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**High-tech**

# Industry 4.0 in the medical technology and pharmaceutical industry sectors

**The digitalisation of industry affects the entire value chain. From individual products to digitising workflows in companies and connecting companies with clients and service providers via the Internet of Things – Industry 4.0 makes completely new manufacturing processes possible and requires new and specific business models.**

Information and communication technologies (ICT) are an integral part of the human environment in 2016. The so-called Internet of Things (IoT) with its intelligent sensors makes life easier in many areas. Examples include tracking parcel deliveries and wearables (portable computer systems), which provide assistance in everyday life. A change is also taking place in the industry. The keyword is "Industry 4.0".

The term "Industry 4.0" was used in public for the first time at Hannover Messe in 2011, and subsequently integrated into the German government's high-tech strategy. The term "Industry 4.0", as defined by the German Academy of Engineering and the Science and Industry Research Union (Forschungsunion Wirtschaft – Wissenschaft), is the "technical integration of cyber-physical systems (CPS) into production and logistics, as well as the application of IoT and services in industrial processes – including the resulting consequences for value creation, business models and downstream services and work organisations."[1] Industry 4.0 is the digitalisation of production, which then leads to the provision of associated services (smart services, servitisation).[2]

CPS is the integration of mechanical and electrical components with linked software modules. Nowadays, this process can be done over the Internet. This means that the CPS-controlled process can also be controlled externally. In contrast to Industry 3.0 (= computer-integrated manufacturing), Industry 4.0 is the ability of machines and people to connect and communicate with each other via the Internet of Things.

## Increasing profits thanks to digital automation

The Innovation Factory in Tuttlingen where sterile containers and motors are produced.



Industry 4.0 is already being applied In the medical device sector and has become an integral part of Aesculap AG's Innovation Factory. The "smart" factory was officially opened in June 2015 and manufactures sterile containers for hospitals and surgical motors. The factory is integrated into the overall work process as the offices of other company staff are located right next door. The integration of Industry 4.0 into factories is therefore also accompanied by a change in workflow.

With the Innovation Factory, Aesculap plans to more than double the number of sterile containers it produces while keeping staff numbers at the current level. To achieve this, a fully automated container production line with ten processing stations and seven networked robots has been integrated into the factory. The Fraunhofer Institute for Labour and Organisation IAO in Stuttgart sees tremendous growth opportunities in Industry 4.0. The Institute's researchers envisage an additional value-added potential of 78 billion euros through Industry 4.0 technology in 2025. This represents annual growth of 1.7 percent.[3]

## Workpieces and machines control production

But how does a smart factory actually work and what do smart manufacturing processes mean for the product and the customers? The first difference when compared to mass production in the past is the individualisation of the product and the workpiece. Siemens AG's electronics plant in Amberg produces printed circuit boards (PCB) that show what product-

Siemens' electronics plant in Amberg, Germany - the "digital factory"

driven manufacturing is all about. Each printed circuit board is given an individual barcode that enables it to communicate with the machines and the manufacturing machines to access the individual file of the each printed circuit board. The components also receive individual codes so that they "know" at which point in the process and at what point in time they are needed. The components are then automatically directed to their destination on the basis of the information the transport system receives through the code.[4]

## Humans have control

As soon as the blank enters the machine, it is recognised by the barcode. The machine can retrieve all processing information from the file system in real time. The plate is then loaded with various components, such as microchips. Each component and the subsequent steps are also documented and monitored in real time by numerous scanners. The machines also indicate in good time if a certain component is no longer available or a technical problem occurs. Inspection engineers monitor the entire value chain of the circuit board on the computer.[4]

## Making drugs counterfeit-proof

The aforementioned example from the electrical industry is also applicable to the pharmaceutical and the medical technology industries. Robert Bosch GmbH's Bosch Packaging Technology is an excellent illustration of the traceability of products. Amongst other things, Bosch manufactures piston filling machines for liquid pharmaceuticals such as cough syrup. The modular machine is part of a digital network and is monitored via a human-machine interface. This also includes quality checks, maintenance by a connected service technician and an immediate alert from the machine as soon as it realises that a certain component will soon be unavailable. Like the manufacturing of printed circuit boards, the manufacturing of piston filling machines is what is referred to as networked production, which makes it possible to produce smaller batch sizes, adapted to customer requirements.[5]

A particular application for drugs is the use of a data matrix code that makes drugs more counterfeit-proof. The digital code gives the packaging for each cough syrup a specific identity, enabling the drug to be clearly identified after it has left the company. This makes it traceable across the entire logistics chain, and consequently more difficult to counterfeit. From 2019 onwards, medicines can only be sold within the European Union if the packaging has an individual serial number and is clearly undamaged. The Industry 4.0 application therefore goes beyond production and encompasses the entire value chain.[5]

## The pharmaceutical industry still needs to catch up

The huge amount of data generated harbours a lot of information that can, amongst other things, be used for quality assurance measures. Cloud services are used to store the data. This allows companies to scale their IT resources much more easily and cost-effectively. However, it also entails potential data security issues.[2] But what about digitalisation and Industry 4.0 in the pharmaceutical industry? Is it sleeping through the trend as reported in an article that appeared in the Handelsblatt newspaper in October 2015?[6] The article featured a survey carried out by Mannheim-based Camelot Management Consultants AG.[7] The PHARMA Management Radar survey came to the conclusion that the Internet of Things will only become a major issue in the pharmaceutical industry in around 15 years' time. Around 60 percent of survey respondents believed that digitalisation mainly concerned logistics and supply chains. The main obstacles cited included high investment requirements and the companies' low level of automation.[8]

## Medical technology – barcodes for endoscopes



The endoSTORE® software uses a barcode scanner to registers endoscopes.



ESCAD Medical GmbH has already successfully entered Industry 4.0. The small medical device company specialises in endoscopy. The company has adopted a storage system called endoSTORE®, which has enabled it to improve a weak spot in endoscope processing. The disinfection phase has always been well monitored, but the subsequent drying and storage phases in hospitals were characterised by gaps in documentation as well as hygiene problems.

In the new system, the endoscopes stay in a transport basket to be processed in a closed circuit that can be centrally monitored and documented. The endoscopes are registered with a barcode scanner and a security query feature prevents an improperly disinfected endoscope from reaching the patient. The company was also one of the winners of the "100 Places for Industry 4.0 in Baden-Württemberg" competition.

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