University Joints Industry
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Quality Control

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1. WHY?

- 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

- 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?

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?

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

Future opportunities

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

Change of department
✓ Quality Assurance
✓ Project Management
thank you!