TECH TRANSFER

University Joins Industry

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Synthon Hispania

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About me…..

- Chemical Degree (UAB) / Master In Pharmaceuticals and Related Products(IUCT) / Master In Project Management (La Salle)/Different trainings trough my professional experience

- Working in Pharma industry for nearly 20 years: (IUCT/ Sanofi-Aventis/Combino Pharm/ Synthon)

- Experience on Formulation Development, Scale up and Pilot Plant and Commercial processes.

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- Tasks and Responsibilities
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- Technical Evaluation
- Personal Skills
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What is Tech Transfer?

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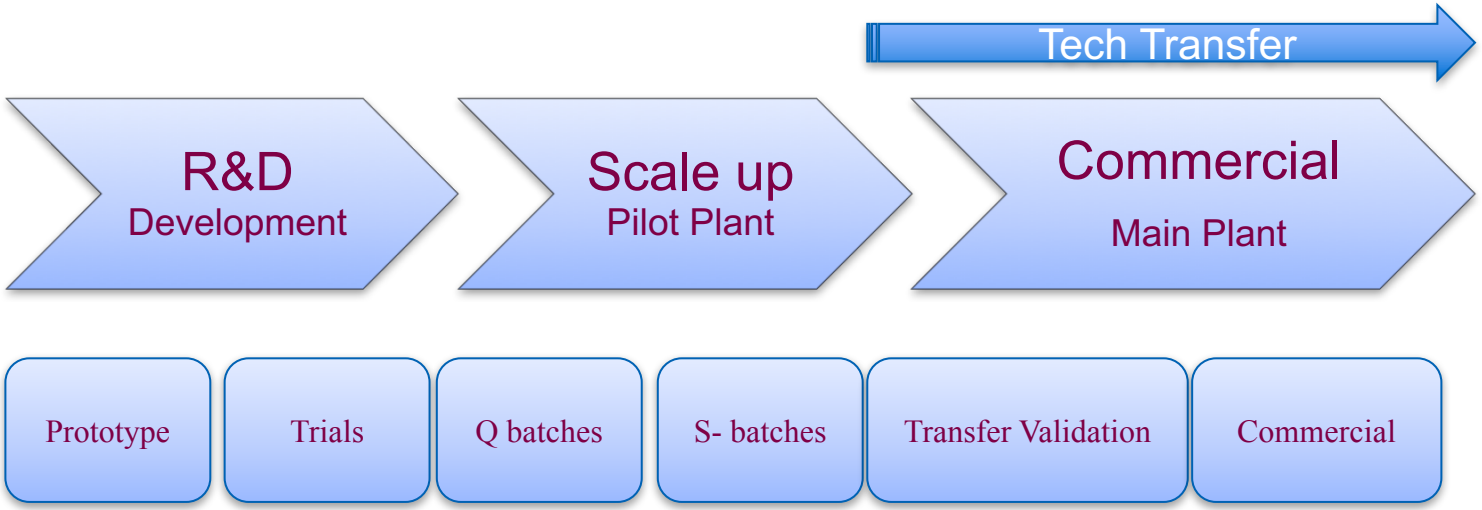
Definition: *"is the process of transferring technology from the places and in groups of its origination to wider distribution among more people and places"*

What does this means?

✓*Deeply Knowledge of the Product and Process and Persons*
✓*Transfer of Knowledge to internal and external people*
✓*Transfer of processes: to internal and external plants*

Where does our responsibilities start?



Tasks and Responsibilities

First….understand with "whom" we are involved"

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And then…. what are our tasks????

- Transfers (New or already commercial):
  - ✓Manufacturing Processes Transfer
    - •Launch: from the Pilot Plant to a Main Plant (Internal or external)
    - •Between Plants
    - •Scale up
  - ✓ Packaging

- Process Optimization:
  - ✓Reduce Costs, Times, Operational procedures
  - ✓Quality improvements o process variability

- Troubleshooting
  - ✓Solve problems….as fast as you can!!!!!!! (Internal or External)
  - ✓Improvements to avoid quality recurrences

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And then…. what are our tasks????

- Others:

✓Evaluation of manufacturing processes still on R&D phase
✓Revision of Submission Dossiers
✓Investigate Deviations
✓Be involve in Health Authorities and Customers Audits
✓Evaluate new excipients or drug substance suppliers
✓Evaluation of new CMO's, new equipments, new technologies
✓Technical support in the regulatory submissions
✓Technical support to Engineering, maintenance, QC,QA, manufacturing
✓Evaluation of costs (validations, process costs..)
✓Product Surveillance / Trend Analysis (continued process monitoring, APR's revision..)
✓Trainings

We are the definitition of…… ..**MULTITASKING!!!!!!!!!!!**

Background, key points and basic knowledge

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Our maximum commandment: manufacturing products with the required quality. But…always taking into account costs, time and flexibility.

What we have to know to be excellent????

- *The product:*
  - *Formulation: physical and chemical characteristics of excipients and drug substance; percentages, special requirements (sensible to the humidity/light..)*
  - *Product development. Evaluation of the development in the R&D stages*
  - *Final product specifications*

- *The process:*
  - *Facilities*
  - *Equipments: main equipments and auxiliary (ex. Pumps, tubs…)*
  - *People!!!!!!!!*

Background, key points and basic knowledge

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- *Submitted dossiers*
  - *What are the phases, equipments or settings approved?*
  - *Type of product: standard, non standard*
  - *Types of variation involved. What is needed to change the batch size, manufacturing site, equipment, settings….*
  - *Countries?????*

- *Quality requirements: GMP, FDA, JPN?????*

- *IP patents. Can I change the excipient grade? Or change a setting or a manufacturing step?*

WE HAVE TO KNOW ALL ABOUT OUR PRODUCT, PROCESS ,QUALITY, MARKET AND CLIENTS EXPECTATIONS.
AND WITH ALL THIS INFORMATION WE PERFORM THE ASSESSMENT

Technical Evaluation

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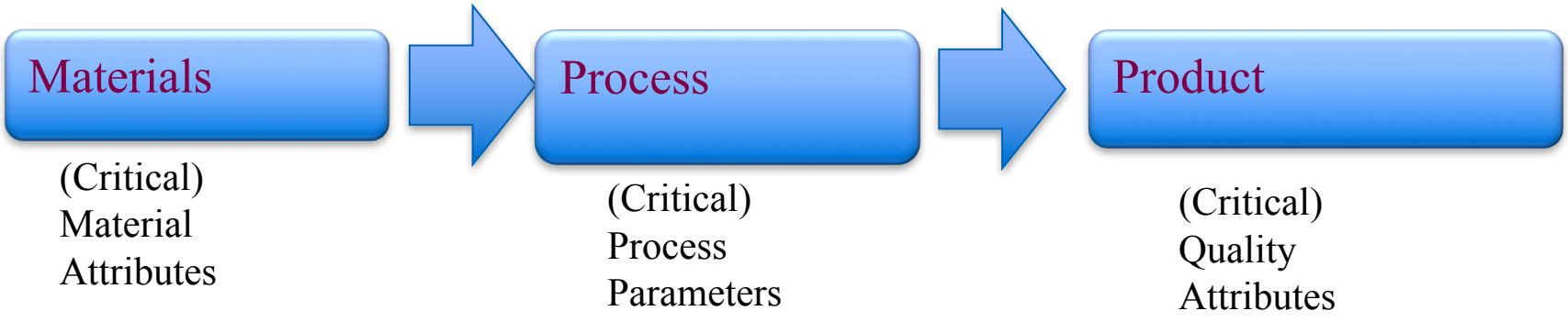
Once the previous evaluation is completed, the materials, process parameters and quality attributes are listed, categorized (critical or non critical) and related to each other.



Example: Granulation in a High Shear Mixer.

Operation unit	Materials	Process parameters	Quality attributes affected
Granulation	API Lactose Povidone Water	**Mixing Time** **Impeller speed** **Solution Addition time**. Process time	**Dissolution**/ Disintegration Uniformity of dosage units **Assay**

Technical Evaluation

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According to the previous study, the risks are categorized and the mitigation actions are planned.

Operation Unit	CPP	Risk	CQA affected	Mitigation Risk
Granulation	Mixing Time and speed	High	Assay	Blend Uniformity Granulate
	Addition	Medium	Dissolution Disintegration	Control of Torque

Technical Evaluation

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When all the manufacturing steps, attributes and materials have been evaluated then ….we evaluate the type of final study that we need:

- We need to perform Trials for a better evaluation? For example when we have to transfer a manufacturing process between sites but we have non similar equipments
- Qualification batch. We buy a new machine but it is equal to the previous used for the manufacturing and the risk is low. We made only one batch.
- Validation. Changes with high impact. For example. Transfers between sites, batch size increase…. Than we have to chose the type of validation and how many batches are involved.
  - ✓Traditional process validation: · batches, complete validation
  - ✓Continuous process verification: CQAs and CPPs (when the R&D applies Quality by Design)
  - ✓Hybrid approach Traditional validation+ Continuous Process Verification

Skills

- Degree in Life Sciences
- English

But Also…..

- Optimistic, curious, able to learn everyday
- Multi-task, capable to work under pressure
- Pragmatism
- Resilient
- Capable of making decisions
- Open minded, emphatic
- Work in group
- Like to travel

Career Development

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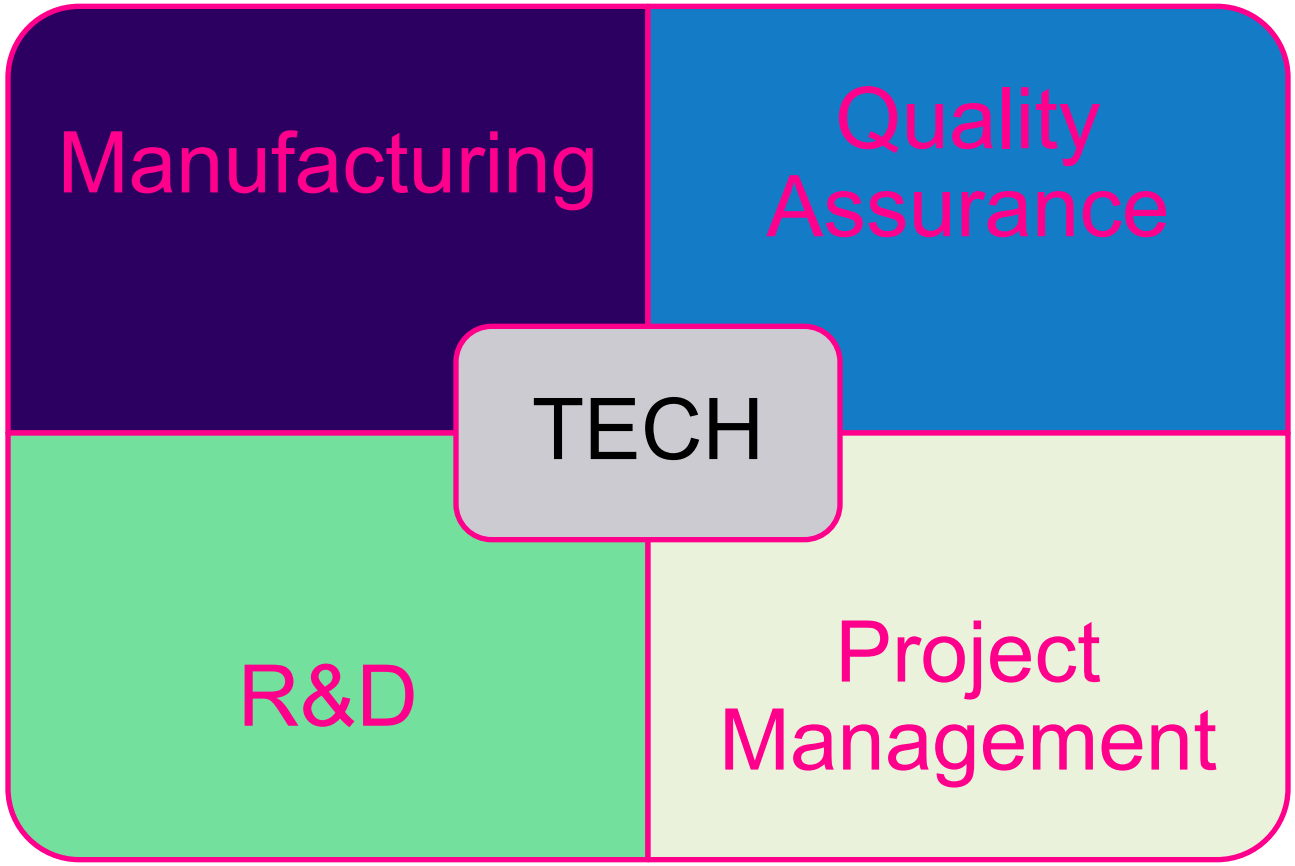

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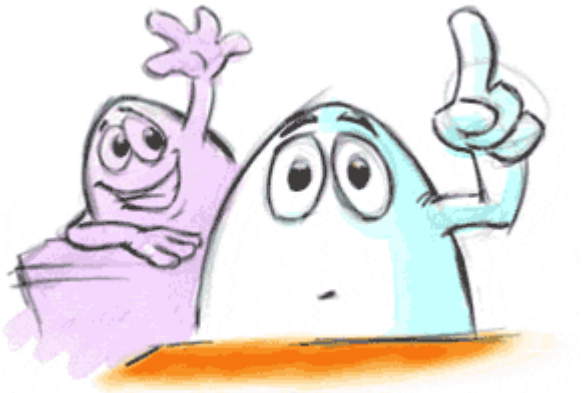
Questions?



THANKS FOR YOUR ATTENTION!!!