Industry 4.0 Technologies in the Life Sciences

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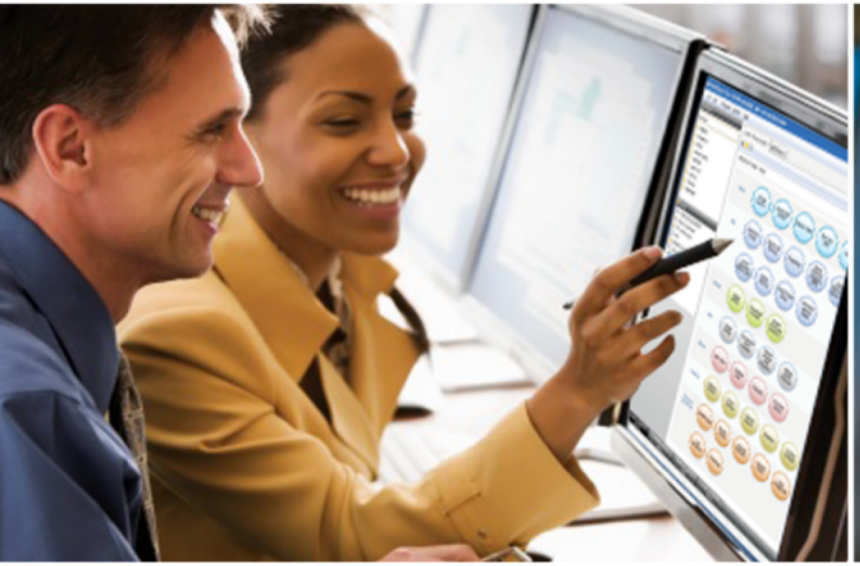
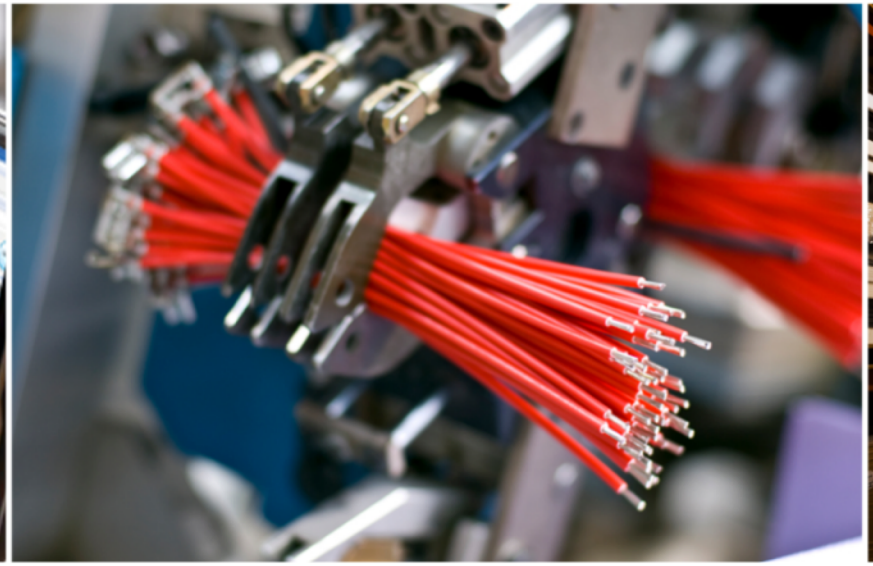
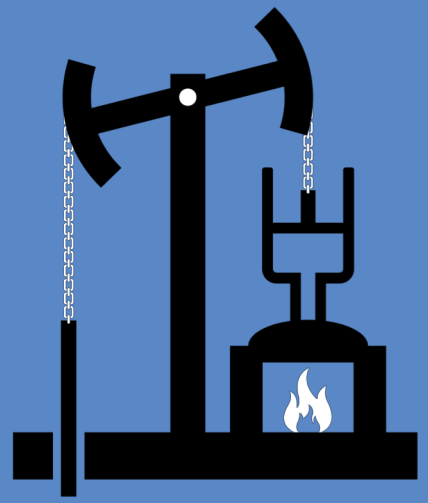




Industry 4.0 – Driving Advanced Technologies

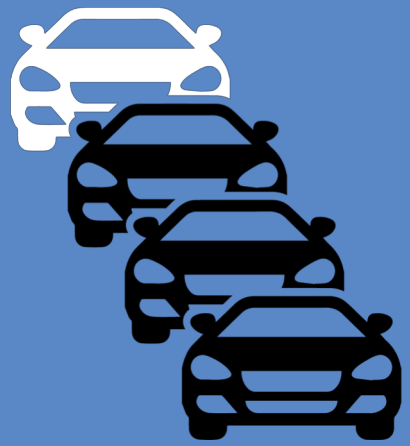
1st

Mechanization, Water Power, Steam Power



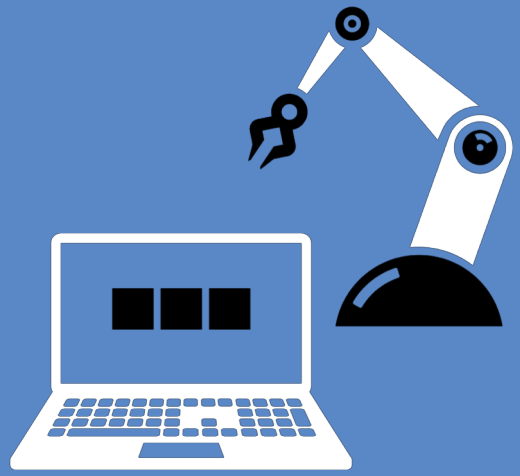
2nd

Mass Production, Assembly Line, Electricity



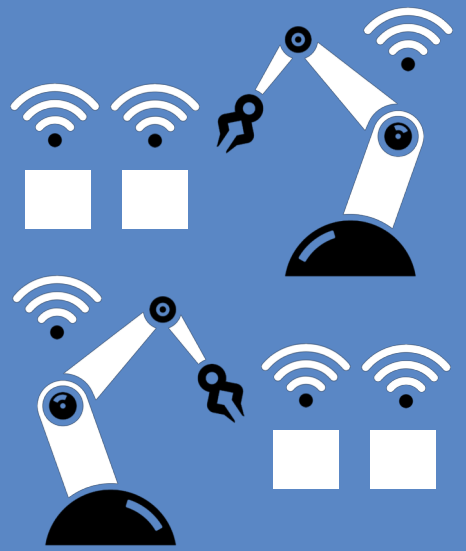
3rd

Computer and Automation

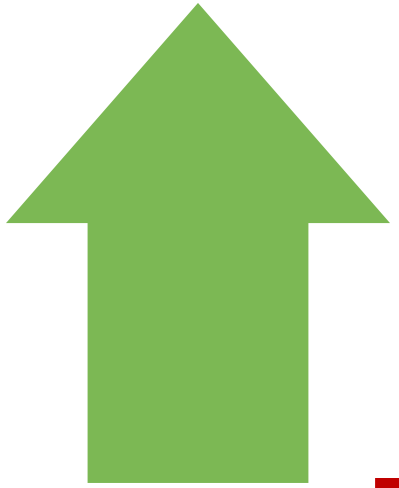


4th

Cyber Physical Systems



Is Industry 4.0 Technology Compatible with Life Sciences?



Industry 4.0 concepts encourage…

- Closed-loop feedback systems…
- Smart machines making independent decisions during processes…
- Machines adjusted mid-process (changing speeds, etc.)…

Does Industry 4.0 conflict with…

- …validation?
- …verifying processes?
- …controls?

Industry and Regulators Adopting Industry 4.0 Concepts

Manufacturers

- Connected Manufacturing
- Smart Factories
- Automation

Industry Groups

- ISPE
- PHARMA 4.0

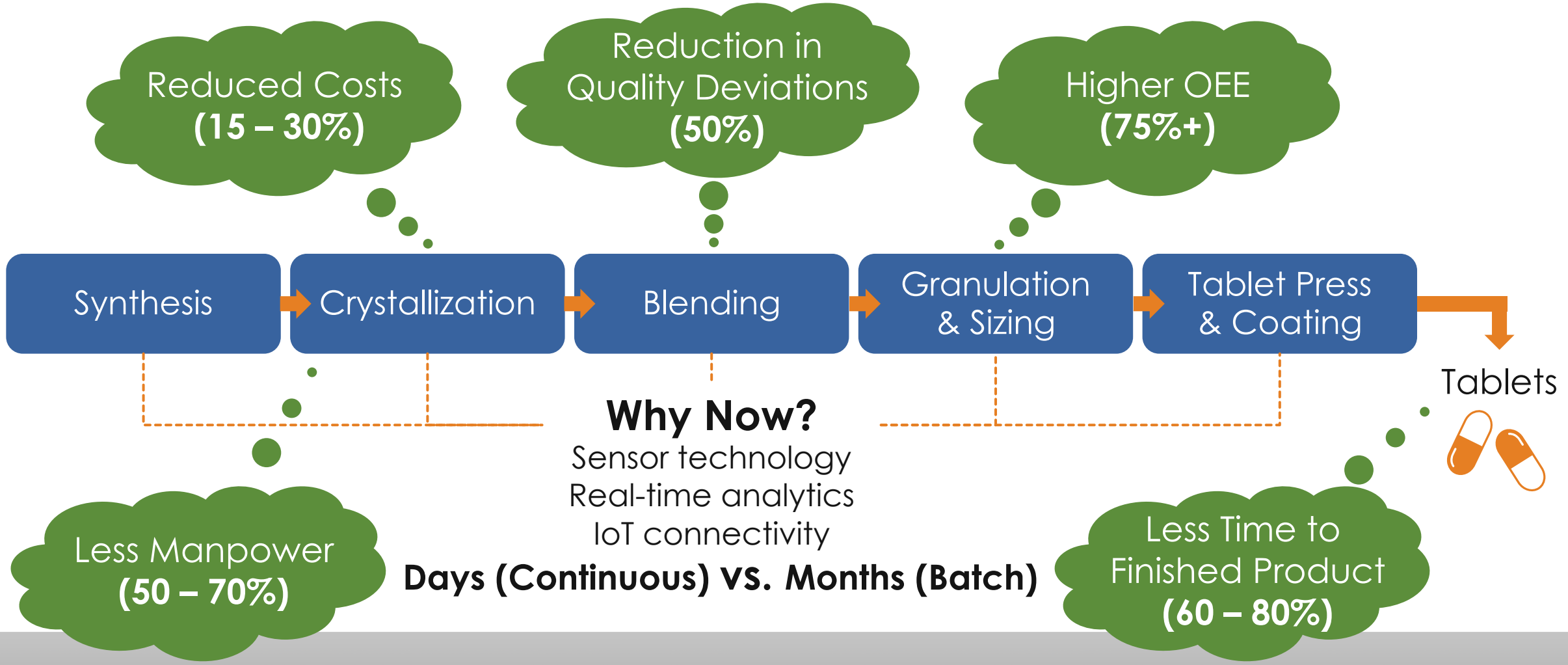
Regulators

- FDA's Emerging Technology Program

Advanced Technologies in Life Sciences Manufacturing

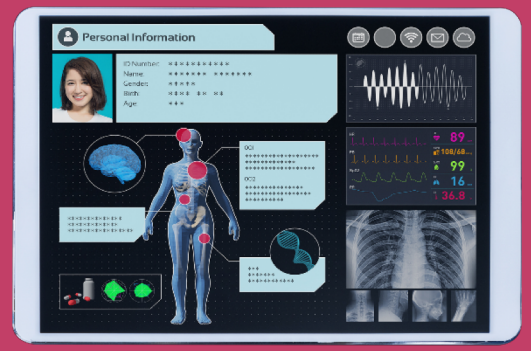
Equipment	Labor	Inventory	Process
• Predictive maintenance • Asset management • 3D printing • Sustainable operation • Performance monitoring • Integration	• Virtual and augmented reality • Safety compliance • Tracking equipment and tools • Operator training • Lead time management	• Demand, production, procurement and distribution modeling • Inventory replenishment • Warehouse optimization • Expiration date monitoring • Warranty • Supplier quality management	• Production flow monitoring • Real-time supply chain monitoring • Quality analytics • Service level management • Production line simulation • Capacity monitoring

Continuous Manufacturing in Pharma



Internet of Medical Things (IoMT)

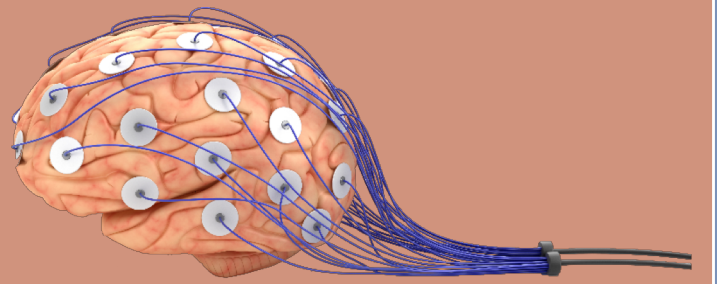
Clinical Efficiency



Telemedicine

Fitness Wearables

Biometric Monitors



Brain Sensors

Sleep Monitors

Additive Manufacturing (3D Printing) in Life Sciences

Implications for…

Supply Chains

Manufacturing

Distribution

Additive Manufacturing (3D Printing) in Life Sciences

Medical Devices	• Highly customized products • Functional parts • Shorten design cycle (prototyping) • Low cost surgical tools
Pharmaceuticals & Biotechnology	• Personalized drug dosing • Unique dosage forms • More complex drug release profiles • Printing living tissue

Modeling and Simulation - Life Sciences

Patient data
Clinical data

Inventory data
Manufacturing data

Product data
Demand data

Traceability data
Genomic data

Data Mining and Business Intelligence

- What happened?
- Why did it happen?

Predictive, Decision Support

- What will happen?
- What actions recommended?

Automated Actions and Simulation

- AI or algorithm makes decision
- Simulations and Digital Twins

Today

Tomorrow

Modeling and Simulation - Drug Development

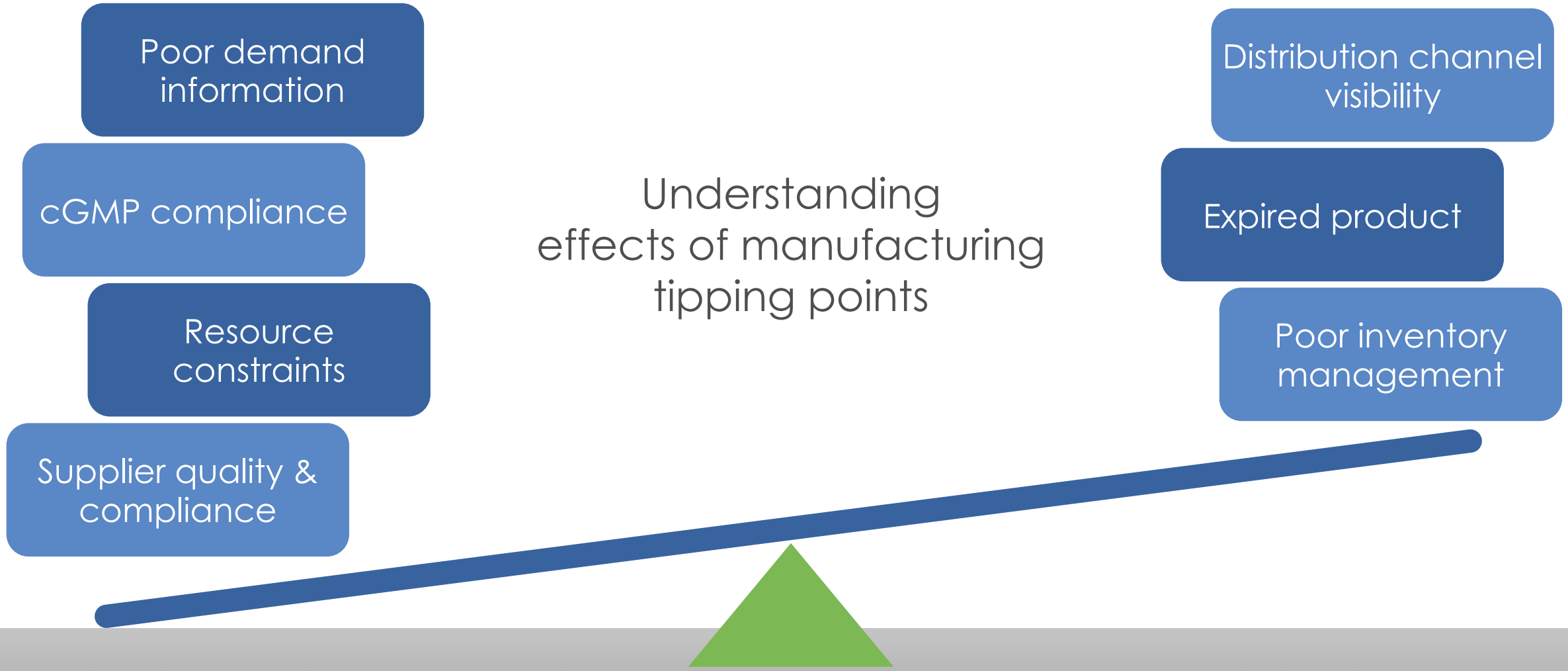
Model-based Drug Development (MBDD)

- Accelerate time to market
- Optimize clinical trial design (desired outcomes, protocols) to provide info on dosing, interactions
- Reduce number of patients required in clinical trials

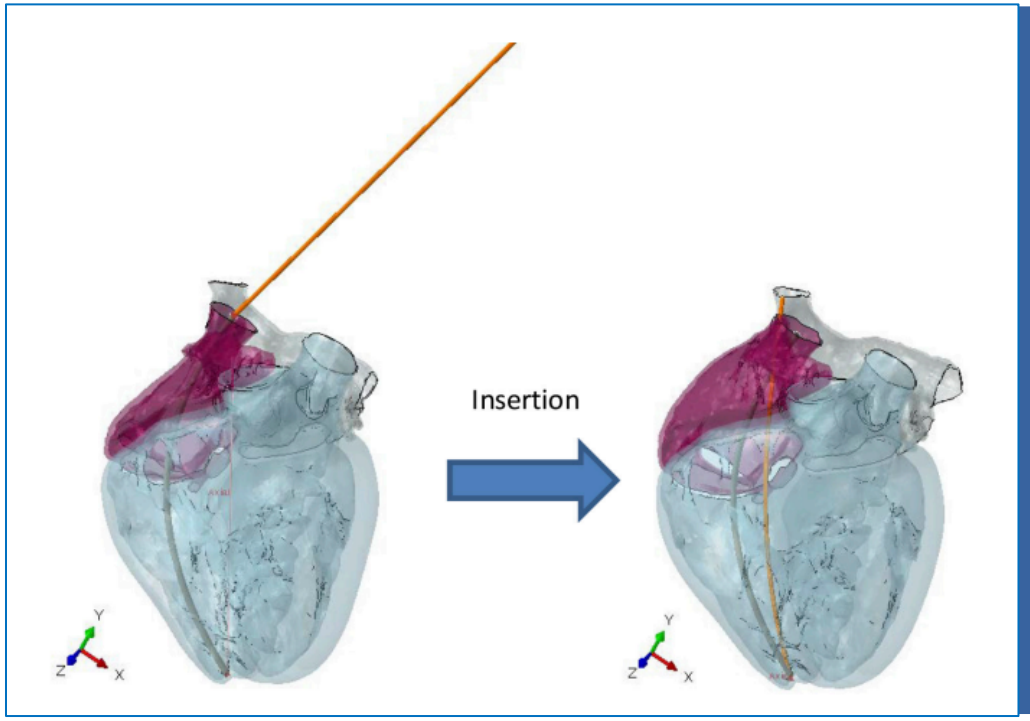
Formulation

- Test impact of each component and assure quality control in formulation and reformulation
- Reduce number of bioequivalence (Beq) studies due to scale-up and post-marketing changes

Modeling and Simulation - Pharma Manufacturing



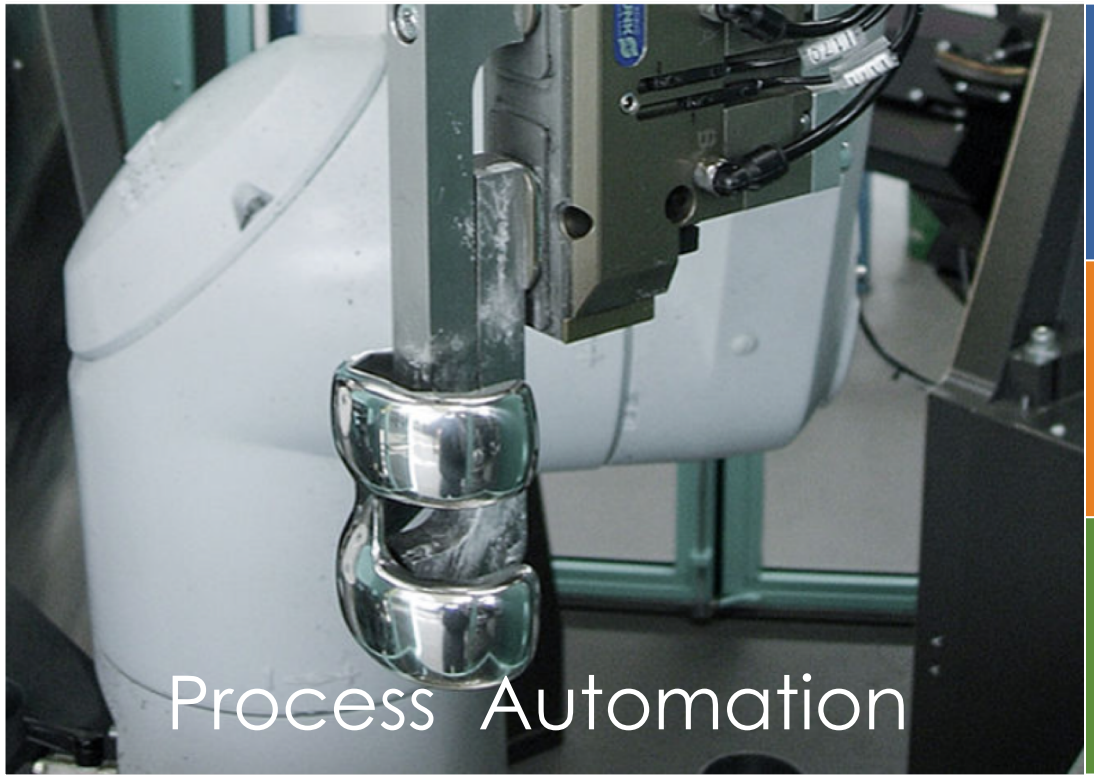
Modeling and Simulation – Human Digital Twin



SIMULIA Living Heart Human Model

- Test new and existing devices without exposing patients to un-necessary risk
- Pacemaker lead virtually inserted and mechanically deformed during the cardiac cycle
- Assess long-term durability of implant

Automation in Life Sciences

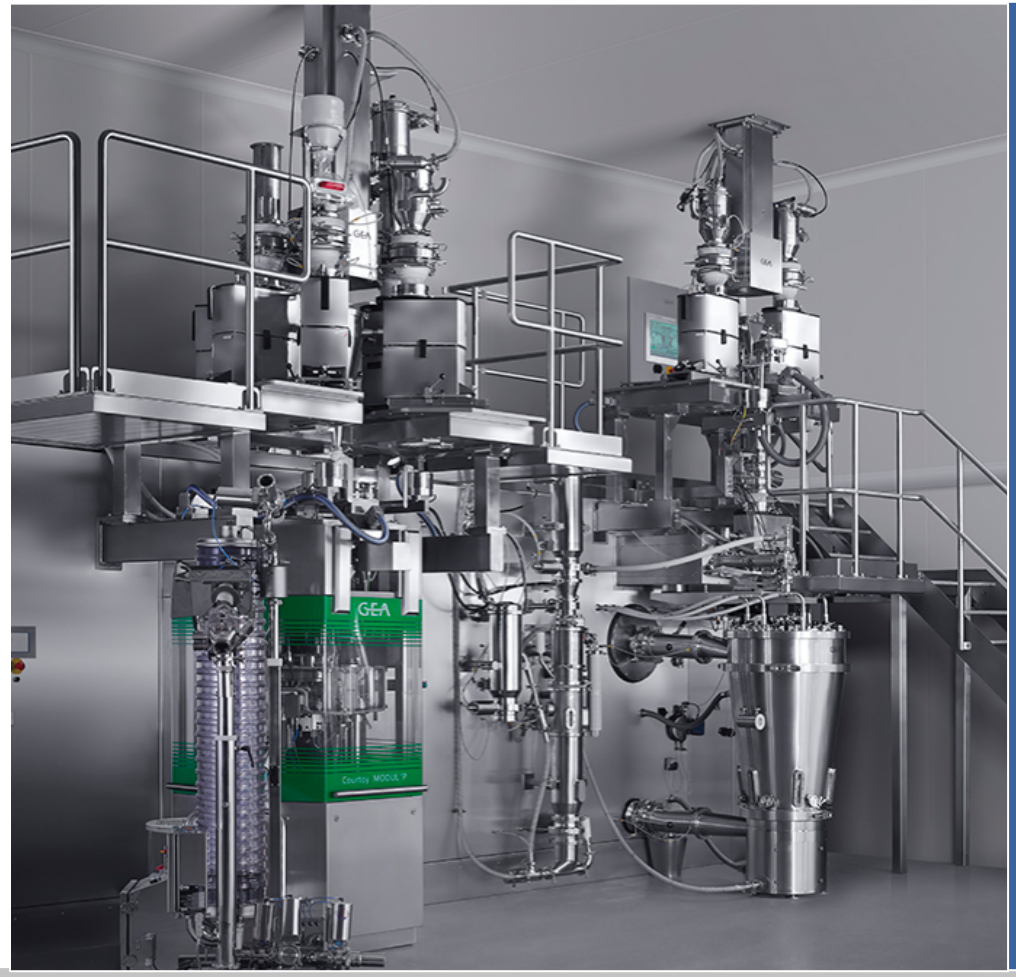


Modular Automation

Miniaturization

Collaborative Robotics

Automation in Life Sciences



Production on demand based (POD) mini-factory

- GEA, GSK, Pfizer, G-CON MFG
- Portable, continuous, miniature and modular (PCMM)
- 60% smaller footprint
- Shipped by truck to any location
- Set-up time less than a year

Blockchain in Life Sciences

Summary

- Industry 4.0 concepts are moving into the life sciences
- Companies and industry orgs embrace advanced tech
- Regulators encouraging use of advanced technologies
- Industry 4.0 tech - significant impact on health care delivery

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