

A person in a white cleanroom suit is seated at a workstation, looking at two computer monitors. The monitors display complex software interfaces with various data fields, tables, and charts. In the background, another person in a similar suit is visible, working at a different station. The environment is a clean, brightly lit industrial or laboratory space with various pieces of equipment and machinery.

## **HYDRA for Life Science**

*Production IT for the Medical Technology  
and other Regulated Industries*

**Digitization** in production is unstoppable  
Companies who want to produce **compliant with regulations** need a  
Manufacturing Execution System (MES).

With manufacturing IT like an **MES** you can **keep an eye on all resources**  
and also design your production processes as **efficiently** as possible.



Why an MES?

**Medical technology** and other **regulated branches of industry** set special requirements to manufacturing IT. HYDRA for Life Science by MPDV observes **regulatory** requirements and also copes with **economical** challenges.

To achieve this, the solution has all the **standard functions** of a classical MES in addition to industry-specific applications.



**Why do you need  
an industry solution?**

The background image shows two workers in white cleanroom suits and masks, working in a high-tech industrial environment. They are positioned in front of a complex piece of machinery with various control panels, buttons, and indicator lights. The worker on the left is gesturing with their hand while talking to the worker on the right, who is looking at the machinery. The scene is brightly lit, typical of a cleanroom or laboratory setting.

## What distinguishes HYDRA for Life Science

Manufacturing companies in regulated industries are caught between **regulatory** requirements and significant **market pressure**.

In Life Science environments more than anywhere else, patient safety is top priority. Resource efficiency is also of paramount importance.

HYDRA for Life Science by MPDV can integrate **all process steps in one system** and offers a **general overview**.

At the same time, the solution provides support for the **validation** of manufacturing processes (e.g. FDA).



**HYDRA for Life Science  
market requirements**

## Regulated manufacturing companies face many challenges:

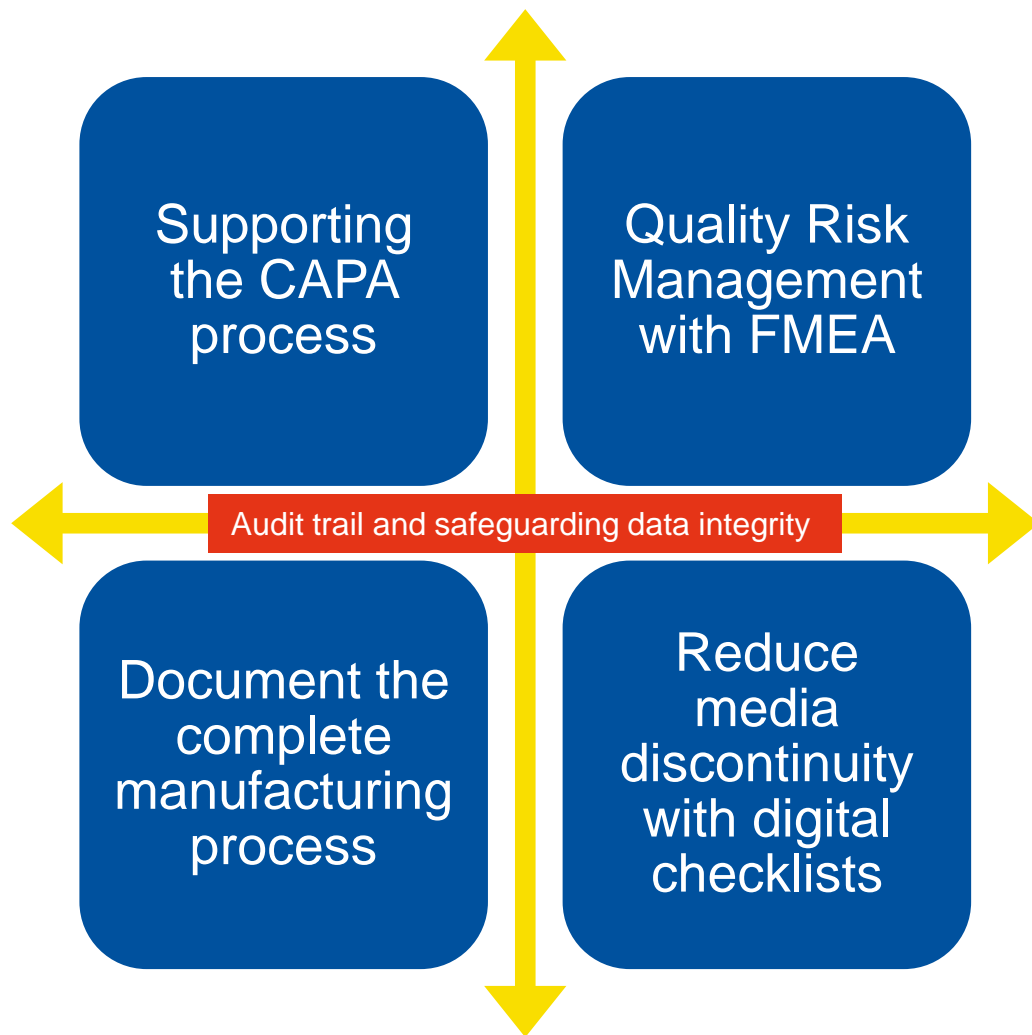
- Ensure data integrity (ALCOA+)
- Completely document MBR, EBR and DMR & eDHR.
- Live the CAPA process consequently
- Maintain measures & quality risk management

## Regulated manufacturing companies generally have two options to accomplish this:

- Certification according to DIN EN ISO 13485
- Setting up a QMS according to DIN EN ISO 14971



**Regulatory requirements**



HYDRA for Life Science records **all information** along the **complete** value chain, **documents** all relevant actions and ensures **data integrity**.

Typical use cases in the Life Science environment

# HYDRA for Life Science can ...

- ... detect and document deviations.
- ... initiate and track measures.
- ... support to eliminate and to prevent deviations.
- ... promote a consistent communication and documentation with workflows.



**Support the CAPA  
process**

# With HYDRA for Life Science, you can ...

- ... identify failures at an early stage.
- ... evaluate risks with key figures.
- ... document and analyze correlations with failure networks.
- ... specify measures to correct and prevent failures.



## Quality Risk Management with FMEA

## HYDRA for Life Science can ...

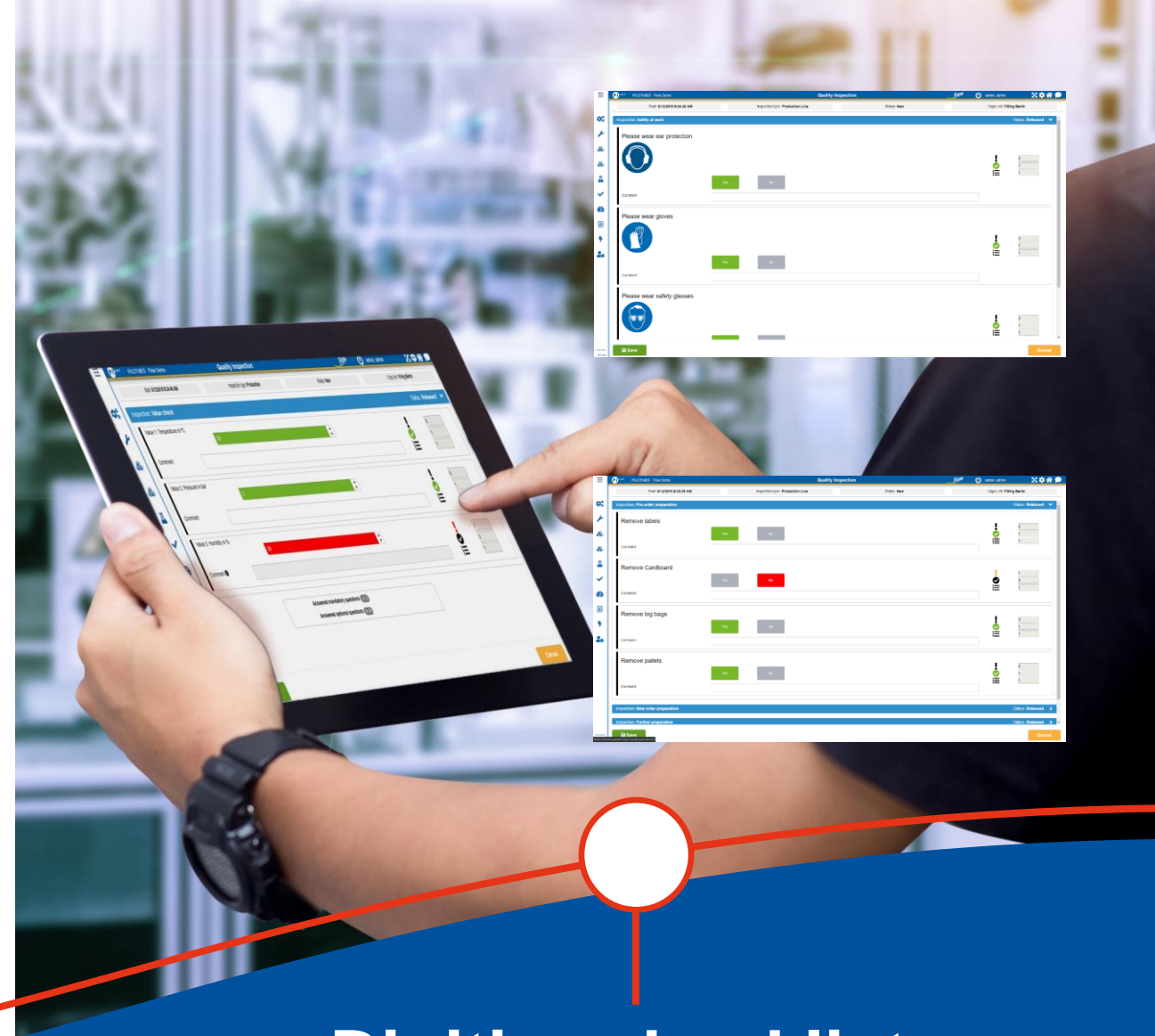
- ... collect and save all data.
- ... document material consumption and the use of machines and tools.
- ... verify personnel assignment in form of a qualification check.
- ... ensure traceability.
- ... Generate eDHR or eBR.



**Document the  
manufacturing process**

# With HYDRA for Life Science, you can ...

- ... easily digitize paper-based checklists.
- ... simply develop questionnaires.
- ... ensure the execution of tasks and checks.
- ... document results transparently.



## Digitize checklists

# HYDRA for Life Science supports you to ...

- ... fulfill GxP requirements according to ALCOA+.
- ... document each time data is changed.
- ... ensure that changes are assigned to the person who executed them.
- ... prove data integrity during audits.



**Audit Trail: ensure data integrity**

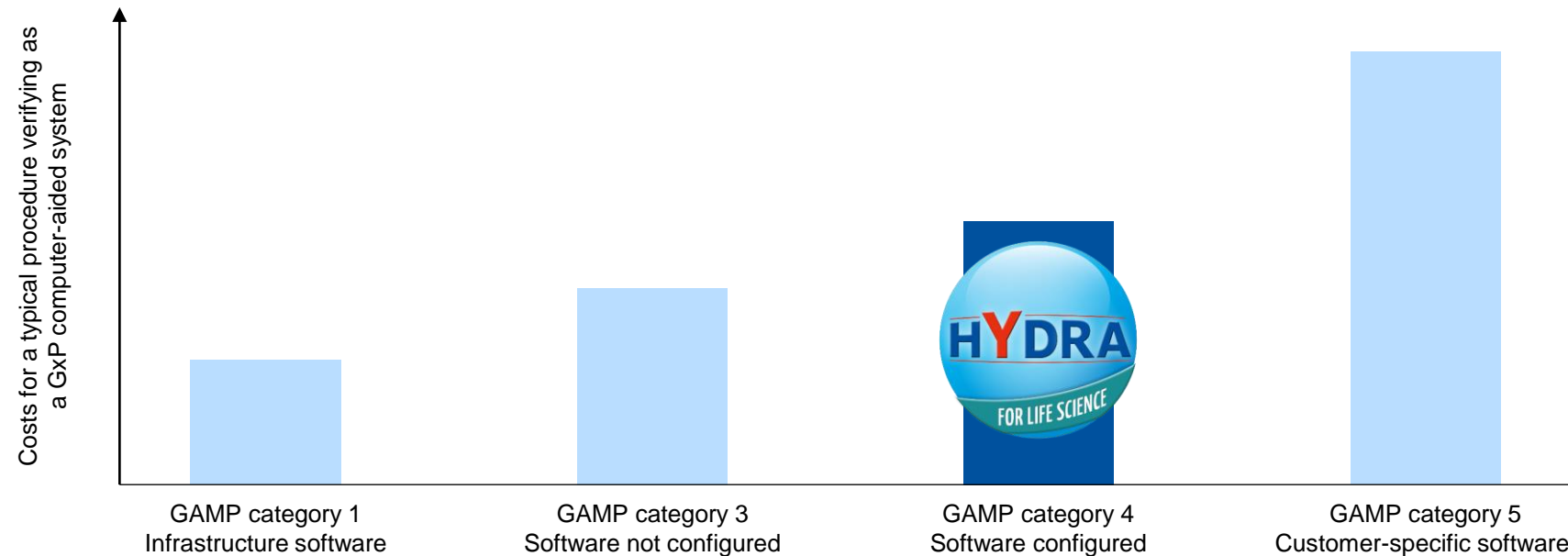
Functions of the HYDRA for Life Science industry solution from MPDV incorporate **GAMP 5 requirements** and thereby support manufacturing companies in validation.

We have already successfully assisted various HYDRA users in the **validation of their processes** (e.g. FDA).



Meet regulatory  
requirements

Due to the high proportion of **standard functions**, HYDRA for Life Science can generally be classified in the **GAMP category 4** (configurable software), which reduces validation efforts compared to individual software solutions.



**Verification as GxP  
computer-aided system**

A person wearing a white cleanroom suit is working in a laboratory. The laboratory is filled with various pieces of equipment, including glass-enclosed cabinets and machines. The person is standing in the foreground, facing away from the camera, and appears to be working on one of the machines. The background shows more equipment and a clean, bright environment.

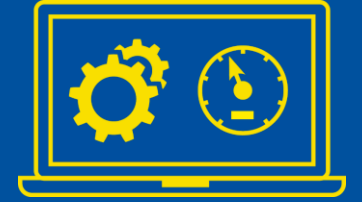
## Main advantages of HYDRA for Life Science



Efficient  
**resource  
management**



Keep an eye on all  
**process steps**



Easily calculate  
**KPIs**



Maximum  
**data integrity**



Ensure  
**traceability**



Fulfill  
**regulatory  
requirements**

**Features**  
**HYDRA for Life Science**

A photograph of a modern industrial building complex. The main building is white with blue accents and multiple windows. To the right, a taller building has a blue facade with the MPDV logo. In the foreground, there is a small pond and a paved area. A red line with a white circle at the end is overlaid on the image, pointing towards the text box.

## About MPDV

WE CREATE SMART FACTORIES





**Market  
leader**

for IT solutions in production



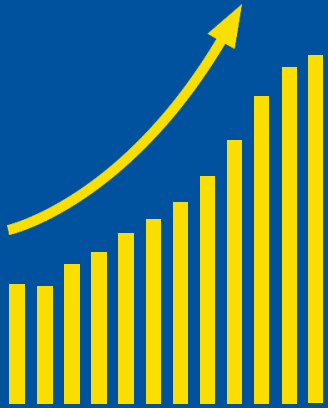
Over  
**45 years**  
project experience



We are at your side on the way to the Smart Factory

**regardless** of  
your **size** and **industry**

**Who are we?**



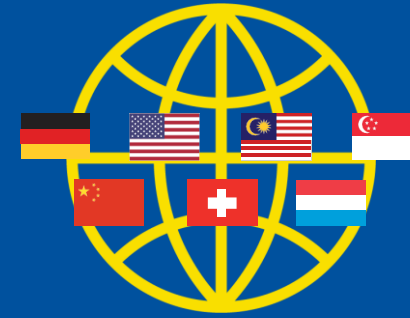
**73 Mil**

Euro group turnover



**520**

Employees



**13**

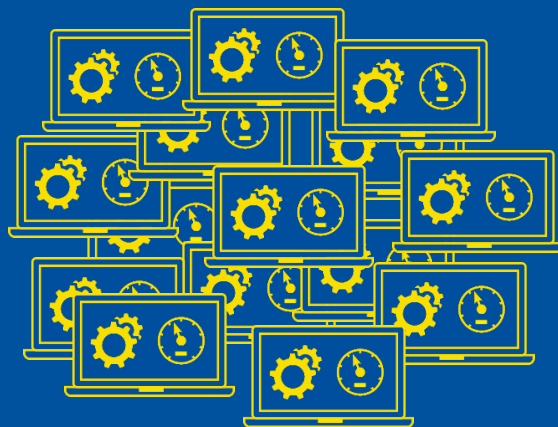
Locations worldwide

**Basic Information**



**100,000**

Machine connections  
worldwide



**1,100,000**

People work with MPDV  
systems every day



**1,750**

Installations

**Basic Information**

# Want to find out more about HYDRA for Life Science?



*WE CREATE SMART FACTORIES*



[www.mpdv.com](http://www.mpdv.com)



[info@mpdv.com](mailto:info@mpdv.com)



[+49 6261 9209 101](tel:+4962619209101)



**Contact**