

University

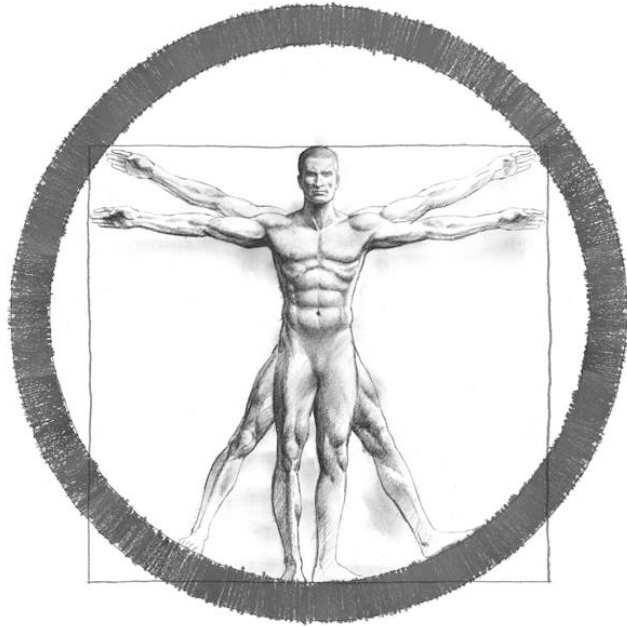
Joints

Industry

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**Galenicum** believe in life





# Quality Control

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# 1 WHY?

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- ▶ In the 1960s, after some trouble with patients treated by Thalidomide, in developed countries are introduced guidelines for safety and control of drug products.
- ▶ Each Company that has a manufacturing authorization should have a **Quality Control** department under the responsibility of Qualified Person and it will be independent of production department and other departments.
- ▶ **Quality Control** lab performs the analysis to ensure if the values are according with the specifications.
- ▶ The parameters to be evaluated in a **Quality Control** activities are: Aspect, Related substances, Content, dissolution test, identifications, fisico-chemical properties...
- ▶ Generally, **Quality Control** is applied to Finish product, intermediates or raw materials.



## 2. ONE DAY IN THE OFFICE

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- ▶ Analysis planning
  - Duration
  - Resources (equipment and analyst)
  - Timings
  - Priorities
- ▶ Documentation review
- ▶ Interdepartmental relations
  - Regulatory Affairs
  - Supply Chain Management
  - Quality Assurance
  - Production
- ▶ You have to deal with:
  - Everybody!
- ▶ Best/worse of the job position
  - Ensure that products are safe for people
  - Pressure from other departments



### 3. WHAT IS THE MARKED LOOKING FOR?

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#### ► Personal skills for quality control



You must be **observant** and very good at paying attention to detail



You will also need to be **patient** as some tests are complex and take a long time to complete.



You should have a logical, **methodical** approach to your work and you must be **accurate** when taking measurements and recording figures.



You should have good **computer skills** because you often analyze, store and display test results on computers.



You may also need the ability to use **technical equipment**, for example, HPLC and automated testing machines.

## 4. ARE YOU THE PERSON?

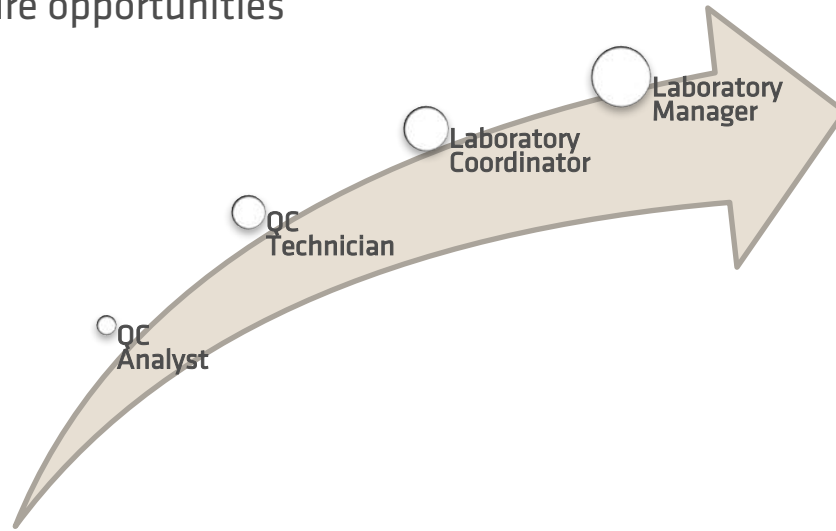
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- ▶ Job description, roles and responsibilities
  - Analysis and analyst planification
  - Analytical support, solving analytical and equipment issues.
  - Ensure that the analysts performs the analysis according to the registered procedures
  - Review the data generated by the analyst
  - Check that the results meet the registered specifications and evaluate these results
  - Edit a Certificate of analysis
  - Maintenance of departments documentation
  
- ▶ Knowledge
  - Highly disciplined, responsible, methodical, decisive and organized individual.
  - Strong attention to detail and analytical frame of mind
  - Capable to work under pressure
  - Equipment knowledge: HPLC, KF, GC, IR, Dissolution test, UV, ...
  - Analytical experience
  - GMP (Good Manufacturing Practices)
  - Excellent oral and written communication
  - Good team player
  
- ▶ Previous Knowledge:
  - Degree in Chemistry or Pharmacy
  - Excellent level of scientific English, spoken and written

## 5. CAREER DEVELOPMENT

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### ► Future opportunities



#### Change of department

- ✓ Quality Assurance
- ✓ Project Management

### ► Knowledge development

- Analytical skills
- GMP (Good Manufacturing Practices)
- Resolving capacity
- Planning capacity
- Teamwork and communication skills

thank you!