



DIVIDELLA
KÖRBER SOLUTIONS

DIGITISATION & INDUSTRY 4.0 IN PHARMA PRODUCTION

Christoph Hammer, Chief Executive Officer, Dividella, gives an overview of the Industry 4.0 concept, and its pharmaceutical application Pharma 4.0. Furthermore, Mr Hammer provides examples of what Pharma 4.0 can offer, discussing solutions shown at Interpak 2017, Düsseldorf.

OVERVIEW

The current trend towards digitisation, including the use of big data and interconnectivity, offers potent advantages for the pharma industry, particularly when it comes to embracing Industry 4.0 design philosophies. To fully realise the potential of emergent “smart” technologies, however, a modular approach must be adopted at every level, from design concepts to engineering, construction and processes. Modularity is essential to fully exploit the connectivity and data sharing capabilities of these technologies, an inherent aspect of the Industry 4.0 concept and its Pharma 4.0 derivative.

MODULARITY AND DIGITISATION

In essence, by taking a modular approach when adopting digitised pharma production, one is able to achieve greater interconnectivity, interoperability, data sharing and information transparency. In turn, this allows for a much higher level of technical support and enables a more decentralised decision making process.

Dividella, as a member of Medipak Systems Group, is part of a modular ecosystem of related skills and competences. Dividella’s process and machinery expertise is combined with the specialities brought by Rondo, Werum IT Solutions, Fargo Automation, Mediseal and Seidenader, using the latest information and communications technologies. Together these companies are making a concerted move towards an

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Industry 4.0 future, thus enabling them to provide a wider range of innovative solutions on materials and packaging, together with easier upgrade and expansion paths.

INDUSTRY 4.0

Industry 4.0 is the fourth revolution in production, following on from mechanisation, mass production and computerised automation. It describes the adoption of data exchange and artificial intelligence (AI) in manufacturing technologies, leveraging “cloud” data storage, cognitive and cyber-physical computing and the Internet of Things (IoT).

Industry 4.0 extols the implementation of smart factories, structured around modular production lines. Such factories would employ cyber-physical systems (those formed of integrated computing, networking and physical components) to monitor physical processes, utilise virtual models to maximise productivity, and operate on decentralised decision making models. Cyber-physical systems can intercommunicate in real time over the IoT, enabling users to offer and share internal and cross-organisational services across the whole production chain.



Mr Christoph Hammer
Chief Executive Officer
T: +41 81 750 3387
E: info@dividella.ch

Dividella AG
Werdenstrasse 76
9472 Grabs
Switzerland

www.dividella.ch

In order to harness the advantages of the Industry 4.0 concept, industrial solutions must obey four basic principles:

1. **Interoperability:** The capability of machines and processes to directly interact with one another.
2. **Information transparency:** The ability of information systems to create virtual models by combining digital plant systems with real time sensor data to create data that can be readily analysed and acted upon.
3. **Technical assistance:** The ability to automatically aggregate and visualise information to solve urgent problems, and also create cyber-physical systems that can take on problematic tasks.
4. **Decentralised decisions:** The usage of cyber-physical systems that are able to make decisions and perform tasks autonomously, only delegating to humans in exceptional circumstance.

PHARMA 4.0

“Pharma 4.0” refers to the application of Industry 4.0 concepts to the pharmaceutical industry, encompassing everything from outflowing goods to the feedback of real

time patient data. Pharma 4.0 is, in part, driven by an overall trend in the pharmaceutical and healthcare industry towards more individualised, patient-specific therapies that is creating a growing need for quality data and diverse formats. This new dynamic comes with ever more pressure to make smarter use of data to avoid production bottlenecks.

This trend towards personalised therapies requires a shift away from traditional mass production processes, which tend to be inflexible in design, to manufacturing individually tailored products. This transformation depends on changing the perception of data and content in three main areas:

- **Moving away from paper:** Many so-called “state of the art” execution systems still rely on paper based processing for GDP (Good Documentation Practice) record keeping. Pharma 4.0 means handling GDP compliant documentation in new electronic formats.
- **Merging data:** GDP relevant records will increasingly be defined by application, making the differentiation between GDP and non-GDP less relevant, requiring greater security for non-GDP areas.

- **Global collaboration:** Freeing content and data from company silos will allow them to be securely shared among virtual teams that can be quickly changed and reconfigured.

INTERPAK 2017

Dividella presented several Pharma 4.0 solutions at Interpak 2017 in Düsseldorf.

Smart Device Control

A Dividella NeoTOP x TopLoad packaging machine for combination products (Figure 1), controlled and monitored remotely via a smart device. With the aid of the device, multiple production units can be scheduled, coordinated and controlled in parallel. The solution, based on HTML 5, is compatible with all systems and mobile terminals.

Condition Monitoring & Predictive Analytics

Dividella also presented a prototype solution for remotely monitoring the status of the NeoTOP x using data captured in real time. The solution then applies algorithms to generate forecasts which predicts critical changes, thus allowing for corrective interventions to be scheduled before any actual failures occur.



Figure 1: Dividella NeoTOP x – a highly flexible TopLoad packaging machine for processing small to medium lot sizes, equipped with a collaborative robot for the greatest possible filling flexibility.

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Figure 2: Rondo uses NFC chips integrated in the pack to improve patient communication. The NFC chip transmits its information as soon as a ‘read’ terminal is within range.



Figure 3: Werum's new Plug & Produce solution allows for fast and easy integration of machines and automation systems into a pharmaceutical production environment.

Smart Packaging

Product personalisation and product security can be taken to new levels by enabling smart communication between the packaging and the patient, as well as by enhancing communication with the machines in the production process. In addition to the actual product, consumers can request additional services via the package, which also communicates with the packaging machine to control settings for individual, personalised products. These solutions use NFC chip technology developed by Rondo (Figure 2).

Plug & Produce

Vertical integration (creation of a standardised interface between production machines and control systems) is fundamental in implementing Pharma 4.0 solutions. Plug & Produce, developed by Werum, is like connecting USB devices, making it possible to 'plug and play' systems or packaging machines within the overall networked system (Figure 3).

Enterprise Manufacturing Intelligence

Enterprise Manufacturing Intelligence (EMI) can improve product quality (process

stability) and productivity (process efficiency) by supervising production almost in real time. Processes can be continuously verified, and subsequently the production data can be applied to support decision making. The customer can make better informed decisions on process stability and process efficiency, to enhance both quality and productivity.

ABOUT THE COMPANY

Swiss-based parenteral packaging specialist Dividella has built up an impressive reputation across the global pharmaceutical industry for the quality and effectiveness of its TopLoad cartoning machines. This success has been established on a holistic approach that recognises that machine and pack design go hand in hand.

Dividella's production units at Grabs in Switzerland exclusively design and manufacture machines for packaging pharmaceutical products, with total focus on the specific requirements of parenteral pack products, i.e. liquid pharmaceuticals that are packaged in syringes, flasks, vials, autoinjectors and the like. These are highly sensitive products that demand thoroughly developed solutions.

FLEXIBLE PACKAGING FOR SCALABLE PRODUCTION

best combination of maximum format flexibility for small to mid size lots

- 100% monomaterial packaging for sustainability
- very fast format line clearance and change over
- large format range
- highest OEE possible

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