Future Trends of Pharmaceutical Manufacturing revealed in Barcelona

A report on the ISPE 2017 Europe Annual Conference

by Sabine Paris, PhD

The European Annual Conference of the International Society of Pharmaceutical Engineering (ISPE) attracted over 520 participants to Barcelona from 3rd to 5th April 2017. The main topic was the future of the pharmaceutical production. Strategies for a modern, flexible and quickly responding manufacturing landscape were under intensive discussion. In plenary and parallel sessions 77 lecturers illuminated on the following topics: Manufacturing facilities of the future, advanced aseptic processing, supply chain management for investigational medicinal products and ATMPs, as well as data integrity.

In today’s leading article I have summed up the most decisive trends and future challenges as seen by the top-class lecturers in the executive plenary and keynote sessions for pharmaceutical production.

Future Trends in the Pharmaceutical Production

“We are about to experience a medical revolution”. With these words Juan Andres of Novartis Pharma started his talk. Classical medicinal production will be adapted accordingly (a must) since sectors such as personalised medicine, prenatal medication and also diagnosing per robot are on the rise. Innovations have been limited in the manufacturing of pharmaceuticals in the past and, as yet, have not been necessary either. Innovations derived mostly from research and development departments.

Reliability, productivity and innovation are the three most important pillars of successful pharmaceutical production in the future according to Juan Andres. This includes not only robust supply chain processes, a high level of customer services (reliability), site efficiency and flexible adaption at the site’s needs (productivity) but particularly being one step ahead of competitors (innovation).

Pierre Alain Ruffieux of Roche added as further enablers for a successful future: A strong quality culture, a robust compliance and a harmonised regulatory environment.

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The following aspects have a decisive influence on future manufacturing, according to Pierre Alain Ruffieux:

- **New Technologies:**
  Further increase of biotechnological products that require different manufacturing concepts

- **Speed:**
  “Everything is quicker”: Patient needs, authorities’ expectations, faster approval processes, business pressure

- **Costs:**
  “What are the costs of quality?”, quality as part of the reputation of pharmaceutical industry

- **Regulatory Framework:**
  Missing international harmonisation of requirements (20 different GMPs, 49 different pharmacopoeias!), greater workload for inspectorates due to third country inspections, but new perspectives thanks to the recently ratified MRA between the EU and the USA

Robert Nass, Merck KGaA, identified **four main future trends**:

- Biologics
- Advanced Therapeutic Medicinal Products (ATMPs)
- Emerging Markets
- Digitalisation

According to his prognosis the market for biologics will continue to grow in the next 5 to 10 years. There will be more pressure to develop new products. Biosimilars will also increase but not to the extent that was anticipated earlier.

“ATMPs will revolutionise manufacturing methods”, according to Robert Nass. Sometimes the question arises: What is even a product?

Another trend is the expansion into **new geographical markets**, because increasing prosperity means a greater demand for high quality healthcare.

The last very important aspect, according to Robert Nass, is **digitalisation**. He foresees a further increase in electronic data, generated on mobile devices. He maintains that the following aspects will play a bigger part in pharmaceutical production in the future: uniform data platforms, smart machines and data connection as a prerequisite for predictive modelling.

**What do these trends mean for the manufacture of medicinal products?**

Robert Nass foresees the following consequences:

- **Continued growth of single-use manufacturing:**
  Wider variation of specialised products calls for greater flexibility. Smaller units will be sufficient – true to the motto: “One vial for one patient”.

- **Process intensification towards continuous processing:**
  Manufacturing must be more intensive in the future, need for compression of space and time, which also makes the process more economical.
• Increasing demand for **end-to-end solutions** to bring affordable medicines onto the market.

• **Digital trends** spread into pharmaceutical industry:
  e.g. 3D printing, DNA-based storage, machine learning, cloud computing, wearable computing devices

**Further future trends that were named in a lot of lectures:**

- Increasing automation
- Increased use of robots
- Better eco-balance
- Smaller manufacturing units – "smaller footprints"
- Simple design
- Shorter cleaning times
- Tubeless facilities Single use
- Pharma 4.0 – Digitalisation + links between data and devices/machines

**Challenges**

All the speakers emphasized that the next step was to contend with the crucial challenges required to follow and successfully implement the trends. They agreed that one of the biggest challenges was the **regulatory uncertainty** and the **lack of international harmonising** of regulations. It was agreed that there were far too many different requirements and pharmacopoeias, creating a major obstacle for globally operating companies.

**Interdisciplinary cooperation** within a company and the **promotion of young professionals** are seen as basic requirements today. Not being able to attract a sufficient number of qualified engineers in the future is one of the main concerns of the pharmaceutical industry. To this end the ISPE specially launched the initiative **ISPE YOUNG PROFESSIONALS** to promote and support junior staff in the pharmaceutical industry.

Another aspect that was mentioned by several of the speakers was the **increasing tendency to “zero risk”**. Due to ever increasing safety needs in recent years, regulations for building and operation in pharmaceutical manufacturing facilities have become more numerous and stringent than ever before.

**Sources:**

Juan Andres, Novartis Pharma: Pharma Manufacturing 2025, ISPE 2017 Europe Annual Conference, Barcelona

Pierre Alain Ruffieux, Roche: Quality 2025, ISPE 2017 Europe Annual Conference, Barcelona

Robert Nass, Merck KGaA: Enabling Future Pharma Manufacturing – Trends from a Supplier Perspective, ISPE 2017 Europe Annual Conference, Barcelona
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