



1° INCONTRO  
**AUTOMAZIONE: LA FIGURA PROFESSIONALE DELL'INGEGNERE**

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**Pharmaceutical industry: opportunities for automation engineers**  
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**The Pharmaceutical Industry in Italy has always been active even in the worst moments of the recent economic crisis.**

- Production has exceeded 30 billion in value in 2017 (+ 2,3% in one year)**
- Export of API and Finished Products worldwide for 21 billion of value (equal to 71% of total value)**
- Excellent company reputation worldwide**
- Italian Pharmaceutical Industry is in the second place at European level (economic value of products)**

**Pharmaceutical laboratories have been subjected to strict controls (inspections) carried out by the competent authorities on compliance with GMPs, both for the production of finished products (FP) and raw materials (API).**

## Evolution over the years

### “Spontaneous” growth (empirical methods)



## Number of pharmaceutical plants in Italy

**Year 1990**      **752 FP**  
**159 API**  
**523 Medicinal Gases (primary and  
secondary production / filling  
of cylinders)**

# Evolution over the years Scheduled Growth (scientific methods)



## Number of pharmaceutical plants in Italy

**Year 1990      752 FP**

**159 API**

**523 Medicinal Gases (primary and  
secondary production / filling  
of cylinders)**

**Year 2018      264 FP (-65% compared to 1990)**

**145 API (- 9% compared to 1990)**

**158 Medicinal Gases (primary and  
secondary production / filling of  
cylindres) (- 70% compared to '90)**

**Pharmaceutical production is strongly regulated and provides pre-marketing authorization for each medicinal product: to obtain the authorization it is necessary to demonstrate**

**1) EFFECTIVENESS**

**2) SAFETY**

**3) QUALITY of the medicinal product**



## **FOR PRODUCTS SUBJECT TO PRE-MARKETING AUTHORIZATION**

- THE PROPOSED STANDARD IS PRELIMINARY  
EVALUATED BY THE AUTHORITY THAT APPROVES THE  
QUALITY OF THE PRODUCT (with acceptability limits)**
- CIVIL AND CRIMINAL LIABILITY, IN CASE OF DAMAGE  
ATTRIBUTABLE TO THE PRODUCT, MUST BE JUDGED  
AND CHARGED BETWEEN ALL THE ENTITIES  
INVOLVED (THE LIABILITIES ARE ADDED).**

**For the production of an authorized medicinal product, the manufacturing plant must also be authorized for the purpose by the competent Authority.**

**In Italy the competent Authority is the Italian Medicines Agency (AIFA).**

**The Plant must be able to manufacture the medicines in compliance with the Good Manufacturing Practices (GMP) which are European Guidelines adopted in all the countries of the Union and are mandatory.**

**Compliance with GMPs is not self-certified: for this reason inspections are carried out with an established frequency by the Regulatory Authority.**

**All production phases and quality control are to be documented to guarantee a complete traceability during all the time of batch validity on the market.**

**The plant must be equipped with appropriate premises and equipment for the purpose, of qualified and suitably trained personnel, of a quality assurance system that always guarantees compliance with production procedures in accordance with the registration dossiers of each product.**

## The control can be carried out ...



or...





## Different approaches

- **PRO AUTOMATION (USA)**
- **INTERMEDIATE AUTOMATION (EU)**
- **MANUAL APPROACH (CHINA AND EMERGING COUNTRIES)**

# CONTINUOUS IMPROVEMENT

## QUALITY PRODUCTS IN ACCORDANCE WITH THE FIXED STANDARDS:

- RULES
- EQUIPMENT AND PROCESSES
- REGISTRATION DOSSIER  
(dossier o CTD)



# CONTINUOUS IMPROVEMENT

## TREND TO:

- CHANGE CULTURAL APPROACH
- MODIFY PRODUCTION PROCESSES
- REDUCE PRODUCT QUALITY PARAMETERS  
LIMITS

We need to remain competitive internationally!

Optimization of:

- Human Resources
- Production Lines
- Suppliers Lists (materials and services)
- Performance of production systems

## CAUSES OF NON CONFORMITY

- LACK OF PERSONNEL AND/OR TOOLS/PREMISES
- OVERWORK
- POOR TRAINING (OFTEN SEEN AS A COST)
- RUSH IN THE EXECUTION OF OPERATIONS  
(INCOMPLETE, INACCURATE, NON-CONTEXTUAL  
REGISTRATIONS)

## MANUAL OPERATION

IN ANY CASE ALL MANUAL OPERATIONS  
MUST BE CHECKED WITH A DOUBLE CHECK  
BY A SECOND OPERATOR, WHICH MUST SIGN  
THE VERIFIED RAW DATA

**There are many job opportunities for those who know how to manage innovation (and automated processes)**

**In comparison with the 567 pharmaceutical companies operating in Italy, over 80% are small / medium enterprises that, by necessity, can not afford to have internal engineering / IT sectors, but rely on external suppliers.**

**The current need to promote the digitalisation of Italian companies, with the modernization of production processes, is, in fact, an essential tool through which small and medium enterprises can further gain competitiveness on international markets.**

**After the three already known industrial revolutions, is now the time of the**

## **FOURTH INDUSTRIAL REVOLUTION**

**which proposes growth based on:**

**CONNECTIVITY of companies**

**DIGITALIZATION on the entire national territory**

**PROMOTION OF TECHNOLOGICAL INNOVATION**

**(super-depreciation of investments made for capital goods, software)**

**RESEARCH AND DEVELOPMENT ACTIVITY INCENTIVES**

**INCENTIVES FOR PERSONNEL TRAINING ACTIVITIES**

**All aimed at guaranteeing an increase in productivity and competence for the production of quality products with a decrease in the relative production costs.**

**Only in this way will be facilitated the competition of Italian industry in comparison with the Third Countries.**

**The digital challenge for the pharmaceutical industry operating in Italy has already begun, but more and more it will enter the way of producing medicines.**

**Just think of the production of TABLETS with 3D copiers.**

**And you can fully assist in this process of innovation and development!**

**For INGEGNOSIS ENGINEERS it's time to get busy.**

**Ad maiora!**



**Thanks a lot for your attention!**

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