



# Circuition

Life Science Consultants

Point of view on

## Life Sciences 4.0

Connecting biology, physics and digital  
For the benefit of human wellbeing

"It is not the strongest of the species that survive,  
nor the most intelligent,  
but the ones most responsive to change"  
- Charles Darwin -

We are at a cross road in history,  
where new needs and new possibilities meet.



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# Life sciences 4.0

## Industrial revolutions

I1

LS4.0

>1800 AD

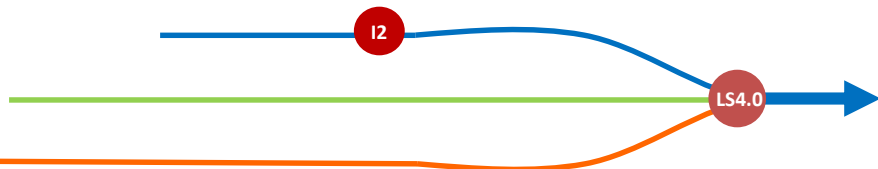
				
Industry	1.0	2.0	3.0	4.0
Change driver		Automation	Computerization	Digitalization
Business driver		<ul style="list-style-type: none"><li>• Need for efficiency</li></ul>	<ul style="list-style-type: none"><li>• Product variability need</li></ul>	<ul style="list-style-type: none"><li>• Need for adaptiveness</li></ul>
Challenges		<ul style="list-style-type: none"><li>• Increase of volume</li><li>• Convince of Taylorism</li><li>• Establish Production Management</li></ul>	<ul style="list-style-type: none"><li>• Increase of rules</li><li>• Accept use of software</li><li>• Establish Quality Control</li></ul>	<ul style="list-style-type: none"><li>• Increase of market pull</li><li>• Omit 2.0 culture</li><li>• Data integrity by design</li><li>• New earnings models</li></ul>

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# Life sciences 4.0

## Industrial revolutions



>1920 AD

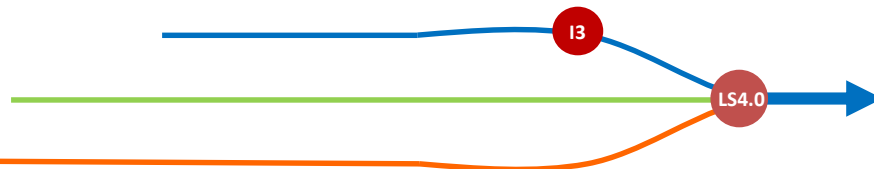
				
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# Life sciences 4.0

## Industrial revolutions



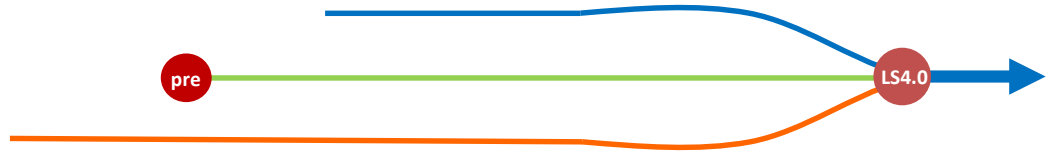
>1980 AD

				
Industry	1.0	2.0	3.0	4.0
Change driver		Automation	Computerization	Digitalization
Business driver		<ul style="list-style-type: none"><li>• Need for efficiency</li></ul>	<ul style="list-style-type: none"><li>• Product variability need</li></ul>	<ul style="list-style-type: none"><li>• Need for adaptiveness</li></ul>
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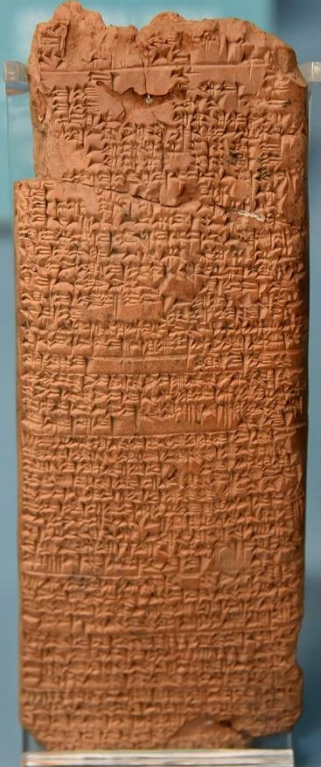
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# Life sciences 4.0

## Information sharing

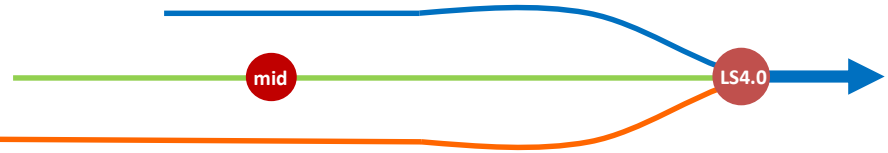


>1800 BC

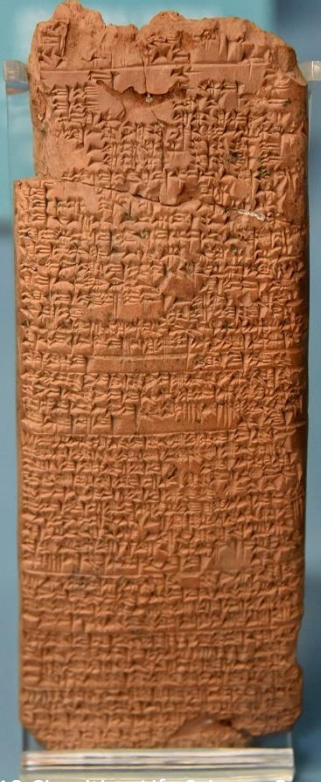


# Life sciences 4.0

## Information sharing



>1800 BC



>500 AD

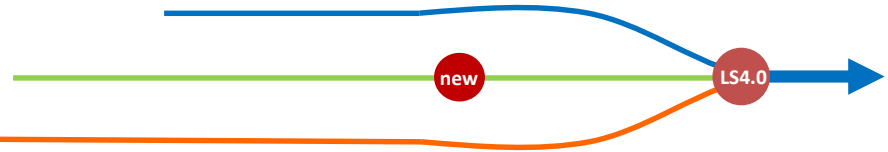
Handwritten/copied books  
provide access to few people



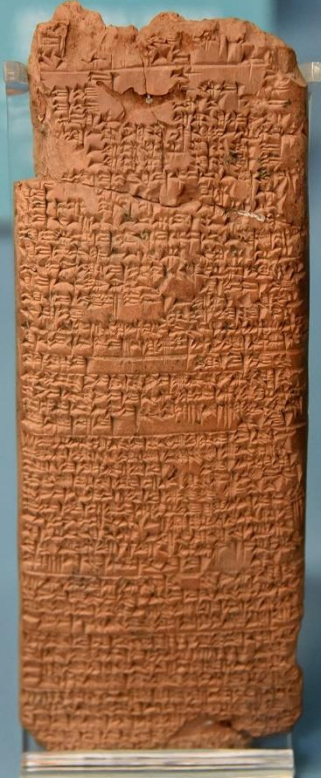
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# Life sciences 4.0

## Information sharing



>1800 BC



>500 AD

Handwritten/copied books  
provide access to few people



>1500 AD

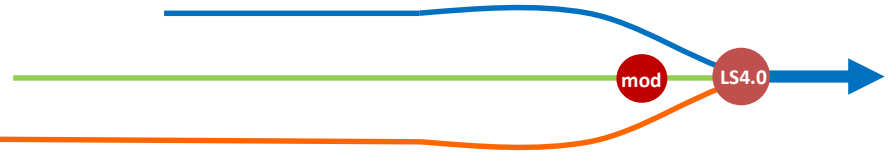
Printed books  
provide access to more people



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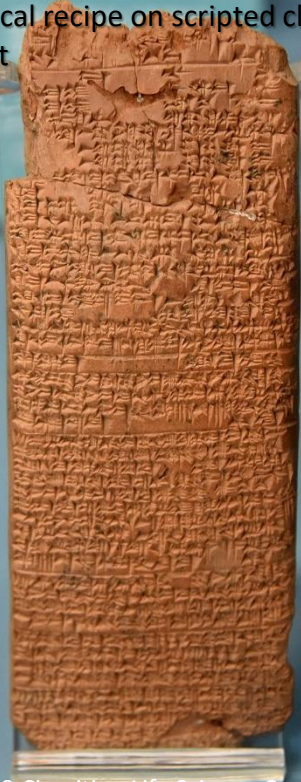
# Life sciences 4.0

## Information sharing



>1800 BC

Medical recipe on scripted clay tablet



>500 AD

Handwritten/copied books provide access to few people



>1500 AD

Printed books provide access to more people



>1980 AD

Internet by people provide access to large population

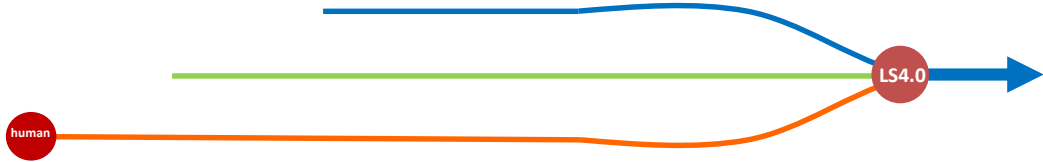


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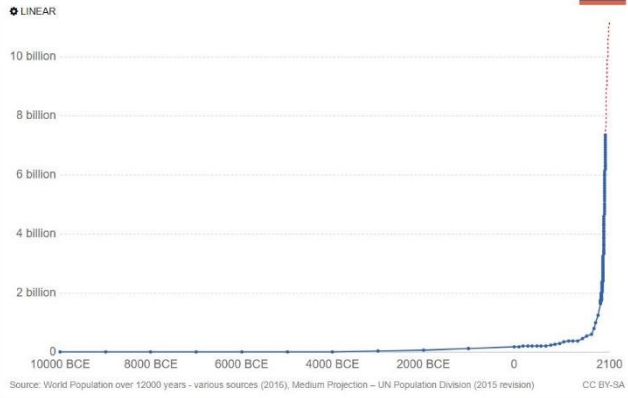


# Life sciences 4.0

## Socio demographic changes

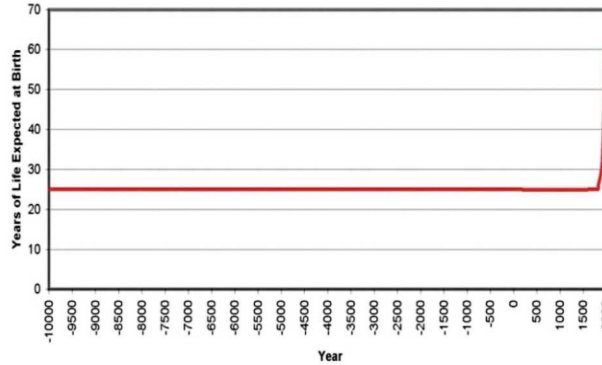


World Population over the last 12,000 years and UN projection until 2100

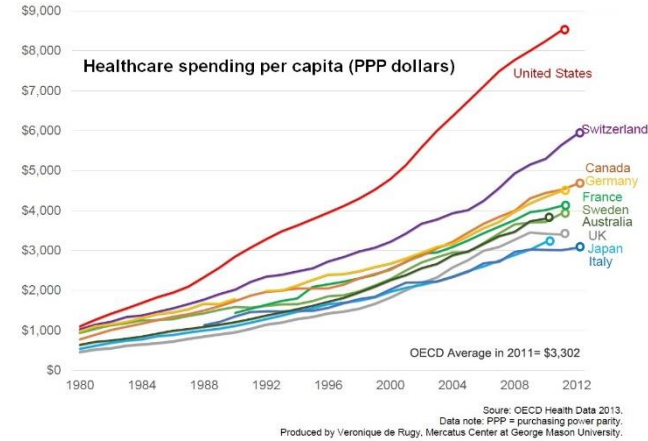


Global life expectancy

10,000BC - 2003

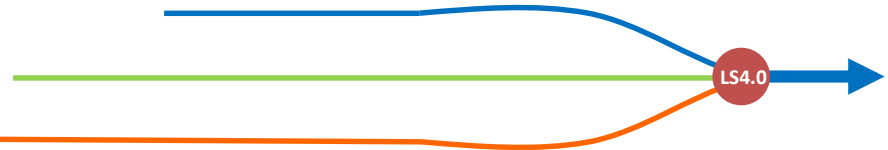


Healthcare spending per capita (PPP dollars)



The world population is growing.....aging with higher health quality.....while health care costs are exploding

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SMART

CONNECTED

VIRTUAL

ADAPTIVE



# Operating model



The 4 areas of any organization's operating model depreciate due to internal and external changes. PHARMA 4.0 is the model for 21<sup>st</sup> century social economics.

# Operating model

## Element “resources”

### Top 5 Physical Resource capabilities

1	Smart	“Things” extended with sensor, memory & communication
2	Connected	Digital Infrastructure
3	Virtual	Digital twin of the real world
4	Analytical	From static documents to dynamic infographics
5	Adaptive	From consistency to controlled variability

### Top 10 Human Resource skills

In 2020		In 2015	
- 1	Complex problem solving	1	Complex problem solving
↑ 2	Critical thinking	2	Coordinating with others
↑ 3	Creativity	3	People Management
↓ 4	People Management	4	Critical thinking
↓ 5	Coordinating with others	5	Negotiation
↑ 6	Emotional intelligence	6	Quality control
↑ 7	Judgment & decision taking	7	Service orientation
↓ 8	Service orientation	8	Judgment & decision taking
↓ 9	Negotiation	9	Active listening
↑ 10	Cognitive flexibility	10	Creativity

Human Machine Interface

### Examples

- Augmented & Virtual reality
- Infographics
- Voice AI
- Chat robots

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# Operating model

Element resources

Adaptive

FDA approved the first 3D printed tablets for public use



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## ADVERTISING FEATURE

### Top employers embrace change based on a stable foundation

By Chris Tachibana | Oct. 25, 2018, 2:00 PM

This Advertising Feature has been commissioned, edited, and produced by the [Science/AAAS Custom Publishing Office](#)

Like the biotech and pharma industry itself, the annual *Science* Careers Top Employers Survey continues to change and grow. This year, more than 8,000 responded, the most in the history of the survey, up from 6,950 last year. Of more than 180 companies mentioned frequently by survey participants, 20 emerged as top employers.

in a clinical supply chain

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# Operating model

Element “IT”

## 1D Integration (vertical)

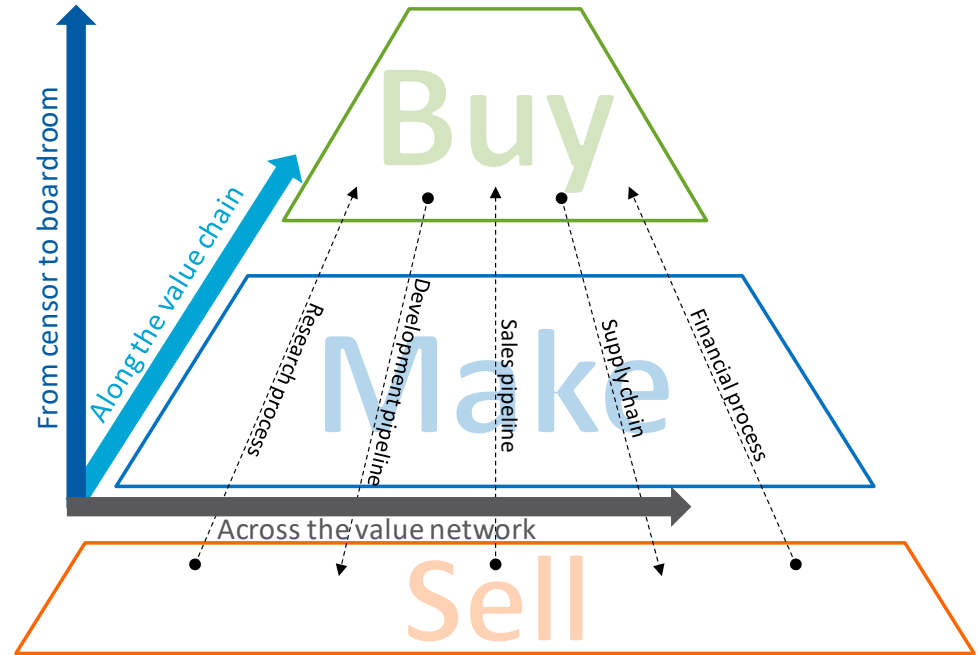
- To the decision hierarchy
- From data to wisdom

## 2D Integration (horizontal)

- Process control
- Along the value chain

## 3D Integration (across)

- Product Lifecycle Management
- Across the value network



# Operating model

## Element “culture”

*Our soft unwritten rules  
are still conditioned for mass production!*

- ~~One size fits all~~
- ~~Copy what is proved to be not wrong~~
- ~~Go with big business partners only~~
- ~~Consistency over creativity~~
- ~~Belonging to 1 organization with 1 boss~~
- ~~Presence based rewarding~~

*Mind sets must change  
from T-Ford to CAR-T*



"This really is an innovative approach, but I'm afraid we can't consider it. It's never been done before."

# Operating model

## Element “organization”

- **Empowered**

Restructure to

- Replace experience based decisions with data driven decisions
- Lower decision hierarchies
- Ensure all decision levels have decision information

- **Value driven**

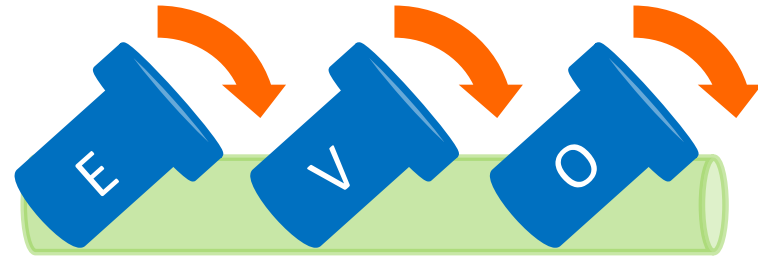
Restructure to

- Minimize hand offs in the value chain
- Maximize collaborations across the value network
- Focus on health care risks & value

- **Organization**

Architect to

- Align responsibility with capability
- Handle external to the company as internal to the value chain
- Enable collaboration communities next to value chain organizations



# Digital maturity

What is it

Operating  
model





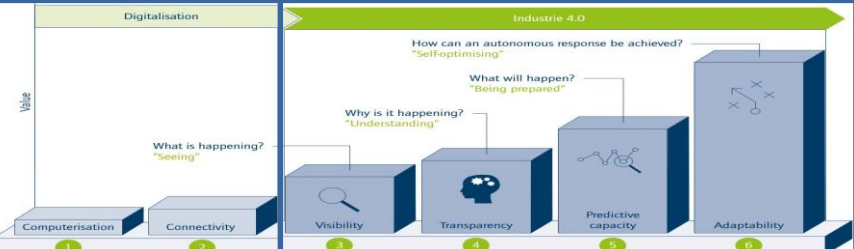
Digital  
maturity

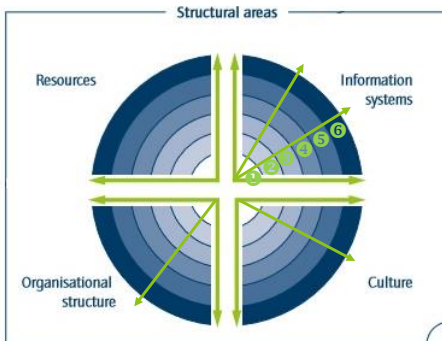
How to evolve to 4.0  
Different organizations have different start  
and endpoints

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# Digital maturity

The ISPE Pharma 4.0 maturity model, powered by Acatech

				
Industry	1.0	2.0	3.0	4.0
Information	Unit operation	Production Process		
Culture	Internal focus Adaptive behavior	Internal focus Stabilizing behavior		
Organization	Craft shop	Taylorism		
Resources	Mechanic	Electric		



**ISPE** | PHARMA 4.0

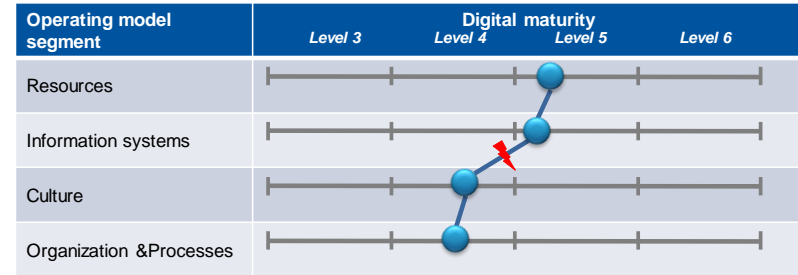
- ① Move from paper to computer
- ② Integrated system / system integration
- ③ Visibility into business partner organization
- ④ Trend view and analysis along the value chain
- ⑤ Predictive analytics
- ⑥ Automated controls

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# Digital maturity

## Some first experiences

- Asynchrony within an organization leads to no effect and tension
- Asynchrony between organizations leads to mismanagement



Setting targets and planning the journey, needs an “outside in view”

We found 3 different drivers:

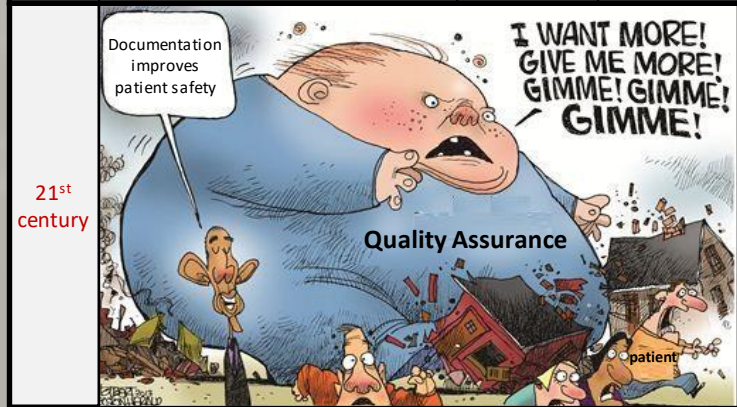
- Strategic enablement
- Technology push
- Risk resolution

# Let's shape the future of life sciences together!

Year	Product	Pages	Volume
1938	Adrenalin	27	1
1948	Benylin	73	1
1958	Poal	439	2

## Softenon disaster

1962	Norlestrin	12370	31
1968	Ketalar	72300	167
1973	Dantrium	200.000	456
1983	Voltaren	300.000	852



From  
imitation  
to  
innovation

**FDA** U.S. Food and Drug Administration  
Protecting and Promoting Public Health [www.fda.gov](http://www.fda.gov)

## FDA's Pharmaceutical Quality for 21<sup>st</sup> Century Initiative

**Vision**

*"A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high quality drugs without extensive regulatory oversight."*

- Dr. Janet Woodcock



 OFFICE OF PHARMACEUTICAL QUALITY

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