

Industry 4.0 - Inspiration for the Pharmaceutical Industry?

A report on the ISPE European Annual Meeting 2018



by Thomas Peither



More than 600 industry experts and 30 regulators attended the ISPE European Annual Meeting, held from 19 – 21 March 2018 in Rome. The theme of the 5th ISPE Europe Annual Conference was “LEAD AND MANAGE A PARADIGM SHIFT”. The conference brought together key companies and experts across a wide variety of pharmaceutical fields, from advanced pharmaceutical production to facility and equipment design.

In this report I will provide you with some insights into the conference, especially with regard to Industry 4.0. They can only be snapshots, because of the tremendous amount of information involved. This text (and many more) was also published in my live reporting from the conference on [LinkedIn \(#gmppublishing\)](#).

Industry 4.0 in Pharma: **Thomas Zimmer**, ISPE Vice President of European Operations, opened the ISPE European Annual Meeting 2018 with this major buzzword topic. He focused on the question of what Industry 4.0 could mean for the pharmaceutical industry. An estimated 250 people followed the presentation in the executive forum of the 1st day.

The first session was an inspiring one, with some good points, especially by **Gunter Beitinger** from Siemens. He took the participants on a journey to Industry 4.0, which includes topics about time-to-market, flexibility and quality. The goal for Siemens is to meet six sigma! And with that goal we all remember the quality guru Deming, who promoted this and other quality goals as the basis for improvement.

For 15 years Siemens has been working to achieve this goal. -Now they have taken the hurdle of five sigma. The processes are already better than five sigma, but the goal of six sigma is still on the agenda. This is really a long-term project. I wonder: Where is the pharmaceutical industry today? I suppose there is still a long way to go!

Gunter Beitinger showed an example of x-ray testing at their manufacturing site, where they reduced the testing by 42% using predictive analytic models. Do you have a clue as to how much could be saved by reducing testing in our medicinal drug manufacturing facilities? Why don't you start tomorrow?

Thomas Uslander highlighted the perspective of Fraunhofer IOSB in his talk about Industry 4.0. Again, the examples shown come from a number of industries, except pharma. When will we have the first case studies from pharma? Thomas Uslander talked about some obstacles we have to overcome when using the Internet in a business environment (see Figure 1). The presentation also covered some harmonisation initiatives in this area. This is surely a key expertise of the Fraunhofer Institutes.

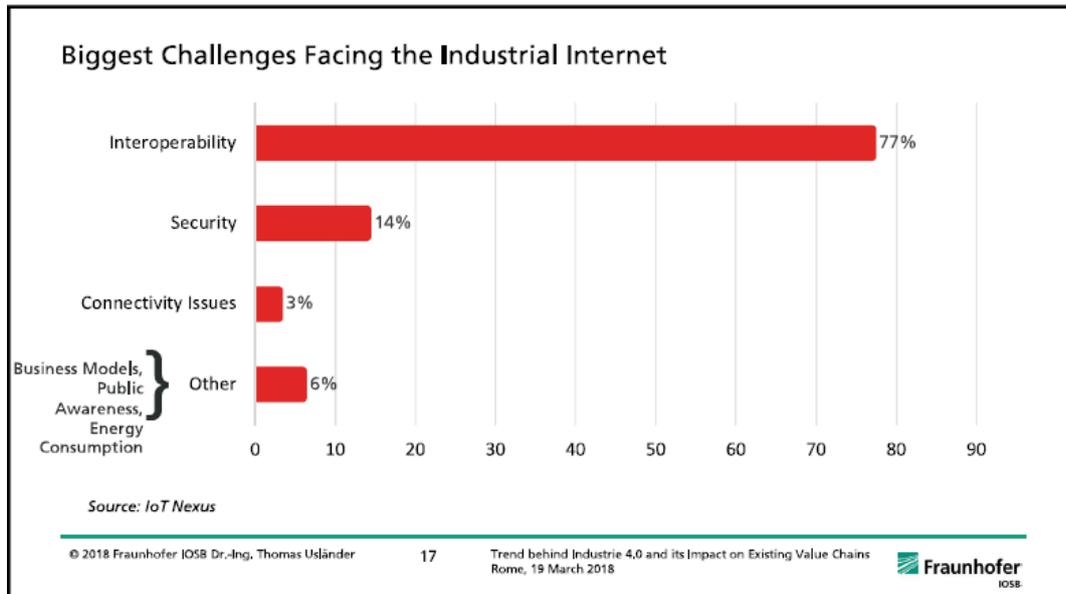


Figure 1: Biggest challenges facing the industrial internet

Pharma 4.0 can also be seen as a practical approach

New Holistic Control Strategy - let Industry 4.0 be brought into pharma, and it is all about optimisation and people. In his keynote lecture **Christian Woelbeling** talked first about the problems. He focused on the differences from other industries - the regulatory situation is one of the keys! Great - now we come to the real problems in the drug business.

Christian Woelbeling talked with enthusiasm about the practical integration of Industry 4.0 into Pharma 4.0 operating model, control strategy, maturity models - and we want to make it happen (see Figure 2). A lot of information and new definitions. It is a high-speed ride through all the new topics that shall change the future of the pharma industry.

And again: people! We need knowledge and education for the people, because knowledge is an enabler for all of these new technologies and strategies. Do you remember ICH Q10? Quality culture, collaboration and new approaches. There's a lot to do!

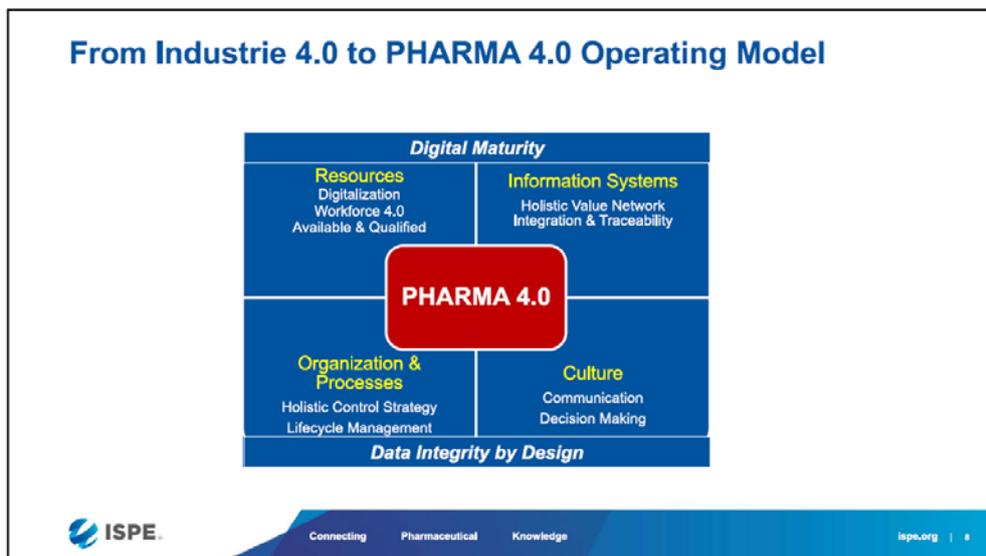


Figure 2: From Industry 4.0 to Pharma 4.0 Operating Model

Pharma 4.0 is on the way to implementation

“Are you ready for Pharma 4.0?” This entry question was asked in the presentation on the ISPE Readiness and Maturity Model. **Uli Kuchenbrod** from Vetter Pharma reported for the special interest group (SIG) Pharma 4.0.

The SIG adapted the specific pharmaceutical aspects: GMP compliance, long-term orientation, regulatory framework, openness for control and audits, risk vs. control, ...

Kuchenbrod focused on areas that impact the maturity:

- People, organisation, leadership and management
- Patients, market & supply chain
- Manufacturing
- Hardware & software, equipment, product & process

The big question is: Where are you as a company? As every company is different, you have to define: What is important for your company?

There is not enough space in this article to explain this model. Please go to the ISPE website to look for further information. I think this will give you tons of inspiration. This was a great talk for people looking beyond their own horizons!

“We identified a struggle with the lack of harmonised and consistent information flows in the industry”, said **Volker Roeder**, consultant at Arcondis Group, in the Pharma 4.0 track. He focused on the journey from process mapping to data mapping.

This is a very technical process supported by tools and of course real numbers from the departments. I was able follow the process and the process steps, but I couldn't describe this in a brief, understandable way. If you are a data analyst I recommend that you contact this SIG (special interest group). Wow - at the end there were slides with much information. And best of all: Volker Roeder was able to explain it. It's really down to earth - but in the end experts especially need this support to reach the next step! What I learned is that this helps to improve data quality, release faster and trace data better. Well done!

„Do you know the difference between Digitisation and Digitalisation?”

This question marked the beginning of a fast journey led by **Clemens Hohfelser**, Novartis. He provided insight into the operation maturity model of a big player.

From strategy to technology via the processes is the route. Strategy drives the processes and the processes drive the technology - it only works this way - it's a one-way street.

Seven process phases blaze the way to implementation: design, harmonisation, transformation, readiness, delivery, execution and monitoring (see Figure 3).

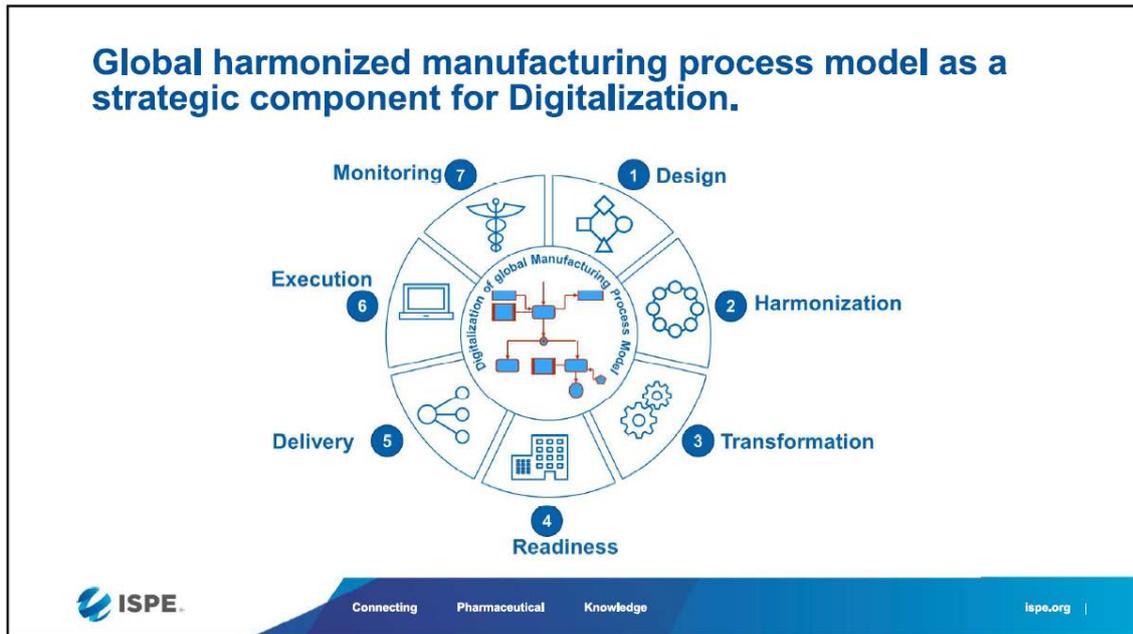


Figure 3: Seven process phases of a global manufacturing process model

Hohfelser talked very openly about his challenges in a global company. And you can imagine that harmonisation in such a company is a tremendous topic to handle. And you always have to consider the overlying process from strategy to technology. Especially when it comes to "readiness", it takes a great effort to bring the process and technology to the manufacturing sites.

At the end he showed a digital maturity model for a master batch record - from manual to predictive records - fantastic! This effort can certainly be handled by a big player - I wonder if this is also true for a medium-size or small manufacturer. They must be standard if this is to be required by regulators one day. Thank you - great insights!

Sources:

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