



HYDRA X
Regulatory & Compliance Management

HYDRA X

"Every time an **audit** approaches, we are in a state of emergency. We gather up **paper files**, explain changes, and check signatures. We **live in constant fear** that a **missing piece of documentation** will be our downfall."

"Our production processes must comply with strict regulations, however a lot of data is still generated in **isolated systems** or even **manually**. Finding out who changed what and when often requires a **great deal of effort**, which costs **time** and **patience** and undermines **confidence**."

"**Electronic signatures** have long been a twilight zone for us. Are they really **audit-ready**? Is the approval clearly assigned? This uncertainty is something we deal with every day, especially in critical approval processes."

"We should actually be focusing on **quality and efficiency**. Instead, regulatory issues predominate our day-to-day work. We do not consider **FDA or customer audits** as routine inspections, but as a **real business risk**."



Your Issue



- **Central, digital data basis** for all audit-relevant production and quality data
- **Automatic, comprehensive audit trails** documenting every change in an audit-proof manner
- **Electronic signatures and clear role-based rights**, technically secured and not only regulated
- **End-to-end digital processes** avoiding paper, media disruptions, and data silos
- **Standardized validatable systems** facilitating audits instead of turning them into a risk



Our Solution



- Support in **complying with** regulatory requirements
- **Compliance** according to FDA 21 CFR Part 11, EU-GMP (incl. Annex 11) and ISO 13485
- Structured **control** of manufacturing processes
- Generating electronic logs, audit reports, and production data "at the **push of a button**"
- Strict process and operator guidance in a closed system **ensuring** compliance with regulatory requirements



HYDRA X

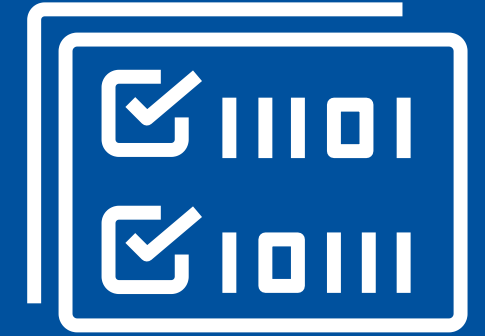
Regulatory & Compliance Management

- **Building confidence in production data** by ensuring integrity, completeness, and traceability in the long run
- **Reducing manual effort and errors** through standardized and digital processes
- **Making audits manageable** by meeting regulatory requirements in a continuous and traceable manner
- **Ensuring clear responsibilities** by means of uniquely documented approvals, changes, and accesses
- **Focusing on quality and efficiency:** Compliance is not seen as a business risk, but as an integral part of everyday production



Your Benefits

- Centralized, system-supported **organization and execution** of manufacturing instructions, which helps standardize and reliably manage processes
- **End-to-end digitalization** of all manufacturing and documentation processes replacing paper-based workflows and media disruptions
- **Complete tracking and tracing** of batches, actions, and changes throughout the entire manufacturing process
- Significantly **reduced administrative effort** thanks to automated documentation, reports, and analyses
- **Standardized** manufacturing processes with **less errors** reducing the workload on employees and increasing process reliability
- **Measurable efficiency gains** in batch documentation and verification, including real-time analysis
- Improved **product and process quality** through transparent and consistent data available at any time
- High **regulatory reliability** with electronic signatures, four-eyes-principle, and approvals, as well as audit and inspection capability at short notice and clearly reduced compliance risks



Your Benefits in Detail

With HYDRA X **Regulatory & Compliance Management**,
you fulfill requirements such as
audit trails, electronic signatures, and data integrity:
end-to-end and traceable.

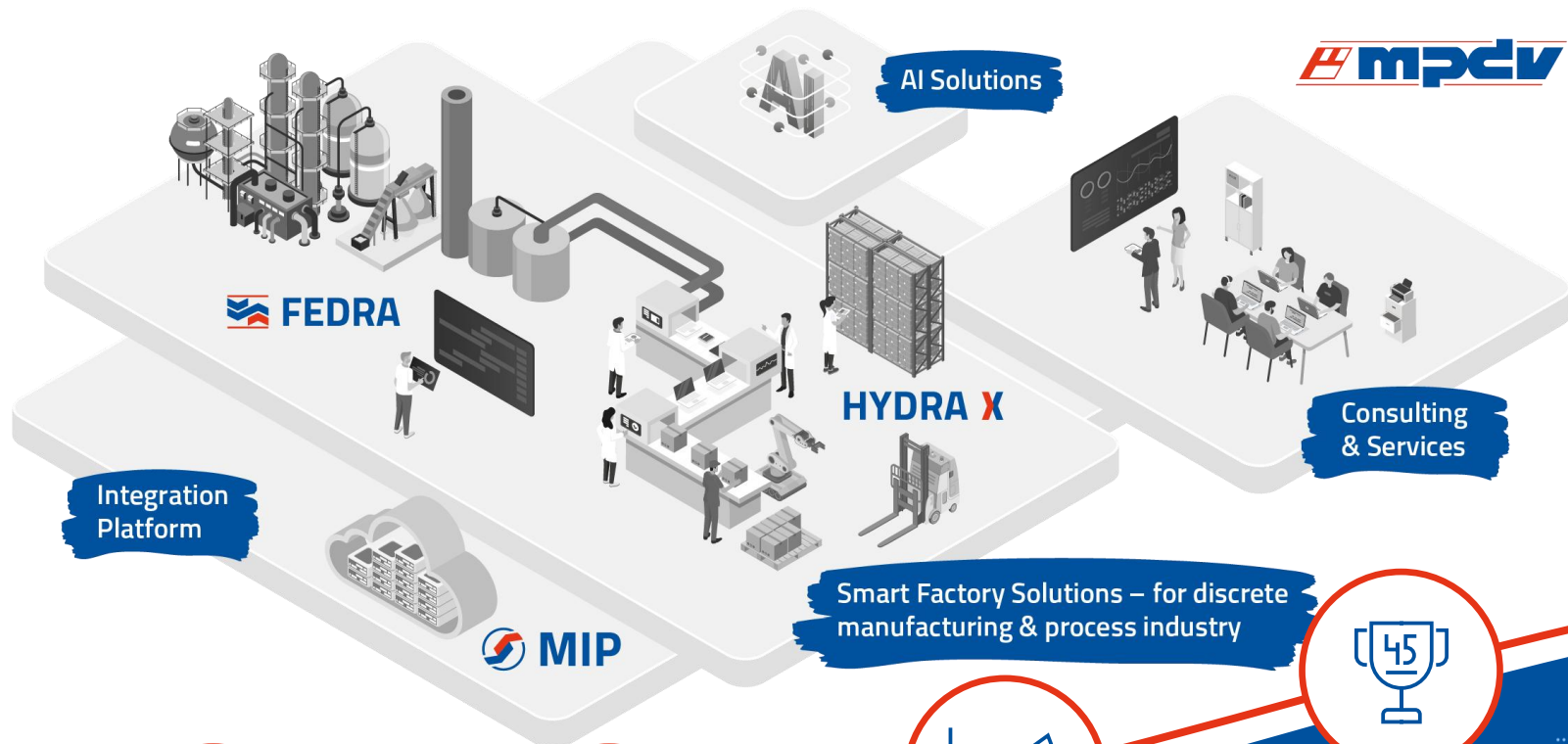
Compliance is no longer an organizational risk, but a
technically secured standard
in day-to-day production.



Get Started Now!

A photograph of a modern industrial building complex. The main building is white with blue accents and a large glass entrance. To the right, a blue-roofed structure features the MPDV logo. A small pond is in the foreground. A white box with the text 'About MPDV' is overlaid on the left side, connected to a blue circle by a red line.

About MPDV



people work with our solutions every day

1.485.000

installations in all industries

2.430



Worldwide present



530
employees



80 Mio.
euros group turnover



45
years in the market & market leader for manufacturing IT



Would you like to find out more about Regulatory & Compliance Management?



WE CREATE SMART FACTORIES



www.mpdv.com



info@mpdv.com



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



Contact