



ISPE PHARMA 4.0™ SPECIAL INTEREST GROUP

ISPE e il Pharma 4.0™

- ISPE CONFIDENTIAL -

Autore: Edoardo Schiraldi

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# Edoardo Schiraldi



## Job Title e Studies

- ❑ **Job Title:** Menarini Corporate Business Solutions | RPA CoE
- ❑ **Education:** Master's Degree in Economics and Management
- ❑ **Previous Job:** Accenture
- ❑ **LinkedIn:** [Edoardo Schiraldi](#)

## Job Description

- ❑ 5 Years Plan Definition and Maintenance
- ❑ ICT Budget and Forecasts Definition
- ❑ Project Managers Coaching and Support
- ❑ RPA Strategy & Roadmap definition
- ❑ Market scouting for new innovative solutions

## Main Competencies

- ❑ ICT Projects Portfolio Management
- ❑ Project Management
- ❑ Business Relationship Management
- ❑ New technologies (e.g. RPA, Process Mining)

# Pharma 4.0™

ISPE and its members are developing the **roadmap** to introduce **Industry 4.0**, also called the **Smart Factory**, to the pharmaceutical industry as **Pharma 4.0™**.  
Implementing **new industry 4.0-based** manufacturing concepts in **Pharma 4.0™** requires alignment of **expectations, interpretation, and definitions** with the pharmaceutical **regulations**.

## Mission Statement

We provide **practical guidance**, embedding regulatory **best practices**, to accelerate **Pharma 4.0™ transformations**. Our objective is to **enable organizations** involved in the **product lifecycle** to leverage the **full potential of digitalization** to provide **faster innovations** for the benefit of **patients**.



# Industry 4.0 vs Pharma 4.0™: Customer versus Patient

## Industry 4.0

Applicable law and regulations

Applicable industry standards

Applicable certification requirements (e.g.: ISO)

Moving from Industry 4.0 to Pharma 4.0™ we have to consider specific regulations in the sake of patients



## Pharma 4.0™

GxP regulations

GAMP guidelines for digitalisation  
Within a regulated environment

Specific product quality requirements

Pharma industry language

# SIG Pharma 4.0 Sub-Working Groups

**Management  
Communication Strategy**  
the elevator pitch for  
management



**Validation 4.0**  
The new paradigm of a less  
complex validation model



**Process Maps &  
Critical Thinking**  
how to develop process and  
data mapping to digital twins



**ISPE** | PHARMA 4.0™

**CPV & Process Automation**  
The way to parametric release



**Holistic Digital  
Enablement Team**  
How to bridge from ICH Q 8, Q 10  
and Q 12 to Pharma 4.0



**Plug and Produce**  
How to develop  
machine learning and automation



# Management Communication Strategy

## 01

### **Annual Survey on Pharma 4.0™**

On 2021 has been released the 5th edition of the ISPE Pharma 4.0™ survey with the aim to analyze the status, the goals and the mindsets about Pharma 4.0™

## 02

### **Articles on Pharmaceutical engineering**

Detailed articles on the enabling technologies are periodically published on the PE by industry experts

## 03

### **“ISPE Pharma 4.0™” LinkedIn Group**

[LinkedIn group](#) (≈900 members) dedicated to Pharma 4.0™ is used to foster discussion with all the group members

## 04

### **FOYA Category Pharma 4.0™**

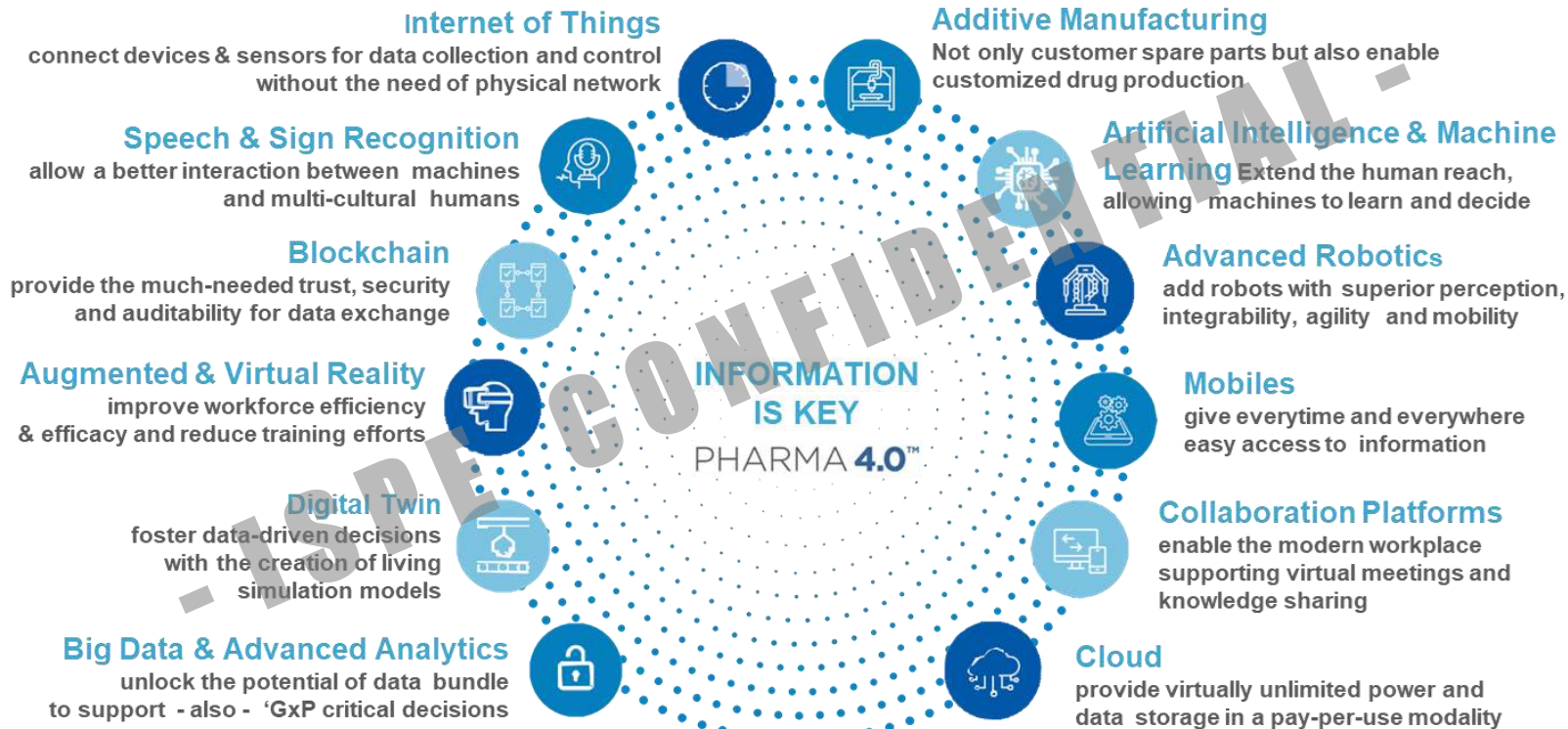
“Facility of the Year Award” has been launched in 2021 to reward the best Pharma 4.0™ concept

## 05

### **“ISPE SIG Pharma 4.0™” Baseline Guide**

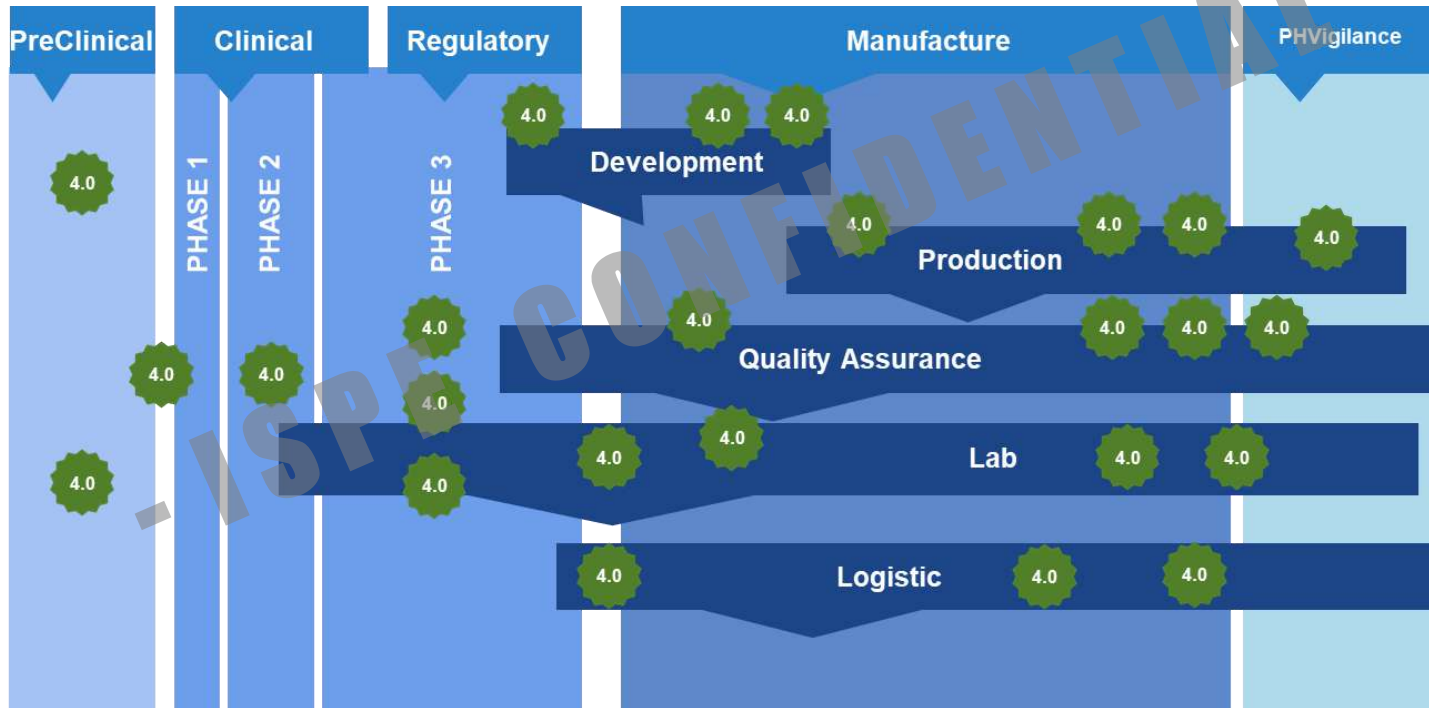
Define an holistic digital transformational approach for pharma companies with practical use cases

# How 4.0 enabling technologies provide Solutions



# Pharma 4.0™ Use Cases on the Value Chain

Based on ISPE events presentation, PE Articles and experts knowledge the Pharma 4.0™ SIG is going to analyze the use cases along the whole pharma value chain.





# Use Case Template

**COMPANY**

Name:

Area:

Dimension:

Status:

**DESCRIPTION**

**ENABLING TECHNOLOGIES**

<input type="text"/>	<input type="text"/>	<input type="text"/>
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**CONSTRAINS**

<input type="text"/>	<input type="text"/>	<input type="text"/>
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**BENEFITS**

<input type="text"/>	<input type="text"/>	<input type="text"/>
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**KEY LESSONS LEARNED**

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## Q&A Session

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For any questions or just for information, feel free to contact me at:  
Edoardo Schiraldi [eschiraldi@menarini.it](mailto:eschiraldi@menarini.it)