Both regulations stipulate that a company must validate critical production processes of results that cannot be verified by subsequent monitoring or measurement. This includes injection moulding processes in mass production, where 100-percent inline inspection is usually not logical. However, the implementation of the validation is not specified either in the American regulation or in the European standard. Only the tasks to be performed by the manufacturer are recorded in various directives and guidelines.

It is common practice to validate injection moulding processes on the basis of machine parameters. However, changing ambient conditions that influence the viscosity of the melt and

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can lead to rejects are not taken into account. Many processors are asking themselves how the new dynamic process control can be integrated into a validation strategy for the manufacture of medical technology products in compliance with current laws and standards. The key lies in the definition of process windows and the validation of these process areas. ENGEL iQ weight control offers the possibility of limiting the scope of readjustment. Based on experience or test results, limit values are determined for the adjustable parameters switchover point, injection profile and holding pressure, respectively, and are stored in the control system. This ensures that the process parameters do not fall outside of the validated range despite dynamic process control, and that the process complies with the regulatory requirements.

Adapt the validation strategy to the product

First, product requirements must be defined by measurable acceptance criteria. This is usually done based on the risk analysis and is described in a validation master plan (VMP). The VMP contains the validation strategy of a company and should clearly define the key elements of the qualification and validation program. To this end, the VMP must describe very specifically which validation principles are implemented in the company and how, and who assume the responsibility at which level and in what form. This task should be performed by a group of experts, known as the Task Force, consisting of product and process engineers at the plastics processor.

Every product has critical quality attributes (CQA), which in injection moulding production can be, for example, a linear measure or the surface quality. In the validation, it is necessary to find the corresponding critical process parameters (CPP) that affect the CQA. The experts define these critical injection moulding parameters on the basis of data sheets and figures based on experience with comparable injection moulding processes. In the case of critical components such as functional elements of a drug delivery system, the statistical design of experiments (DoE) is used to determine the process limits. For the majority of applications, simplified planning based on empirical values is sufficient to define a permitted parameter window. If the CQA are within the accepted limits, parameter ranges in which the process can be adapted can be set. In addition, the stability of the process is examined in this phase.

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Control process parameters in real time

The iQ weight control assistance system is a real-time control software that adjusts process parameters during production to ensure consistent high part quality. The software compares the injection pressure above the screw position with a reference pressure curve and identifies deviations in injection volume and viscosity. The automatic adjustment of the switchover point, injection profile and holding pressure compensates for target deviations shot by shot. Consequently, the switchover point and holding pressure level must be defined as CPP in the validation strategy.

The limit values for the switchover point and holding pressure determined in the DoE are adopted in the CC300 controller of the ENGEL injection moulding machine as the limit value for process control by iQ weight control. If it is necessary to regulate the parameters outside of the validated limits in order to achieve the specified product quality, a corresponding procedure can be defined in the control system. For example, the respective shot can be declared as scrap or the production process can be stopped if the limit values are exceeded. Simplified rules are also possible. For instance, by keeping the switchover point constant and adjusting the holding pressure, or vice versa, keeping the holding pressure constant and adjusting the switchover point.

The validation strategy described makes it possible to use intelligent assistance systems in medical technology as well, in order to further increase process consistency and process reliability. This allows quality fluctuations of the raw material and changes in ambient conditions to be dynamically and reliably compensated for in the validated process. Using simple logic, the innovative algorithms used by intelligent assistance systems can be integrated into the validation strategy.

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iQ weight control

Producing moulded parts of a consistently high quality shot by shot is the aim of every processor. However, this will not be achieved by simply using a precise injection moulding machine. Even minor changes in ambient conditions or in raw materials and wear have an effect and may require the readjustment of parameters. The iQ weight control software makes it possible to automatically recognise deviations and compensate for them in the same shot. In this way, process consistency and reproducibility are increased and rejects are drastically reduced. The result is higher productivity with consistently high product quality.

Intelligent assistance is a key feature of the smart factory as described by the objective of Industry 4.0. ENGEL was quick to focus on the trend towards digitalisation and networking of production processes, and today offers a range of mature and repeatedly proven products for this purpose. The modularity of ENGEL's inject 4.0 approach makes it especially easy for plastics processors to utilise the new possibilities. Even individual solutions like iQ weight control provide a huge benefit.

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European standard and American law

There are many similarities between European and American standards. Nevertheless, there are differences to be noted: The Americans have higher documentation requirements, and the logical grouping of documents is also unknown in EN ISO 13485. Conversely, the European focus on customer satisfaction and continuous improvement of the QM system goes beyond the requirements of 21 CFR part 820. Furthermore, there are significant differences in the handling of complaints and the reporting system. The FDA does not accept ISO 13485 certification as proof of compliance with the requirements of 21 CFR part 820. In contrast to ISO 13485, there is also no certification according to 21 CFR Part 820.

Intelligent assistance systems, which make production even more predictable, reliable and stable, open up new opportunities. In the manufacture of medical technology, they require new approaches in order to integrate them into the rules and regulations accepted by the auditors.

The control of the injection moulding machine is becoming increasingly intelligent. With the help of assistance systems such as iQ weight control, the injection moulding process is continuously self-regulating.

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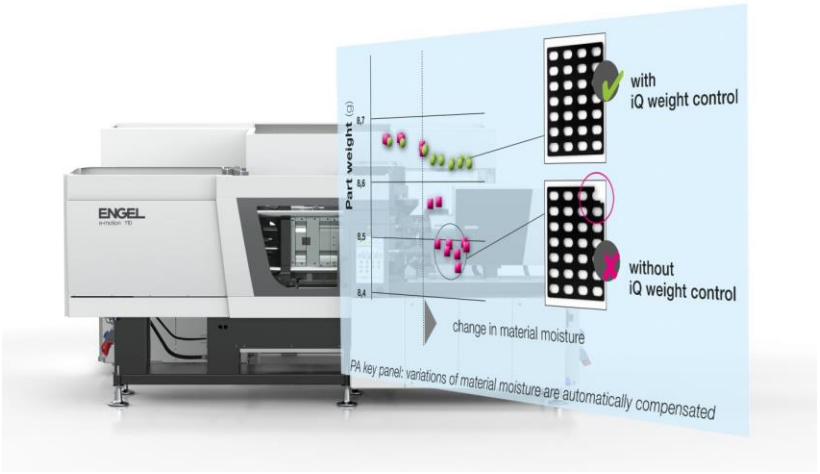
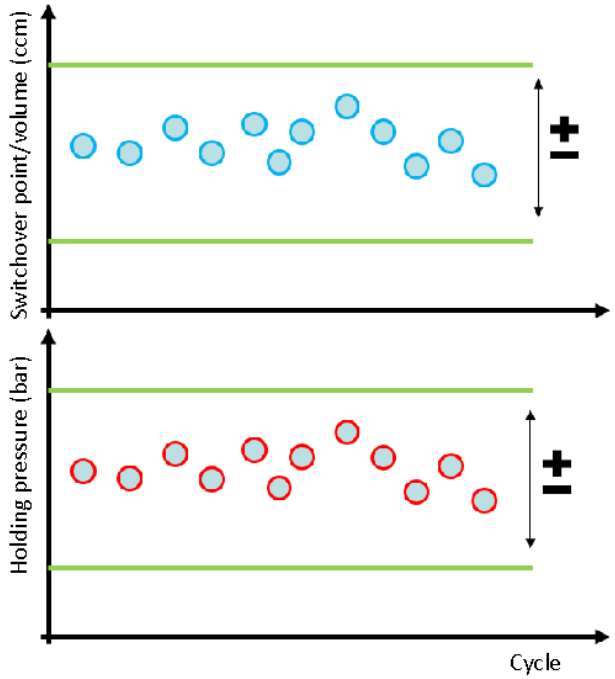


iQ weight control by ENGEL automatically compensates for fluctuations in raw material and ambient conditions even before rejects are produced.

A wide variety of factors influence the consistency of the injection moulding process and thus the quality of the end product.



The key for the validation of processes with dynamic control lies in the definition of process windows for the adjustable process parameters.

Pictures: ENGEL