White Paper | January 2020

WE CREATE SMART FACTORIES

MES Solution for the Medical Technology

Standard Software Facilitates Regulated Manufacturing Processes

Figure 1: HYDRA for Life Science offers a wide range of standard functions for regulated manufacturing companies (Source: MPDV, Adobe Stock, Gorodenkoff)

Standard Software Facilitates Regulated Manufacturing Processes

The medical technology industry and other regulated industries face two key challenges: producing efficiently while complying with a wide range of requirements, including data integrity. The use of suitable software is almost compulsory. With the new solution HYDRA for Life Science, MPDV supports regulated manufacturing businesses to master the two big challenges.

Apart from the regulatory requirements, most medical technology manufacturers and suppliers are quite ordinary manufacturing companies. They process plastics, metal, paper and other raw materials to products with the highest quality standards. Therefore, it is hardly surprising that a production IT like the Manufacturing Execution System (MES) is perfect to integrate and service standard production processes. An integrated MES can also meet additional requirements such as traceability, data integrity and special processes and terminology. However, the number of providers is dwindling when it comes to providing actual standard applications.

At the same time, the validation of process software – including an MES – with ISO 13485:2016 has become a mandatory requirement. Also, regulated manufacturers must operate a quality management system in accordance with this standard in order to pass the usual audits of FDA inspectors.

Production IT for medical technology manufacturers and their suppliers

The new business solution HYDRA for Life Science (Figure 1) is based on the globally and interdisciplinary used MES HYDRA by MPDV. Many of the available functions can be configured or parameterized so flexibly that it is also possible to implement requirements that usually only occur in regulated industries. This includes in particular the Audit Trail and the integrated authorization concept, which enables manufacturing companies to safeguard data integrity across the entire value chain. HYDRA for Life Science also provides the necessary software support for the CAPA process (Corrective and Preventive Actions) and helps to manage the training for production-related employees. HYDRA for Life Science also supports the risk management with an integrated FMEA list.

Typical fields of applications

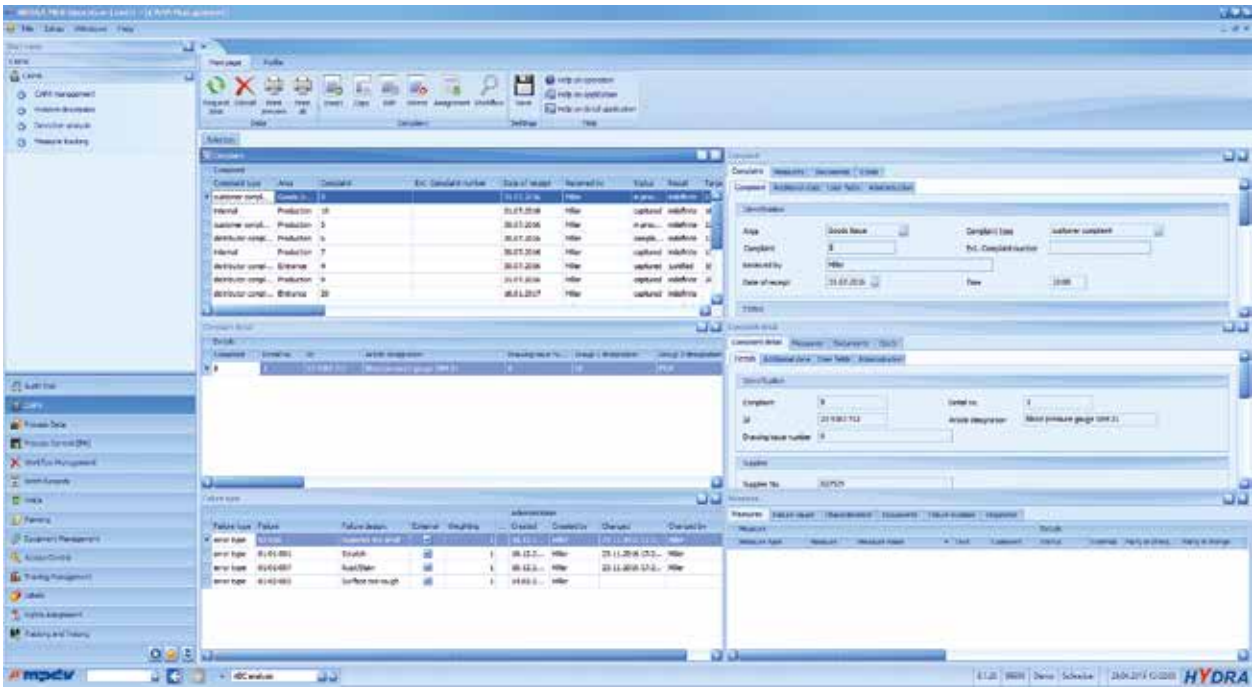
Support of the CAPA process

Regulatory requirements dictate that companies working in the Life Science sector identify and solve problems in the manufacturing process and product at an early stage. These requirements are set out in ISO 13485, 21 CFR 820 and ISO 9000. Both FDA inspectors and ISO auditors have an eye on whether companies are using the CAPA process to identify, analyze, correct and address quality issues. Manufacturing companies can also reduce both rework and scrap.

With CAPA management, HYDRA for Life Science offers the opportunity to record problems in detail (Figure 2). In-depth analysis can detect key problem areas and take measures (Figure 3). The traceability function supports the user perfectly in their efforts to remove and stop problems. HYDRA for Life Science can inform personnel via workflows about generated measures including deadlines.

Figure 3: Extensive analysis of failures with HYDRA for Life Science (Source: MPDV)

Figure 2: Software support of the CAPA process with HYDRA for Life Science (Source: MPDV)

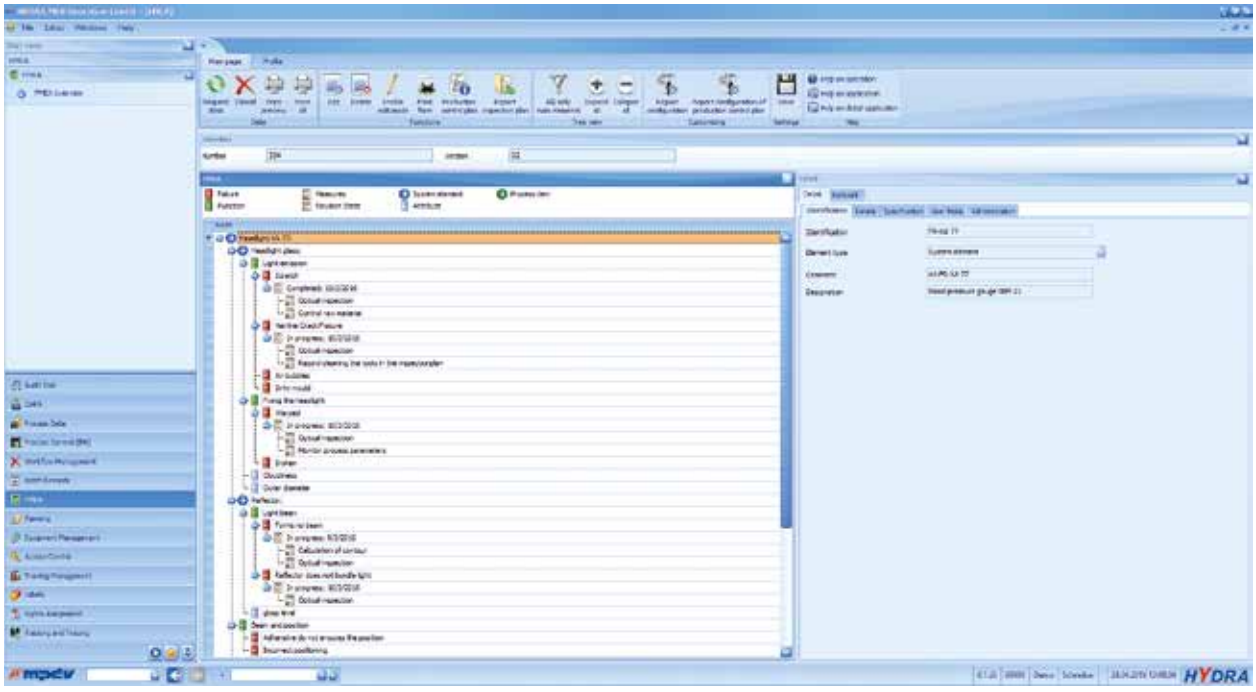


Quality risk management with FMEA

In the Life Science sector, purity and reliability of the manufactured products are indispensable. ISO 13485 and 21 CFR 820 requires businesses to use the risk management. A risk management system is intended to support businesses in maintaining high quality standards for their products and thus to avoid risks for patients and users.

HYDRA for Life Science supports with their application for Failure Mode and Effect Analysis (FMEA) a targeted method to detect failures as early as possible. The creation and analysis of failure nets helps this process. The risks arising from the defects can be assessed using key figures, including the severity of the defect sequence, the probability of occurrence of the cause and of detecting a defect. In addition, countermeasures can be defined and traced.

Figure 4: Quality Risk Management with FMEA in HYDRA for Life Sience (Source: MPDV)



Typical fields of applications

Complete documentation of the manufacturing process

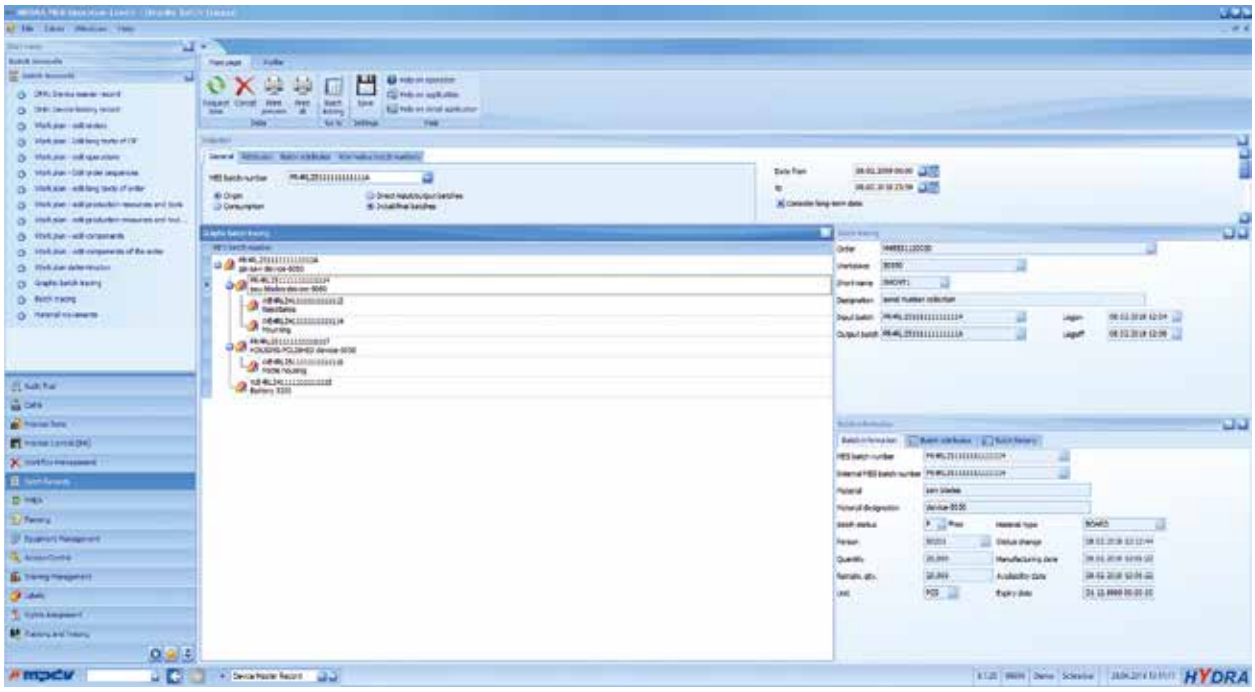
21 CFR Part 11 outlines the requirements to the documentation of the manufacturing process. Key message: The manufacturing process of a medical product must be documented completely. Additional information on the manufacturing process can also be included in the documentation. In addition to the work plans used to create the production orders, this usually includes inspections and releases – both for the work plans themselves and for the product manufactured.

HYDRA for Life Science collects numerous data during a production run. This allows the following questions to be answered:

- Which workplaces and machines were used for production?
- Who has carried out which inspection step?
- How many pieces were produced?
- Which material batches or which parts were used with what serial numbers? (Figure 5)
- The manufacturing process was run on what work plan?

The collected data are used to document manufacturing processes based on the electronic Device History Record (eDHR) or the electronic Batch Record (eBR). In order to reduce the likelihood of errors in the data contained in the documentation, manual data entry should be avoided wherever possible. Functions from our HYDRA machine data module (MDE) support you in that effort by automatically collecting data from your production sites.

Figure 5: Documentation of used material and traceability with HYDRA for Life Science (Source: MPDV)



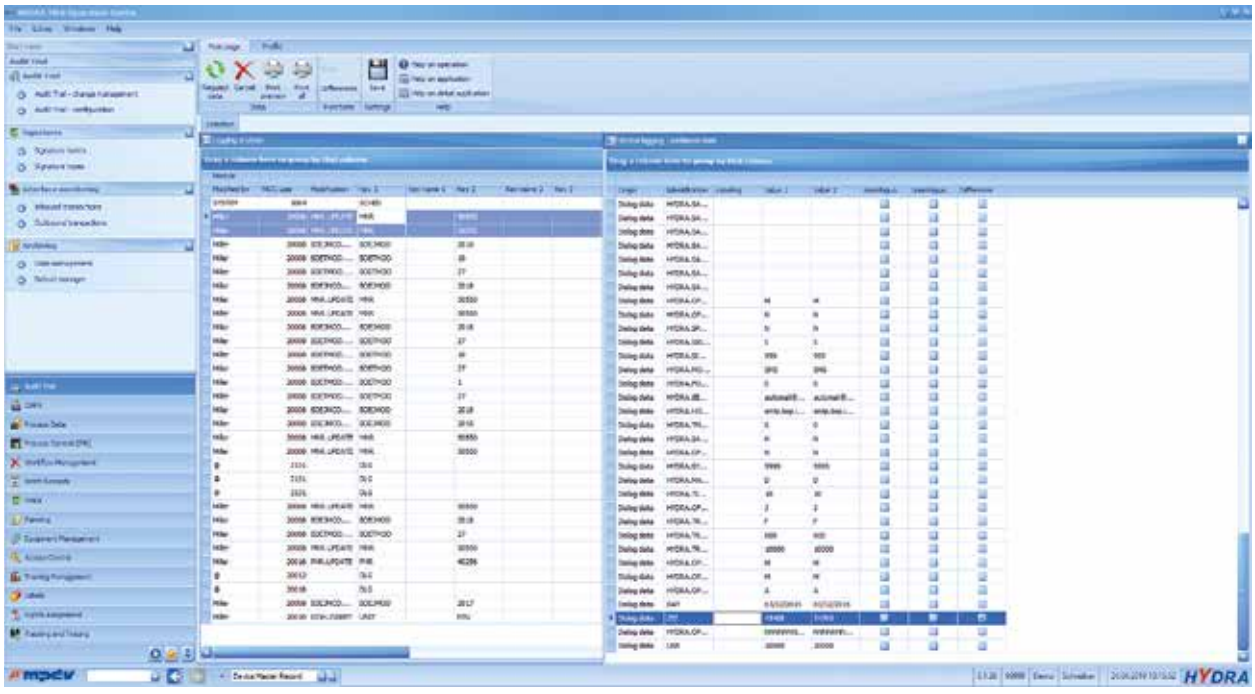
Audit Trail

Audit Trails are requirements to regulated manufacturing companies by the EU GMP Annex 11 and 21 CFR Part 11. An Audit Trail attempts to completely trace all actions of the system user. In case of a conflict, the actions that led to the onset of the problem can be traced. The Audit Trail must be compliant and secure with regards to data integrity. Any intentional or unintentional manipulation must be identifiable. The following requirements are set for an Audit Trail (see ALCO+, info box):

- The creating, changing and deleting of data sets are logged.
- A changed record must not overwrite the original record, but must be depicted as a new entry in the Audit Trail.
- Audit Trails must be stored over a long term.

HYDRA for Life Science supports the user complying with all requirements. The system collects and stores data and logs who has made entries or changes. User-friendly functions, such as highlighting differences between two data sets, can help the user with the analysis.

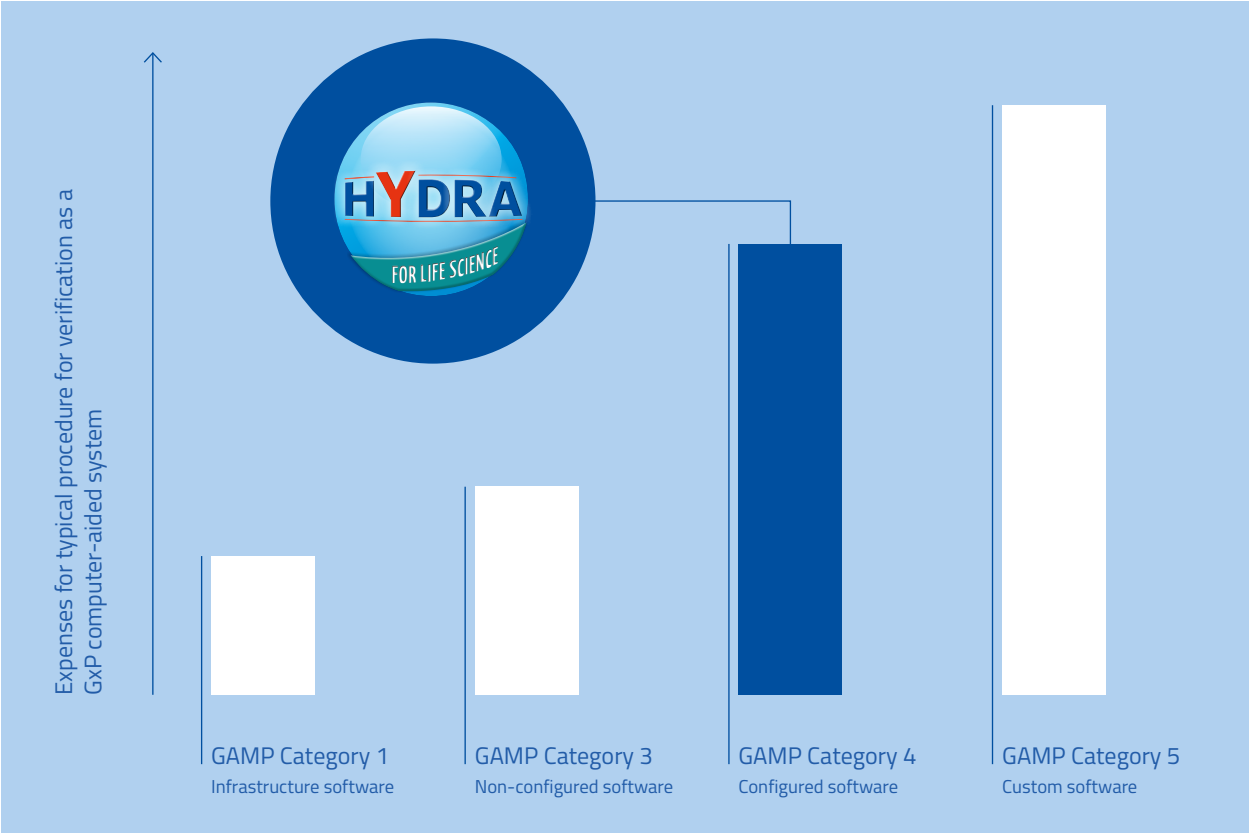
Figure 6: Audit Trail in HYDRA for Life Science supports data integrity (Source: MPDV)



Focus on standard functions

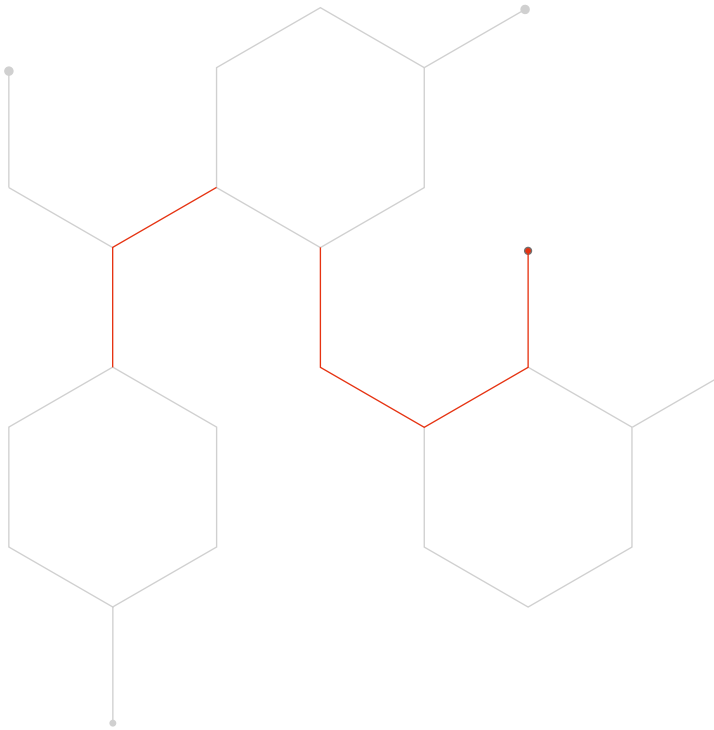
In addition to the functions configured specifically for the regulated market, MPDV's industry solution offers a wide range of applications in compliance with VDI Guideline 5600, which are now used by over 1,250 companies worldwide in a variety of configurations. The functional portfolio ranges from data collection in the shop floor to detailed evaluations of all kinds and the planning of orders, resources and personnel deployment. The documentation of the complete manufacturing process in line with traceability is also part of the standard range of functions. Complemented by applications for quality assurance and personnel management, HYDRA for Life Science makes an enormous contribution to more transparency and efficiency in the shop floor. The system is a standard software as HYDRA is used by a broad range of customers due to its configurability. Therefore, the software can be classified in the GAMP software category 4 "Configured products" (Figure 7). This greatly simplifies the standard procedure for verification as a GxP computer-aided system compared to customer-specific applications (GAMP category 5). It is also beneficial that MPDV operates a quality management system (QMS) which is certified according to DIN EN ISO 9001:2015.

Figure 7: Comparison of the costs for a typical validation as a GxP computer-aided system based on GAMP 5 guidelines (Source: MPDV)



Additional support during the validation process

MPDV also supplies an extensive package of documentation and specification of the standard software. The HYDRA functions for Life Science include GAMP 5 requirements and thus support the manufacturing companies in the validation process. MPDV's experts have successfully accompanied corresponding validation processes with various HYDRA users worldwide.



ALCOA+

ALCOA+ refers to mandatory requirements for data integrity:

A for **Attributable** = Data must be traceable to the person who has collected the data.

L for **Legible** = Data must be readable, even after years in an archive.

C for **Contemporaneous** = Data must be traced back to the recording time.

O for **Original** = Data must kept in the original stage (no overwriting when changes are made).

A for **Accurate** = Data must be absolutely correct.

\+ for other requirements relating in particular to digital data integrity:

Complete = Data must be complete (Evident by the Audit Trail)

Consistent = Data must be consistent (Evident by the Audit Trail).

Enduring = Data must be permanently legible (General data format).

Available = Data must be available at all times (Access to archive).

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About

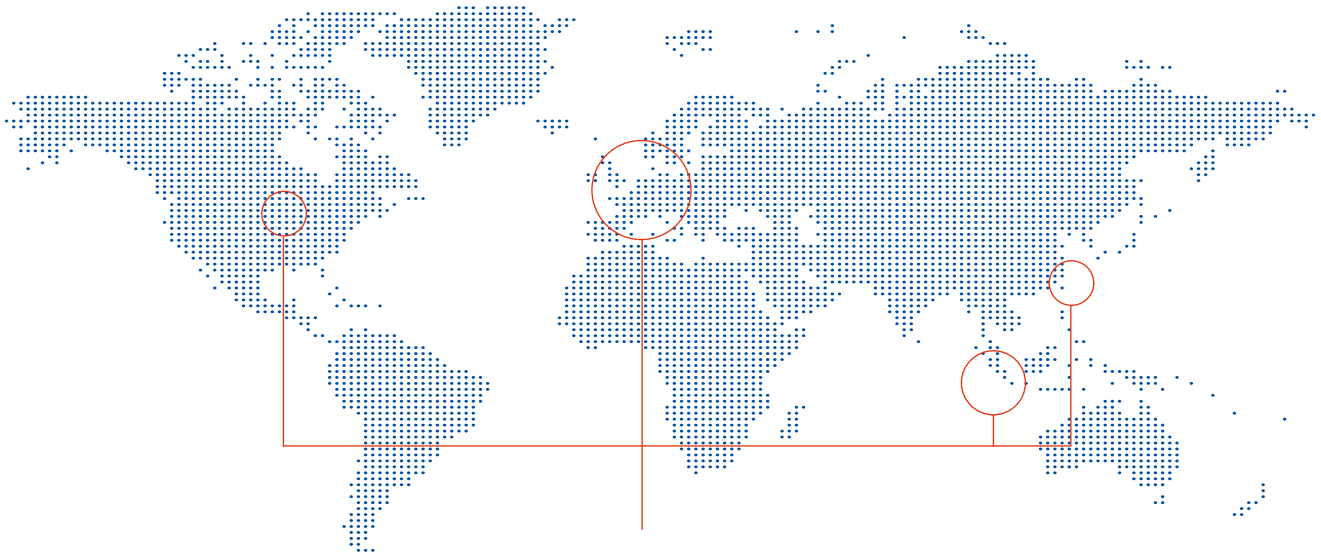
MPDV Mikrolab GmbH

headquartered in Mosbach, is the market leader for IT solutions in the manufacturing sector. With more than 40 years of project experience in the manufacturing environment, MPDV has extensive expertise and supports companies of all sizes on their way to the Smart Factory. Products such as MPDV's Manufacturing Execution System (MES) HYDRA or the Manufacturing Integration Platform (MIP) enable manufacturing companies to streamline their production processes and stay one step ahead of the competition. More than 800,000 people in over 1,250 manufacturing companies worldwide use MPDV's innovative software solutions every day. This includes well-known companies from all sectors. MPDV employs around 420 people at eleven locations in Germany, China, Malaysia, Singapore, Switzerland, and the USA.

MES HYDRA

MPDV's MES HYDRA provides a 360° view of all resources involved in production and can also seamlessly map cross-processes. HYDRA serves as a link between production (shop floor) and the management level (e. g. ERP system). With the system, production-related data along the entire value chain can be recorded and evaluated in real time. If the production process is delayed, employees recognize this immediately and can initiate targeted measures. HYDRA has a modular structure and, with its extensive range of functions, completely covers the requirements of VDI Guideline 5600.

HYDRA has already received several awards and supports users worldwide in producing more efficiently.



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