



# II Всероссийская GMP-конференция

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# Delivering Cost-effective Unconventional Solutions for the Global Bio/Pharmaceutical Industry

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GMP-Integration as a driver of the competitiveness of the pharmaceutical market.  
GMP: next generation factories. GEP global trends.



## Where are we today?

- For the past decades drug manufacturing sites have been designed in the same way.
- Innovation was only aimed at increasing production capacity and process automation in general and partially reducing manual operations.
- By replicating the same design/layout risks of failure have been minimized and profit maximized.

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## New trends

- **Current scientific developments are leading toward production of progressively smaller batches of drugs for customization of therapies (Personalized Medicine). [are changing the way new drugs will be designed and manufactured]**
- **New solutions are needed, different from those we are used to work with today.**
- **Closer collaboration between drug manufacturers and equipment manufacturers is needed.**

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## Process equipment in the field

**What is advertised in the media seldom represents our daily reality.  
As a consequence, vast majority of (our) process  
equipment is underutilized.**

### **Most common inefficiencies:**

- **Processes not optimized for the specific loads**
- **Process controllers not fully understood**
- **Various software functions unused**
- **General lack of training and understanding of processes**

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## Market drivers:

- Increasing pressure on drug prices
- Increasing pressure by (international) regulators
- Increasing competition from emerging countries
- Increasing complexity of primary packaging and drug delivery systems



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**Solution?**

**Drastically increase efficiency!**

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## What is required?

- **Thorough understanding of processes & equipment**
- **Develop internal know-how**
- **Thinking outside of box**
- **Open collaboration/exchange of experiences with equipment manufacturers**
- **Availability to invest in innovative & unconventional manufacturing solutions**
- **Challenge equipment suppliers for developing more cost-effective solutions**