Think forward, think pharma

University Joints Industry

SPEAKER

BARCELONA - 13th MARCH 2019
1. Role of your area within the Pharmaceutical Industry

QUALITY CONTROL ROLE

• The term quality control refers to all procedures undertaken to ensure the identity, efficacy, safety and compliance of a particular pharmaceutical by means of testing.

• Laboratory based inspection role all along the company operational chain

• Procedures may range from simple chemical tests (infrared spectroscopy, etc.), to more complicated requirements (chromatography, microbiology).

• Activities extend to the area of quality assurance:
  - GMP
  - Audits/Inspections
  - Release (CoAs, LIMS)
  - Investigations/ Deviations/ Complaints

SUPPLIERS

API+ Excipients+Packaging Materials
Intermediates, In Process Controls
Final Products
Retain Samples

PATIENTS
1. Role of your area within the Pharmaceutical Industry

ANALYTICAL DEVELOPMENT AND RESEARCH (ARD) ROLE

• Analytical Development role is to develop tools to guide the pharmaceutical development in order to have robust, feasible and quality driven products and processes.

• Laboratory based innovation role based on high analytical and chemical knowledge.

• Different chemical test with different purpose (IP, quality, clinical driven) which some of them need to be transferred to QC as part of product specification.

• Activities extend to the area of regulatory department, galenical and manufacturing departments and usually uses external company knowledge.
2. One day in the **QC** Office

- Planning daily activities with your team (resources allocation)
- Supervision and “release” activities (CoA generation, raw data revision…etc.)
- Troubleshooting
- Company team discussions (investigations, audit preparations, projects being transferred…etc.)

2. One day in the **ARD** Office

- Planning daily activities with analyst and galenical project leader
- Observation, Conclusion, Fine-tuning, Reanalysis, Observation, Conclusion…
- R&D team discussions (What does this result mean?, next steps..)
- Authorities Questions
- Reporting
### 3. What is the marked looking for?

<table>
<thead>
<tr>
<th>Technical skills</th>
<th>QC</th>
<th>ARD</th>
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<tbody>
<tr>
<td>Pharmacy, Chemistry, Biology Degree</td>
<td>Pharmacy, Chemistry</td>
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<td>Analytical techniques</td>
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<td>GMP, ISO Standards in Laboratories</td>
<td>Instrumentation</td>
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<td>Statistical Knowledge</td>
<td>Pharmaceutical Process</td>
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<td>English</td>
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<table>
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<tr>
<th>Soft Skills</th>
<th>QC</th>
<th>ARD</th>
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<td>Detailed oriented person</td>
<td>Result oriented person</td>
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<tr>
<td>Analytical and research skills</td>
<td>Sound judgment and decision making</td>
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<td>Ability for multitasking</td>
<td>Communication skills</td>
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<td>Teamwork</td>
<td>Project Management</td>
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5. QC Career development

QC Analyst

QC Supervisor/Coordinator → Production Supervisor/Coordinator

QA Manager ↔ QC Head/Manager ↔ Production Supervisor/Coordinator

QC Director
5. **ARD Career development**

- **ARD Analyst**
- **ARD Project Leader**
- **RA Project Leader**
- **Project Manager**
- **RA Manager**
- **ARD Head/Manager**
- **R&D Head/Manager**
- **ARD Director**
6. Life Science market evolution

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- Salary Estimation per position/location/experience
- Career plans
- More searched position
- Reasons for talent retention
7. Questions

1. Do QA and QC department perform the same activities in the pharmaceutical industry?
   - a. Yes, they do and because of that both departments work under the same unit
   - b. No, QA assures you are doing the right things, the right way while QC assures that the results of what you have done are the expected ones
   - c. No, QC and QC are totally two independent departments in every single pharmaceutical industry
   - d. No, because QC is the responsible department for releasing the product to the market

2. Analytical Research and Development Department...
   - a. never participates in quality investigations for commercial products
   - b. only develops the methods/tests that are finally used in the QC department
   - c. needs to understand the process and the formula changes to correctly guide the development
   - d. implies the use of limited analytical techniques
Thank you
Goal

• Social Responsibility Program: give students facilities to access to the industry

• Share laboral market knowledge

• Attracting talented students for our internship program

• Creation and diffusion of Galenicum brand and UB in the market.

• Networking