



QUALITY ASSURANCE

Workshop-UB March 2018

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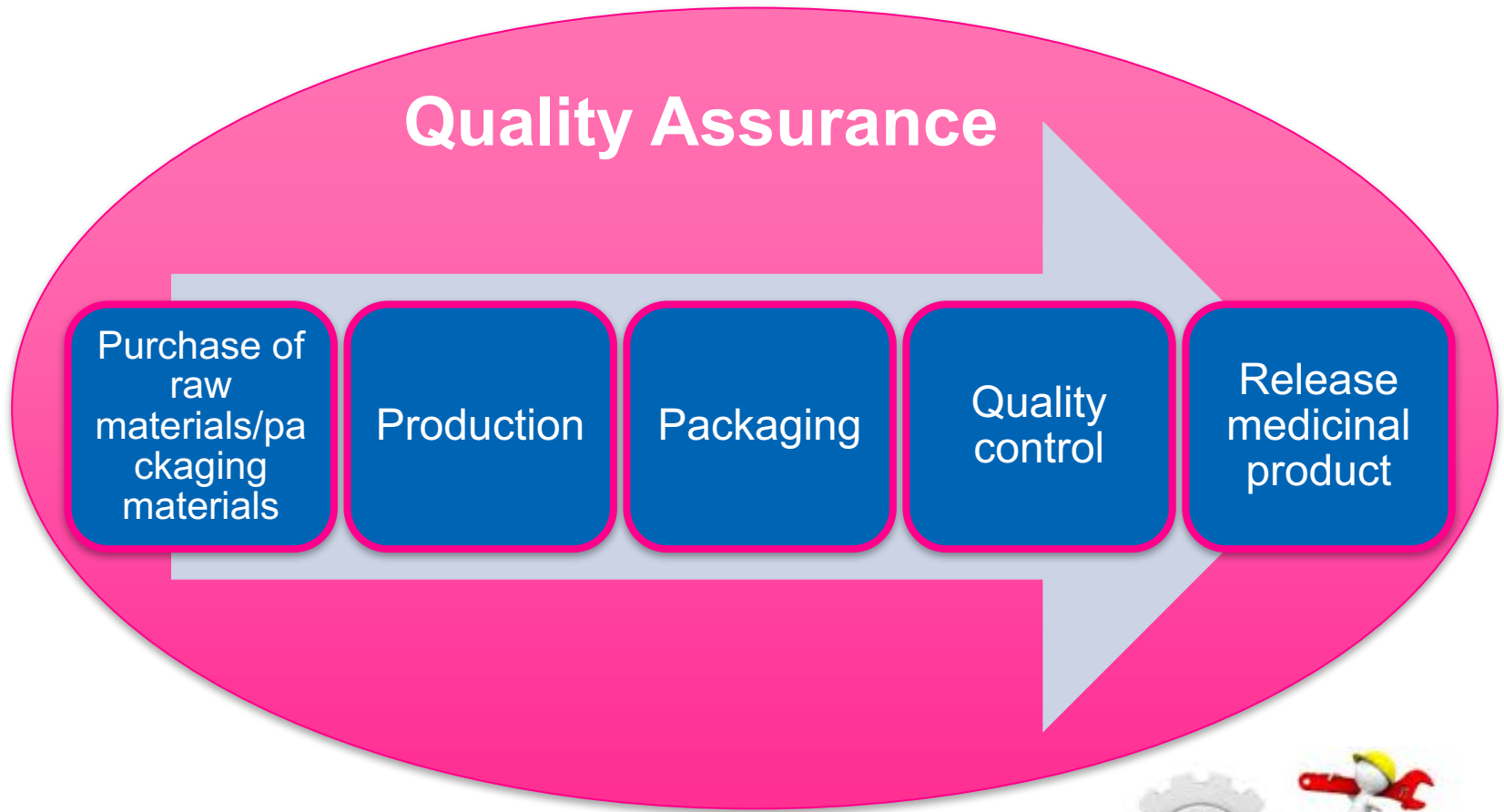
QA_CMO Manager & QP

Synthon

AGENDA

1. Why?
2. One day in the office
3. What is the marked looking for?
4. Are you the person?
5. Career development

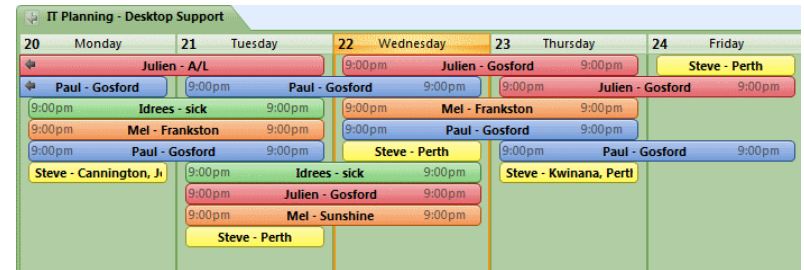
1. WHY?





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

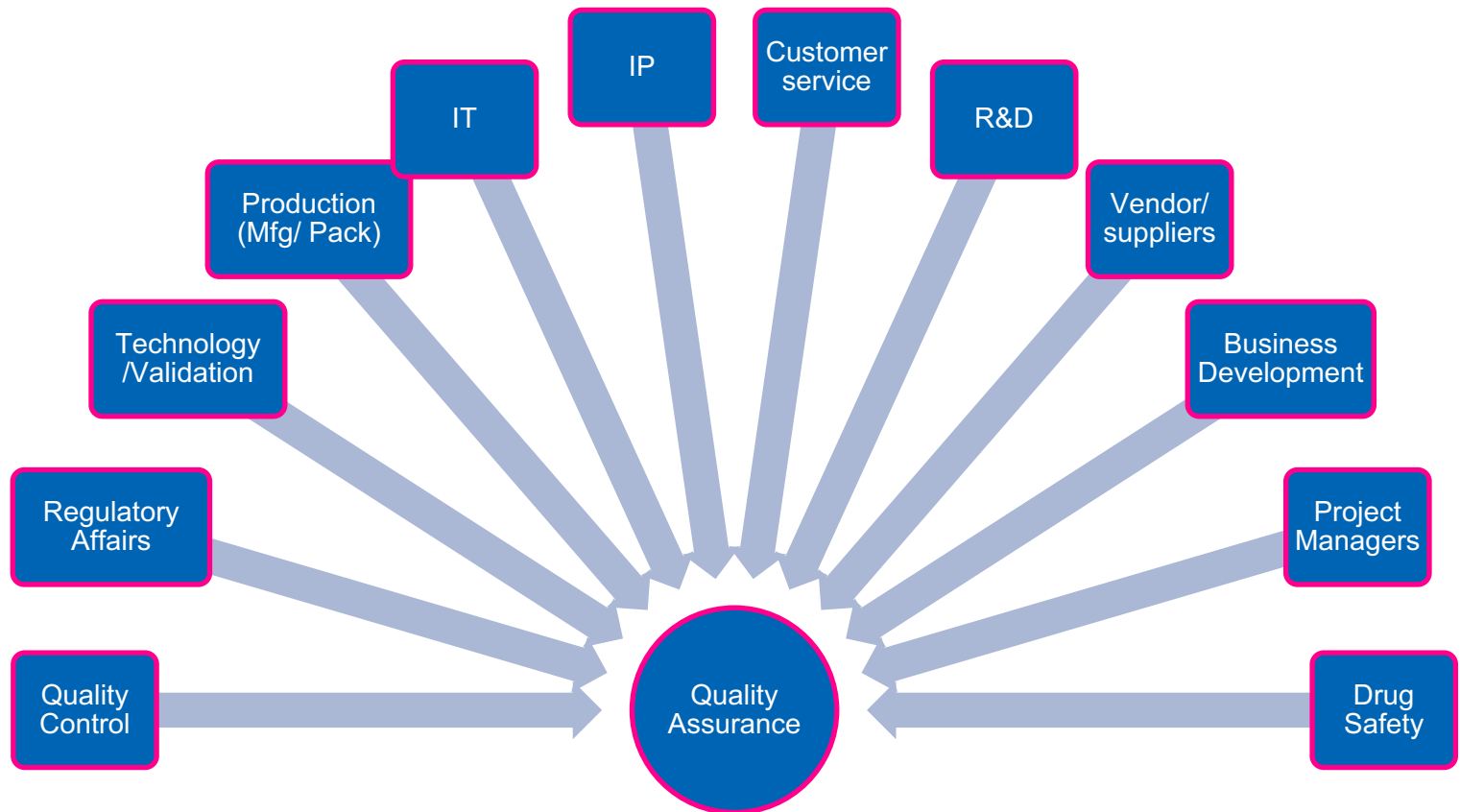


2. Best/worse of the job position

	
Teamwork	Pressure
Good ambient	Urgency
Leadership	Discussions
Global vision	Customer standards
Interdepartamental / Intercompany relationship	
Multitasking	

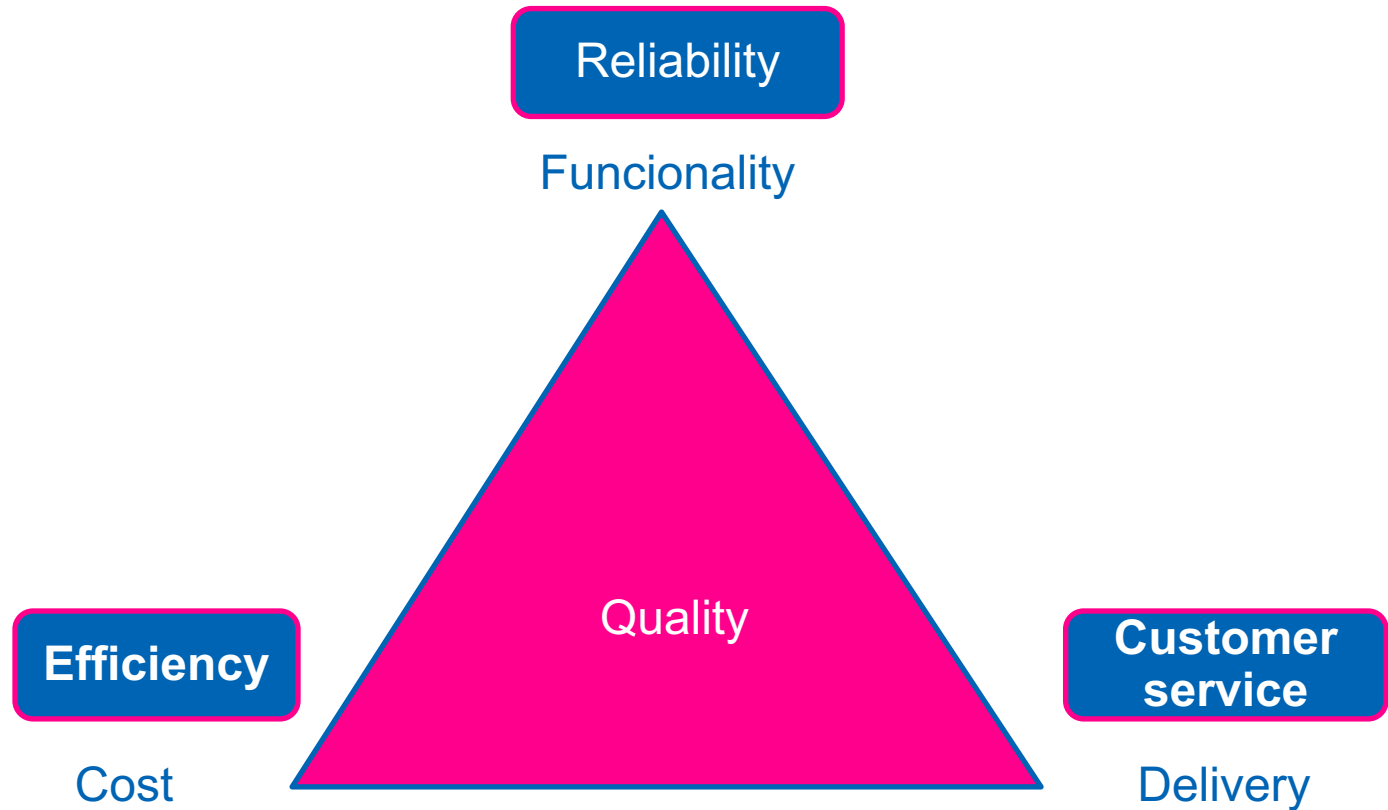
2. ONE DAY IN THE OFFICE?

3. Interdepartmental 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
- Continuous 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
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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 as: 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



Questions??





Thank you!