

Press release

Making all procedures and changes in the production process paperless and traceable with a production-related IT solution

Quality assurance in MedTech companies with MES/MOM solution from iTAC

Montabaur, June 1, 2022 – In medical engineering, extraordinarily high demands are placed on quality and strict regulations apply. In addition, the demand for medical products is rising steadily, due in part to the Covid 19 pandemic. As a result, manufacturing processes are under time pressure, which can affect the defect rate of products and have serious consequences. Quality management (QM) in MedTech companies therefore plays a major role. By using a production-related IT solution, i.e., an MES or MOM, the requirements for complete documentation and traceability can be met reliably and in compliance with guidelines. iTAC Software AG (www.itacsoftware.com) supports these tasks with the iTAC.MOM.Suite.

"The production of medical products is governed by strict regulations and requirements. In addition, the new Medical Device Regulation (MDR), which became effective in Europe in 2021, imposes even higher standards for the QM system of medical technology companies and increases the pressure. This requires appropriate strategies and solutions on the manufacturer side in order to be able to withstand the increasing regulatory requirements in the market and to compete effectively," explains Martin Heinz, management board of iTAC Software AG.

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Compliance: Manufacturing according to regulations

MES/MOM solutions reliably support seamless documentation and traceability in medical technology production and ensure compliance with regulatory guidelines. For example, processes such as the installation of components with serial numbers or the use of test equipment during production must be documented in detail and the corresponding requirements must be met.

"Without a supporting MES, all steps in the production of a medical device are processed and documented on paper. In the production of blood analysis instruments, for example, each work step and each component must be recorded on paper documents, which are then integrated into a manual and time-consuming approval process. If the test requires any necessary rework, this also must be documented manually again and all documents have to be archived afterwards, which can delay the entire manufacturing process by weeks," explains Martin Heinz.

The iTAC.MOM.Suite is a holistic manufacturing management system that provides all the necessary features for digital worker management, process automation and traceability of serialized products in a validated manner. The MES/MOM solution is used in production facilities in the pharmaceutical and medical industries to meet the specific requirements of international and national standards and guidelines and to guarantee the market a flawless, safe product.

With features such as material management including setup control, process interlocking, tool and test equipment management – embedded in a worker management system – the iTAC.MOM.Suite ensures that production only conforms to specifications and that all specified work and test steps are actually carried out. This reduces the time and effort required for approval processes, subsequent assembly and repairs.

Identify and eliminate quality problems in real time

"With Active Traceability, our MES/MOM solution ensures that quality problems in the production processes can be detected in real time, causes can be analyzed and corrective measures can be systematically and promptly evaluated in a continuous improvement process. All production information is made available to the worker in the process in real time. In addition, this data is

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provided in different levels of aggregation to various functional areas of a company – even up to the management level.

In the event of a callback, the product, including batch and serial numbers, can be traced back from the manufacturer to the customer. What is considered a standard function in the iTAC.MOM.Suite represents a decisive competitive function for medical manufacturing companies," explains Martin Heinz.



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About iTAC

iTAC Software AG, an independent company of the mechanical and plant engineering firm Dürr, provides internet-enabled information and communication technologies for the manufacturing industry. Founded in 1998, the company is one of the leading MES/MOM providers. The iTAC.MOM.Suite is a holistic Manufacturing Operations Management that is used worldwide by companies in different industry sectors such as automotive, electronics/EMS, telecommunication, medical engineering, metal casting and energy. Additional services and solutions for implementing IIoT and Industry 4.0 requirements complete the portfolio. iTAC Software AG is headquartered in Montabaur, Germany and has offices in the USA, Mexico, China and Japan and has a worldwide partner network for sales and service. iTAC's philosophy is to connect people, data and systems.

The Dürr Group is one of the world's leading mechanical and plant engineering firms with extensive expertise in automation and digitalization/Industry 4.0. Its products, systems and services enable highly efficient and resource-saving manufacturing processes in different industries. The Dürr Group supplies sectors like the automotive industry, mechanical engineering, chemical, pharmaceutical, medical technology and woodworking industries. It generated sales of € 3.54 billion in 2021. The company has around 17,800 employees and 120 business locations in 33 countries.

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