QUALITY ASSURANCE

Workshop-UB March 2018
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QA_CMO Manager & QP

Synthon
1. WHY?

Quality Assurance

- Purchase of raw materials/packaging materials
- Production
- Packaging
- Quality control
- Release medicinal product
2. ONE DAY IN THE OFFICE?

1. One current day
   - Project meetings
   - Department meetings: follow up activities & priorities
   - Revision/Approval of product documentation: stability, master batch records
   - Review of deviations/pending actions
   - Release of batches
   - Mails
   - Customer requests

2. Best/worse of the job position

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<td>Teamwork</td>
<td>Pressure</td>
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<td>Good ambient</td>
<td>Urgency</td>
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<td>Leadership</td>
<td>Discussions</td>
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<td>Global vision</td>
<td>Customer standards</td>
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<td>Interdepartmental / Intercompany relationship</td>
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<td>Multitasking</td>
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2. ONE DAY IN THE OFFICE?

3. Interdepartamental relationship
2. ONE DAY IN THE OFFICE?

4. What you have to lead with?
3. WHAT IS THE MARKET LOOKING FOR?

Personal skills:
- Attention to detail
- Communication skills - verbal and written
- Leadership
- Process approach
- Data collection, management and analysis
- Problem analysis and problem solving
- Planning and organization
- Judgment
- Decision-making
- Continuos improvement
- Customer service orientation
- Teamwork
4. ARE YOU THE PERSON?

1. Job description
   • Application and constant improvement of the Quality Assurance system.
   • Participate in the annual plan of internal audits and in performance external audits
   • Receive inspections from Health Authorities
   • Evaluate vendor, report and track CAPA (preventive and corrective actions) necessary
   • Management and follow-up of deviations/non conformities and investigation, changes controls, customer complaints and CAPA actions
   • Review technical documentation related to validations, analytical methods and processes production
   • Review testing, inspection of materials, production records of products to ensure finished product quality
   • Participate in finished product releases.
   • Provide continuous training to all staff, as well as guarantee their application and compliance.
   • Compile statistical quality data and perform Annual Product Review
   • ....
4. ARE YOU THE PERSON?

2. Knowledge

• University Degree in Health Sciences, ideally Pharmacy.
• Highly valued Postgraduate or Master in the Pharmaceutical Industry.
• High level of English.
• Knowledge of specific computer systems. Such us: SAP, Lims, Trackwise…
• Methodical and organized person

3. Previous knowledge

• Experience in quality assurance departments in the pharmaceutical industry.
• Experience in quality control or other operational departments such as production, technology, validations…
• Internship in a pharmaceutical company
5. CAREER DEVELOPMENT

Technician

Auditor

Qualified Person

Manager

Director
Questions??
Thank you!