



UNIVERSITÀ  
DEGLI STUDI  
FIRENZE

**DISEI**

DIPARTIMENTO DI  
SCIENZE PER L'ECONOMIA  
E L'IMPRESA

# THE PERSPECTIVE OF CDMOs IN THE FUTURE OF PHARMACEUTICAL INDUSTRY

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## The European Undervaluation of Italy and the South Countries in Europe



Since the global financial crisis in 2008, Italy has always been considered one of the weak point of Europe, together with other south countries (PIGS).

- Low growth rate of GDP
- Large Public Debt
- High Unemployment
- Complex bureaucracy and Public Administration
- High tax pressure

# The narrative of a misunderstanding



Source: The Economist

# Un Unconventional Truth

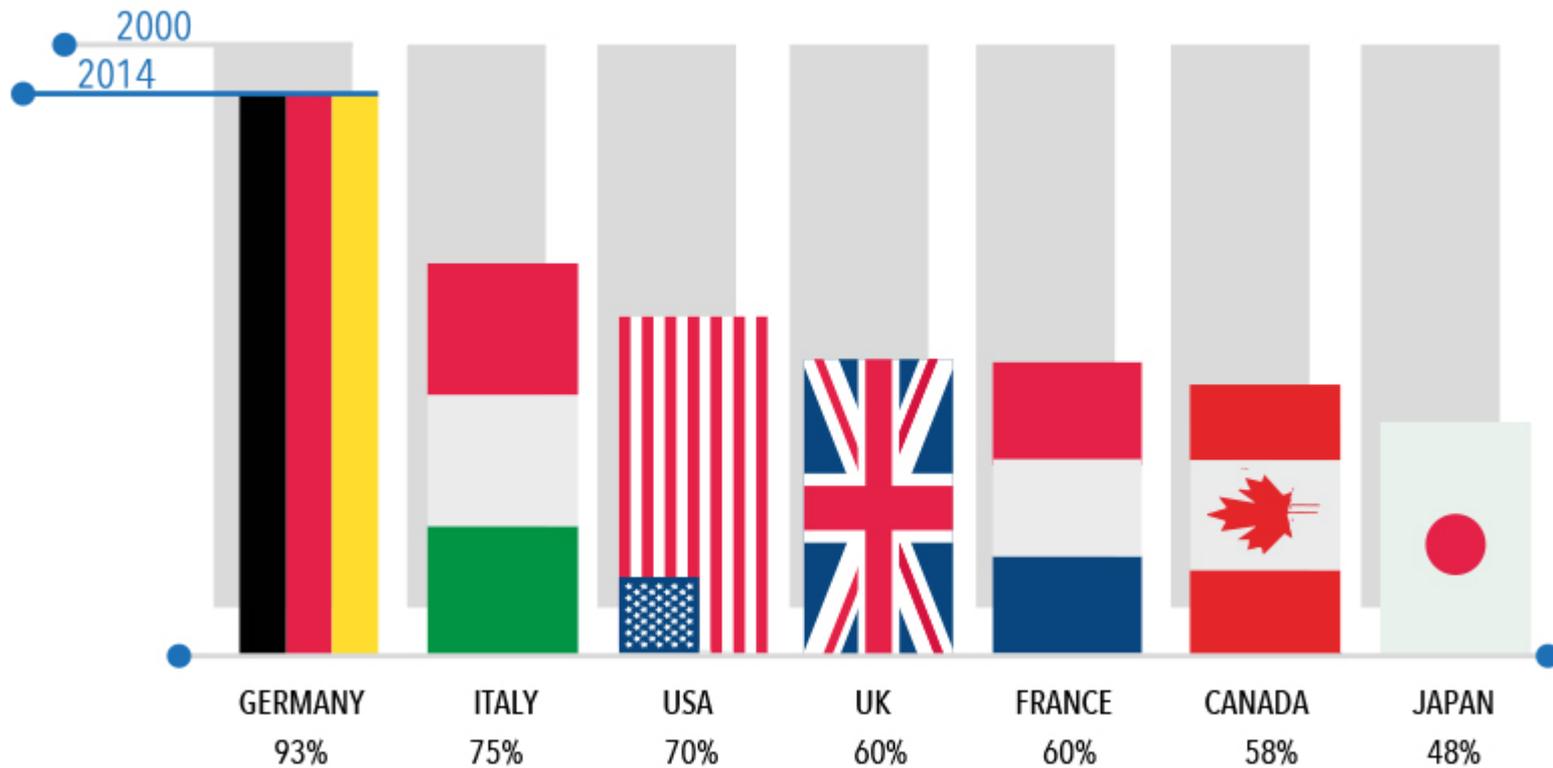
## The Top Five Players in Manufacturing Trade Balance in 2015 (€B)

1st		+738
2nd		+269
3rd		+106
4th		+103
5th		+57

In recent years Italy performed very well in the manufacturing market, achieving the fifth manufacturing trade surplus amongst G-20 countries, surpassed only by Germany amongst European countries.

Source: Italian Trade Agency, IHS Markit - GTA

# World's Export Shares of Manufactured Products (2014 vs 2010)



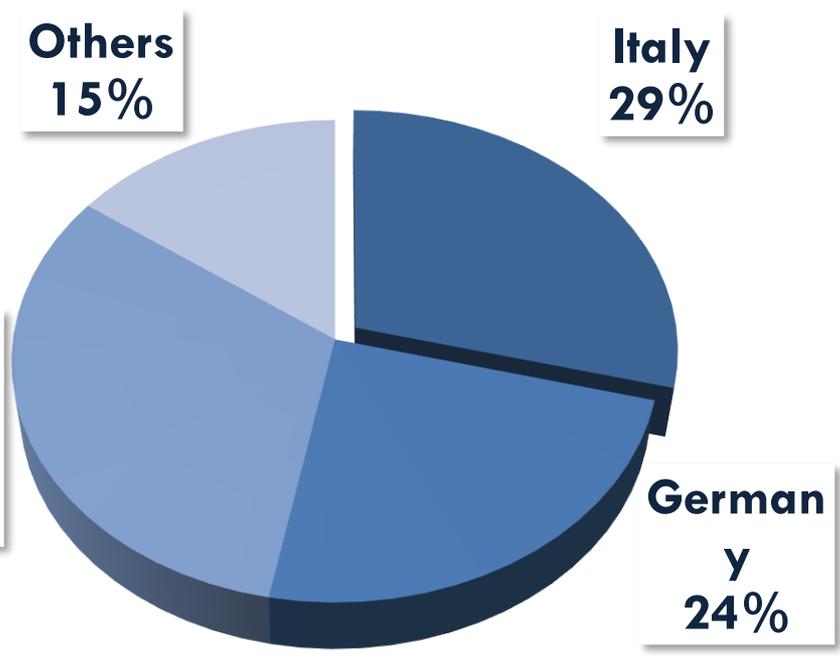
Source: WTO, Italian Trade Agency, IHS Markit - GTA

## Giving a Look at the Pharma Industry in Italy

- 1<sup>st</sup> among all manufacturing sector for investment and export of foreign-owned companies
- 30€ billion the value of production (73% for export - 22€ billion)
- 2.6€ billion total amount of investments (1.4€B R&D and 1.2€B production)
- 70% the share of export on total turnover of italian-owned companies
- 63.500 employees (90% have an academic degree or high school diploma)
- 6.100 researchers (52% are women)
- +15% R&D investments since 2013
- 200 members companies of Farmindustria, that represent more than 90% of the sector in Italy

Source: Farmindustria, Istat, Ocse

# The CDMO Market in the European Union



With a 5.1\$B CDMO's product value in European Union, Italy is the first producer country (1.5\$B) followed by Germany (1.2\$B) and France (1.0\$B), despite tax pressure is 1.5 times higher

Leadership and High Specialization  
CDMO market share (29%) exceeds EU28 manufacturing market share (13%)

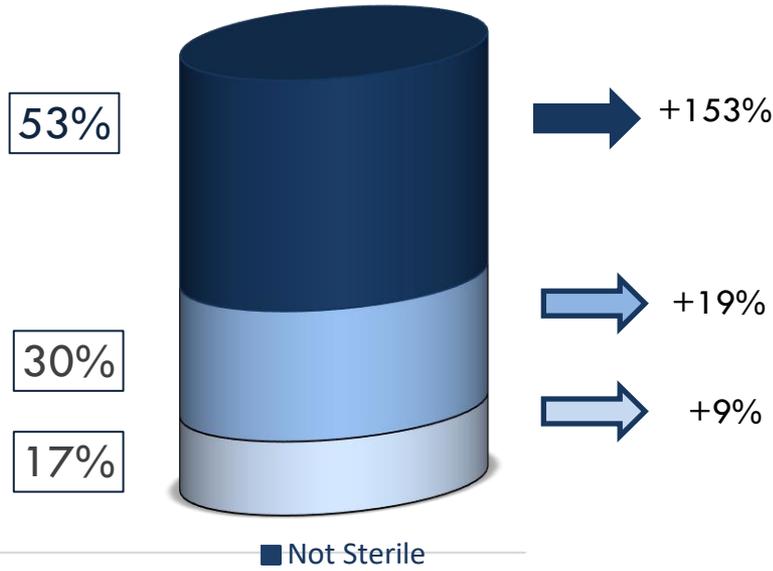
High Qualified Employment  
8.000 employees in Italy, compared to 6.000 in Germany and 5.000 in France

Source: Prometeia

# 5 Years of the Italian CDMO's Market (2010 - 15)

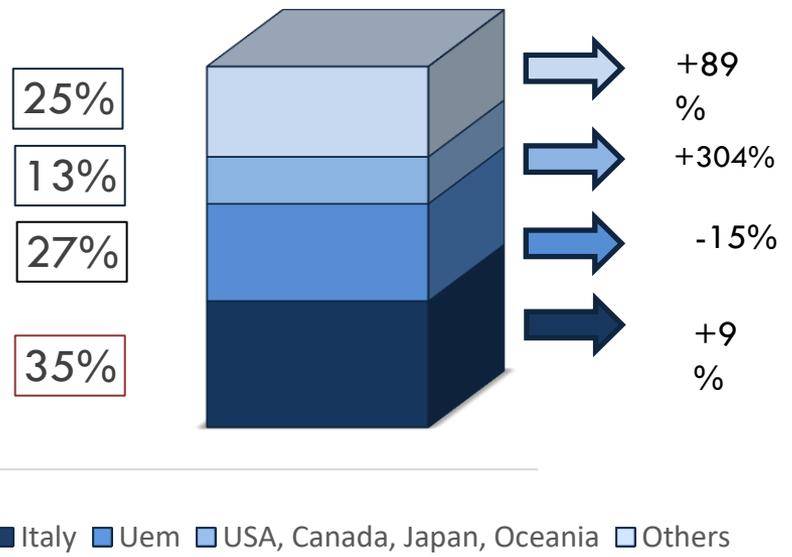
**Production value : +24%**

## Production composition



**Export value : +34%**

## Market composition



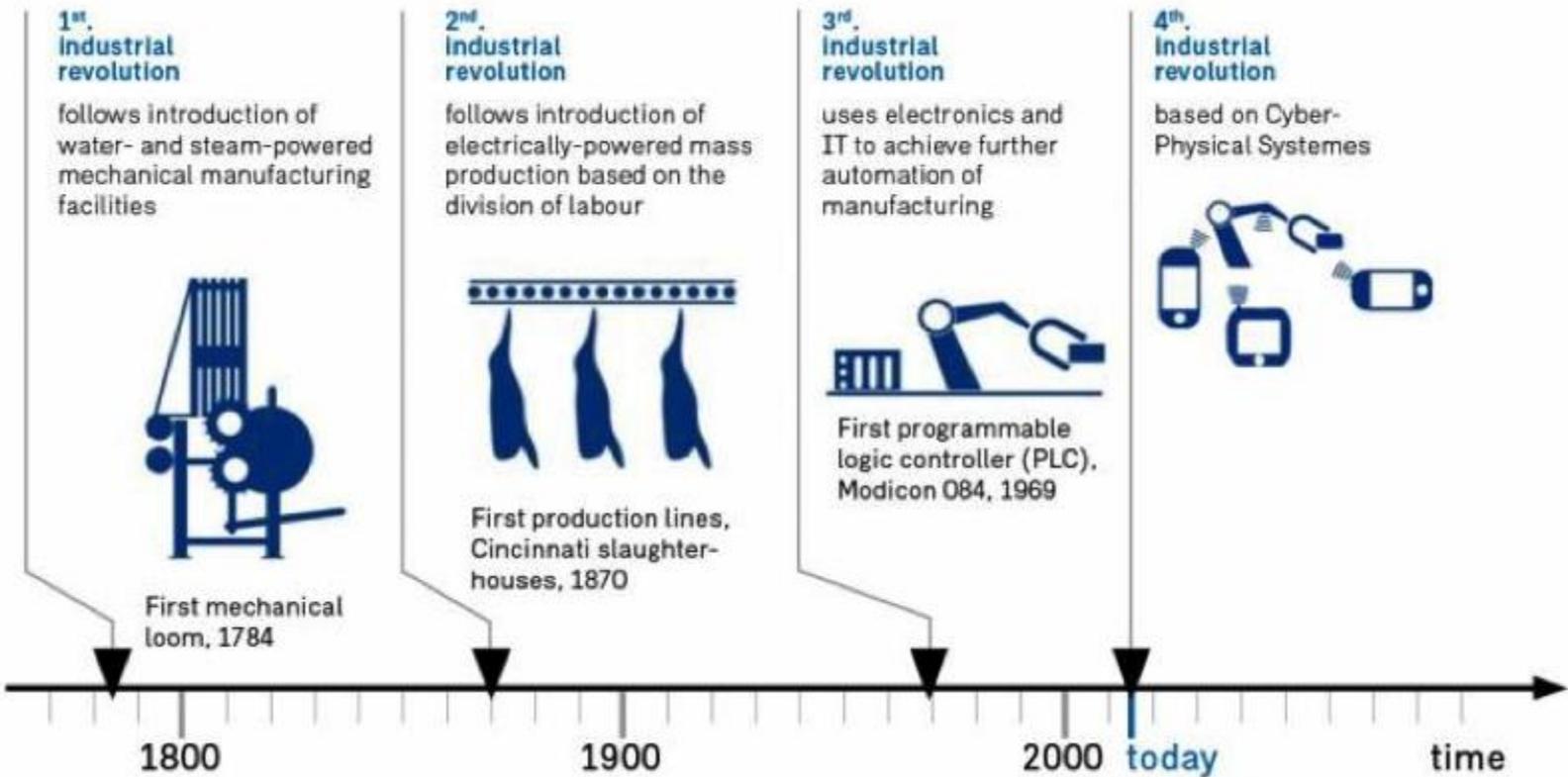
# Which game for CDMOs

		Emerging/specialized technology	Core/foundational technology	Mature technology
	<b>Propensity to outsource</b>	<b>High</b>	<b>Low</b>	<b>High</b>
<b>Strategic Driver</b>	<b>Knowledge</b>	<b>Innovation Driven CDMOs</b> Focused on higher-value market opportunities, including new molecular entities and improved dose forms and formulations of older drugs		<b>Capacity Driven CDMOs</b> Focused on filling largely undifferentiated manufacturing capacity primarily by producing generics, undifferentiated over-the-counter (OTC) medications, and late lifecycle branded products
	<b>Networks</b>			

## What typically gets outsourced?

	<b>Emerging/specialized technology</b>	<b>Core/foundational technology</b>	<b>Mature technology</b>
<b>Characteristics</b>	<ul style="list-style-type: none"> <li>Occasional need</li> <li>Expensive to build/hold</li> <li>High risk</li> <li>Unproven</li> </ul>	<ul style="list-style-type: none"> <li>Central to strategy</li> <li>Performance evolving rapidly</li> <li>High utilization</li> <li>Knowledge-generating</li> </ul>	<ul style="list-style-type: none"> <li>Declining strategic importance</li> <li>Evolution slowing</li> <li>Established procedures</li> <li>Widely-available</li> </ul>
<b>Examples</b>	<ul style="list-style-type: none"> <li>Highly potent API</li> <li>Gene/cell therapy</li> <li>Specialty drug delivery</li> </ul>	<ul style="list-style-type: none"> <li>Mammalian cell culture</li> <li>Injectable fill/finish</li> <li>Methods &amp; form development</li> </ul>	<ul style="list-style-type: none"> <li>Small/molecule API</li> <li>Solid dose</li> <li>Testing with validated methods</li> </ul>
<b>Propensity to outsource</b>	<b>High</b>	<b>Low</b>	<b>High</b>

# The times they are changing – A new Revolution in Industry



# The times they are changing – Top Ten Corporation (Market Capitalization - \$ B)

**2006**  
(\$2,850 B)



**INTERNET**  
**\$294 B**

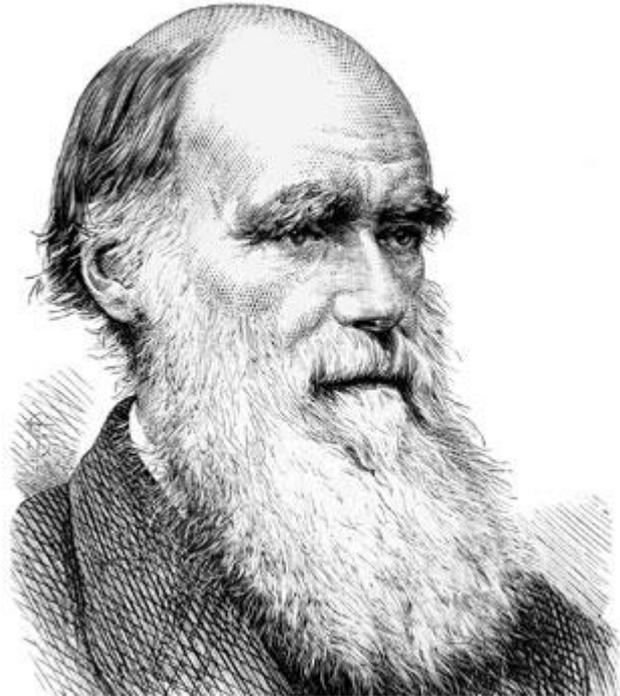
**2016**  
(\$3,623 B)



**INTERNET**  
**\$2.062 B**

Andrea Paci - CPhi Worldwide - Barcelona -  
04.10.2016

# The lesson of Charles Darwin



“It is not the strongest species that survive,  
nor the most intelligent,  
but the ones most responsive to change”

Engraved into the floor of the platform of Academy of Science

## The forth industrial revolution and quick convergence of different industry

“We have reached a critical moment, a point where the digital agenda is fusing with industrial production”

Angela Merkel said in April 2016 at the Hanover Messe, the world’s largest industrial fair.

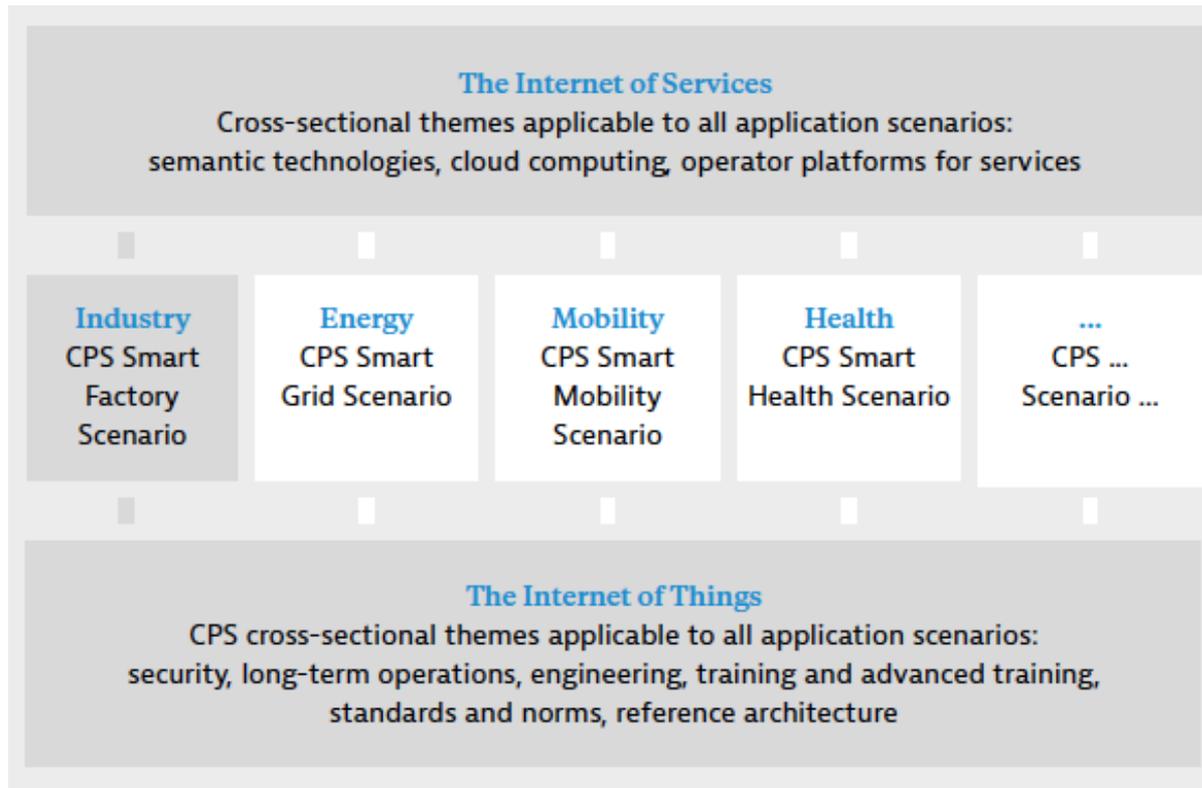
“Nokia didn’t take the challenge posed by Apple and its iPhone seriously and within a few years, it found itself on the brink of collapse and was broken up.

The fear in Germany is that the auto industry is about to reach a similar tipping point as digital advances lower the barriers to entry into the car industry.

While a Google or Apple self-driving car may have been unthinkable just a few years ago, it could soon become reality”.

Source: Karnitschnig 2016, Why Europe’s largest economy resists new industrial revolution in [www.politico.eu](http://www.politico.eu)

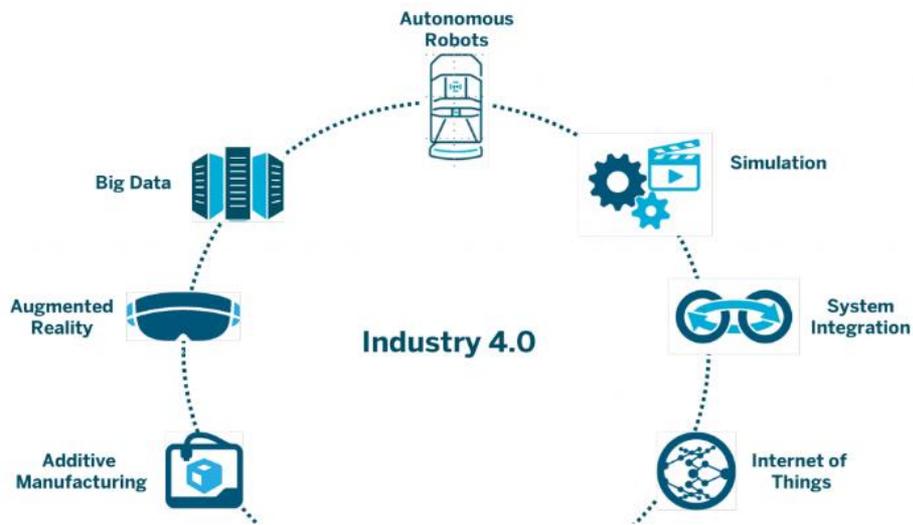
# The Fourth Revolution of Industry and New Scenarios



Source: Germany Trade & Invest, Industry 4.0

Andrea Paci - CPhi Worldwide - Barcelona -  
04.10.2016

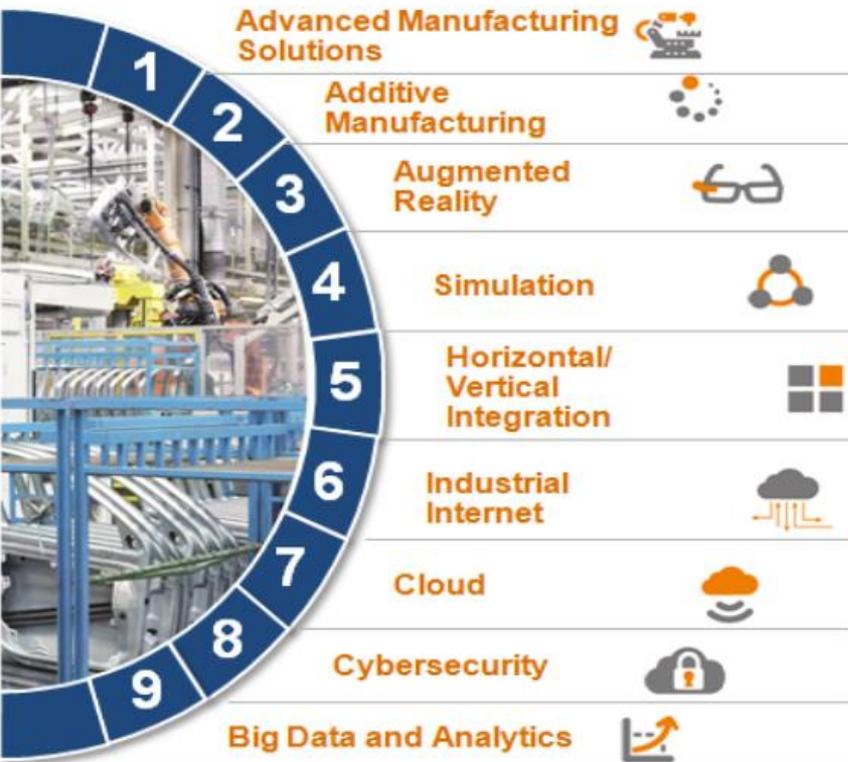
## Why Italy will go on being one of the top manufacturing countries?



Many Italian companies create value through specialization, and Industry 4.0 model, gives a main role to big data and analytics;

- Real Time Replenishment: supply chain's automatic management, with no stop monitoring of warehouses for increase lead times
- Facilities' Remote Control: automated management of the operation and maintenance of production facilities
- Virtual Factory: simulation and verification of feasibility of alternative production scenarios

# What is the Italian Government Doing?



According to 'Piano nazionale Industria 4.0', introduced by Italian Prime Minister Matteo Renzi and Minister of Economic Development Carlo Calenda (September, 2016), in the next 4 years there will be 23 billion of euro of public investments, in order to improve times for the fourth industrial revolution.

New rules for "depreciation" will be included as concessions for improve private investments. Credit taxes for research will be raise to 500,000€ from previous 300,000€, while fiscal deduction will be 30% with a maximum of 1€M (from 19% with a maximum of 0.5€M).

According to government promises and experts analysis, the future of italian CDMOs looks bright.

More than 80% of experts expect a global growth in production by 2020, and for the 44% of them it will be more than 5% for year.

According to Bain & Company, global production will grow more than 10% for year.

According to President of Farindustria Massimo Scaccabarozzi, the obstacle to overcome ask for the creation of new and clearer administrative rules which could improve the CDMOs business, enabling better performance and more competitive advantages.

## The Big Pharma in Search of a New Business Model – New Opportunities for CDMOs

“The old blockbuster model can’t be the centerpiece of big pharma’s strategy going forward.

The old model is dead, and big pharma is struggling to come to terms with what new model is going to work.

What is clear is that scale is not going to do it.”

J. Kimberly, management professor, Wharton - University of Pensilvenya

”The age of the blockbuster also reflected a “one-size-fits-all” approach to drugs.

The drug industry has been moving away from that, toward more of a personalized approach”

J. Loo, health care equity analyst for S&P Capital IQ

## New Business Model at the time of Industry 4.0

“German companies generally consider their work to be done once a product leaves the factory.

But in the world of Industry 4.0, also called the industrial internet, that’s just the beginning.

A matrix of internet-enabled sensors will soon link factories with customers and suppliers to optimize production and service.”.

Source: Karnitschnig 2016, Why Europe’s largest economy resists new industrial revolution in [www.politico.eu](http://www.politico.eu)

# Michel Porter's Generic Strategies Framework Revised

## STRATEGIC ADVANTAGE

**Uniqueness Perceived  
by the Customer**

**Low-Cost Position**

**Knowledge**  
**STRATEGIC  
DRIVER**

**Innovation Driven CDMOs**  
Focused on higher-value market opportunities - including new molecular entities and improved dose forms and formulations of older drugs

**Large Scale Advantage  
(Blockbuster model)**

**Networks**

**Customer Care  
(Industry 4.0)**

**Capacity Driven CDMOs**  
Focused on filling largely undifferentiated manufacturing capacity primarily by producing generics, undifferentiated over-the-counter (OTC) medications, and late lifecycle branded products

## The lesson of Marco Polo (by Italo Calvino)

Marco Polo describes a bridge, stone by stone.

"But which is the stone that supports the bridge?"

Kublai Khan asks.

"The bridge is not supported by one stone or another,"

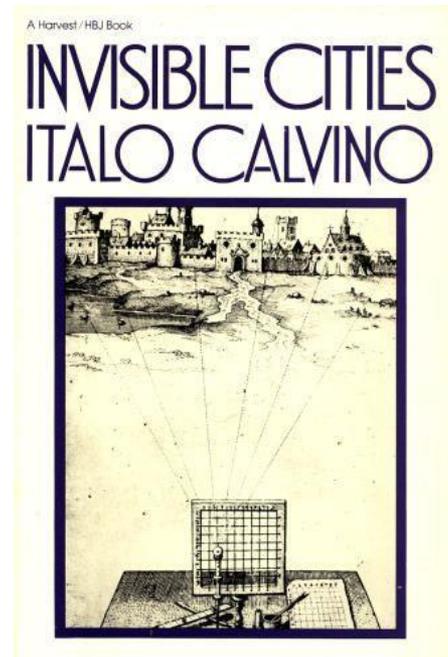
Marco answers, "but by the line of the arch that they form. "

Kublai Khan remains silent, reflecting. Then he adds:

"Why do you speak to me of the stones? It is only the arch

that matters to me."

Polo answers: "Without stones there is no arch."



Italo Calvino 1972, Invisible Cities