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FROM LAB BENCH TO BATCH RECORD

HOW HELBLING'S DIGITAL TWIN MODEL IS REWRITING THE RULES OF R&D

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In the rapidly evolving world of pharmaceutical and life sciences, the boundaries between research, development, and manufacturing are being redrawn. At the centre of this shift is Helbling, whose Closed Loop Manufacturing (CLM) model is changing how laboratories transition from experimentation to full-scale production. The concept introduces a new level of continuity, connecting every stage of product and process design through a single digital framework.

For Sébastien Martin, Head of Digital Transformation at Helbling, this evolution is not about adding technology for its own sake, but about creating meaningful integration. "We aim to position ourselves as the interface between senior management, business, and technology," he explains. "Our goal is to provide end-to-end digital solutions that allow organisations to think holistically about how products are designed, developed, and ultimately produced."

Helbling's CLM model builds on the idea of the digital twin: a precise, data-driven replica of the laboratory that mirrors every process, parameter, and output in real time. In doing so, it bridges the historic divide between research and manufacturing, two areas that have often operated in isolation. While the use of digital twins in product development is well established, applying the same concept to process design and industrialisation marks a fundamental shift.

Sébastien points out that while many industries have used digital tools for product design since the 1990s, few have extended this thinking to the process itself. "What has changed in recent years," he says, "is that companies are starting to use digital tools to design the process itself. CLM defines how to digitally design processes and link them directly to the product. This creates a seamless transition from development to operations."

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The model's strength lies in its ability to provide a consistent data thread from laboratory research to full-scale production. It eliminates the traditional disconnect between departments and replaces fragmented documentation with a single, dynamic environment where every action is captured, verified, and shared. For the pharmaceutical sector, where delays and inefficiencies in tech transfer can be costly, this represents a step change in capability.

At the heart of CLM is the Bill of Process (BOP), described by Sébastien as the "missing link between formulation and manufacturing." The BOP captures each stage of production, detailing machines, configurations, inspection plans, quality checks, and operational sequences in a structured, object-based format. "The Bill of Process starts by structuring the manufacturing process," Sébastien explains. "It attaches all the additional supporting elements needed to execute those steps, from machine setups to quality processes. Built in an object-based way, it becomes the backbone of the digital twin of the process."

Rather than existing as static documentation, the BOP serves as a living foundation for simulation, validation, and automation. It enables scientists and engineers to build digital workflows long before physical production begins. In early stages, the model remains production-site agnostic, allowing flexibility in design. As the process matures, it can be tailored to specific production lines, creating a pre-validated bridge between development and operations. The result is a digital ecosystem where every step can be tested, modified, and approved with full traceability.

This approach also tackles one of the industry's most persistent challenges: the handover between process development and manufacturing. In many organisations, the transition between these two stages is prone to miscommunication and rework. Helbling's model removes this friction by embedding manufacturing parameters,

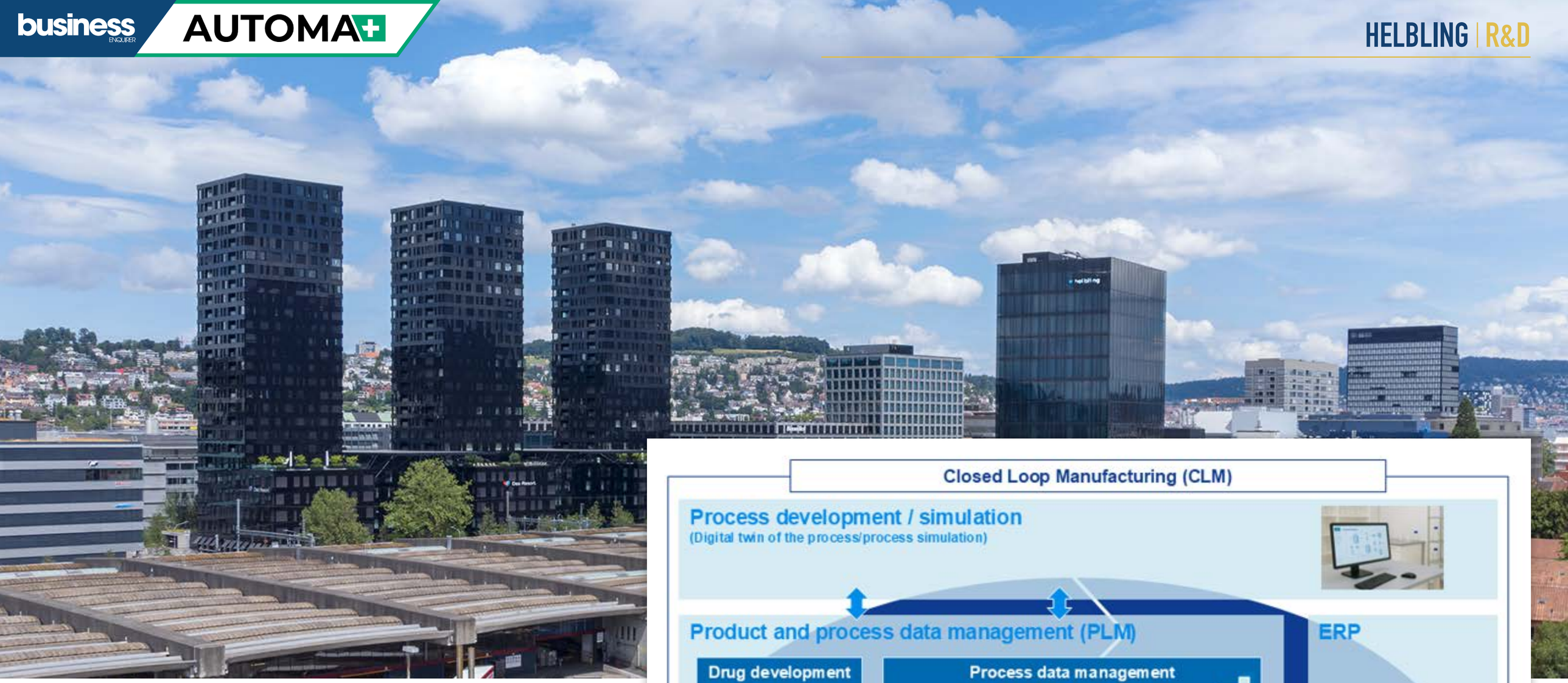
testing protocols, and machine recipes into the process design itself. “By pre-loading what operations need very early in the process, the handover becomes almost obsolete,” Sébastien says. “The process designer can already design the manufacturing process in a way operations need it. All the recipes, machine parameters, and test methods are predefined and digitally available.”

For companies adopting CLM, the benefits are clear. Time-to-market can be cut to a fraction of traditional timelines, with documentation and regulatory preparation automated along the way. Helbling has seen real-world cases where development cycles were reduced to around 30 percent of their original length, alongside significant cost savings in validation and review.

Compliance, one of the most demanding aspects of pharmaceutical manufacturing, is also transformed by this approach. With digital twins in place, laboratories gain full visibility of their operations and can maintain real-time oversight of every batch. Key regulatory documents such as the Master Production Record (MPR) and Master Batch Record (MBR) are digitised, allowing direct comparison between the planned and executed states. “The Bill of Process is almost a digital copy of the master production record,” Sébastien explains. “When both the MPR and MBR exist digitally, compliance checks can be automated, providing continuous traceability and ensuring production is always in line with defined parameters.”

Automated documentation not only reduces the administrative burden but also improves accuracy and reliability. Errors that might once have been discovered post-production can now be detected instantly. For auditors and regulatory bodies, the availability of real-time data and electronic records represents a new level of transparency and confidence.

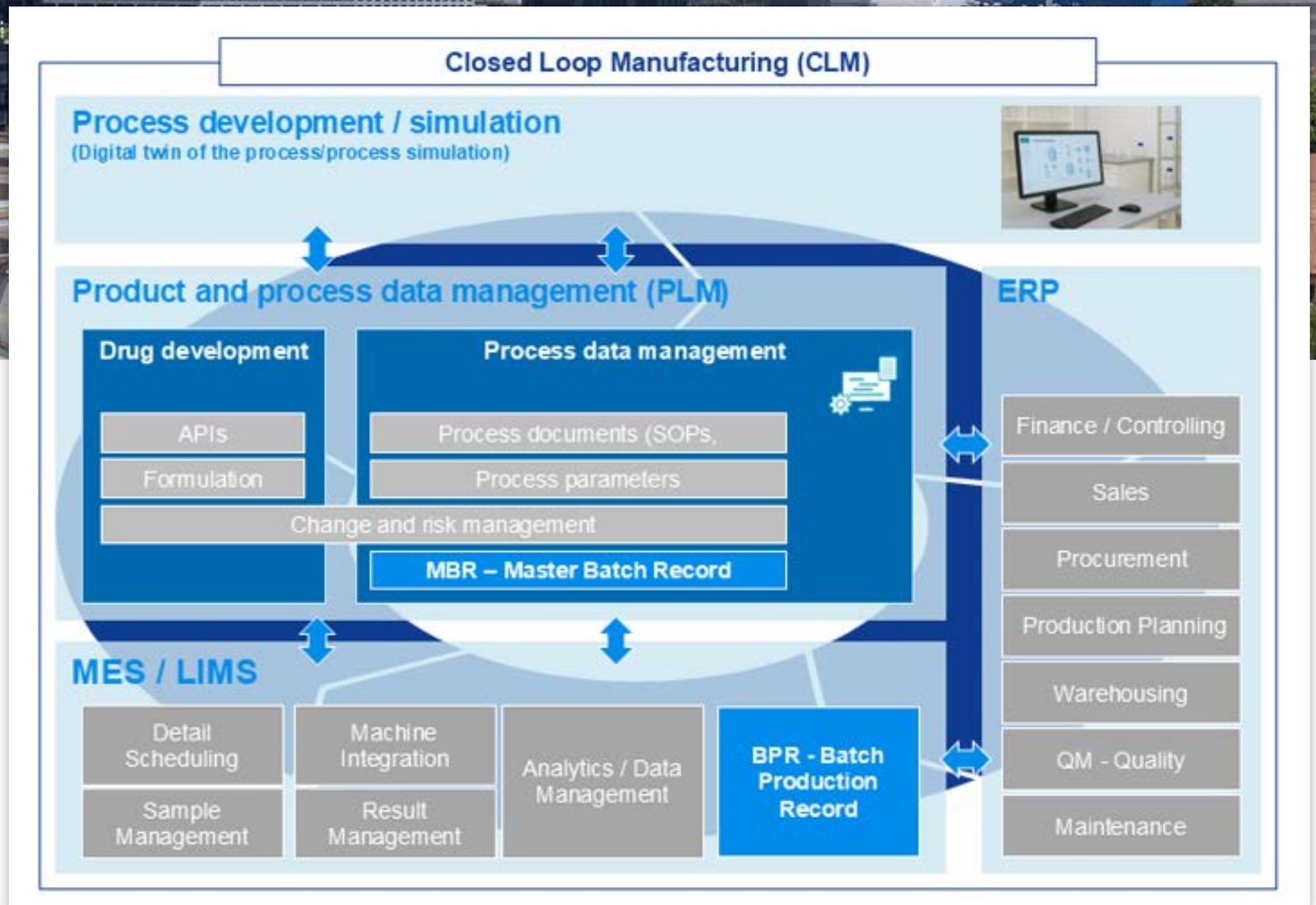
The rise of artificial intelligence and connected technologies is expected to amplify these benefits further. “AI tools and machine learning require a digital



foundation," says Sébastien. "Companies already on the path toward digital twins of their products and processes will see a massive boost. They can automate more, improve accuracy, and even generate regulatory documentation automatically based on configuration."

Sébastien envisions a near future in which AI systems monitor and optimise processes continuously, fine-tuning production parameters as data flows in and supports validation activities. This would enable a level of operational precision that manual systems could never achieve. However, he also recognises that regulation must evolve alongside innovation. "The question is how fast regulation and notified bodies can evolve to keep pace with these advancements," he says.

For Helbling, technology is only half of the equation. The other half is people. "The technological part is often not the hardest," Sébastien observes. "What is truly challenging is the change in how people work. Process Development and Production/Process Engineering are moving much closer together, and in some companies, they are even merging." The company has developed its own change-management methods to guide clients through this transformation, even employing psychologists to assess readiness and support cultural adaptation. "Sometimes it means more effort for one department," Martin adds, "but it results in massive time savings for another. We show teams how early investment in process definition reduces time for scale-up and tech transfer later on."



This cultural alignment is key to sustaining digital transformation. When departments share a common language and understand their interdependencies, collaboration improves naturally. In Helbling's experience, these integrated teams not only work faster but also produce higher-quality results, with innovation cycles shortened and documentation standardised across functions.

Looking to the future, Helbling sees CLM as a foundational technology for emerging areas such as personalised medicine and small production batch in general. Production must adapt to unique or constantly changing requirements, something that manual systems struggle to achieve. "When you produce patient-specific treatments, every batch is unique," Sébastien explains. "The only way to manage that efficiently is to have digital systems that can automatically generate regulatory documentation, adapt processes in real time, and transfer data directly to production lines."

Helbling's vision extends beyond technical innovation. The company views its role as that of an integrator, uniting strategy, operations, and technology into one cohesive system. "We see ourselves as the connector between management, business, and technology," says Sébastien. "Our mission is to provide an end-to-end perspective - from product development through quality, regulatory and operations - that integrates all dimensions of the enterprise."

This integration, he believes, is the future of laboratory and manufacturing environments. The CLM model creates an ecosystem where experimentation, validation, and execution coexist seamlessly. Every analysis step, equipment use, and recipe is captured digitally, forming a foundation for virtual prototyping, automated documentation, and full traceability.

From lab bench to batch record, Helbling's Closed Loop Manufacturing model demonstrates what digital transformation looks like when applied with precision and purpose. It is not simply about digitising existing processes, but about redesigning them to work smarter, faster, and with built-in compliance. In Sébastien's words, "The future of laboratory and production environments lies in digital modularisation. By structuring product and process development digitally, companies can seamlessly integrate automation, data integrity, and regulatory documentation."

As industries continue their move toward fully digital, compliant-by-design systems, Helbling's approach is setting a new benchmark. The company is showing how data can connect every stage of the product lifecycle, turning what was once a complex chain of handovers into a continuous, intelligent process. It is a vision that makes the laboratory not just a place of experimentation, but a central hub of innovation and production, where every insight is captured, validated, and ready for the next breakthrough.

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