TECH TRANSFER
University Joins Industry

Maite Aguado
Pharmaceutical Technology PL
Synthon Hispania
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.
INDEX

- What is Tech Transfer?
- Tasks and Responsibilities
- Background, key points and basic knowledge in
- Technical Evaluation
- Personal Skills
- Career development
What is Tech Transfer?

**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*
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
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 definition of……__MULTITASKING!!!!!!!
Background, key points and basic knowledge

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

- 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

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.

<table>
<thead>
<tr>
<th>Operation unit</th>
<th>Materials</th>
<th>Process parameters</th>
<th>Quality attributes affected</th>
</tr>
</thead>
</table>
Technical Evaluation

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

<table>
<thead>
<tr>
<th>Operation Unit</th>
<th>CPP</th>
<th>Risk</th>
<th>CQA affected</th>
<th>Mitigation Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Granulation</td>
<td>Mixing Time and speed</td>
<td>High</td>
<td>Assay</td>
<td>Blend Uniformity Granulate</td>
</tr>
<tr>
<td>Addition</td>
<td>Medium</td>
<td></td>
<td>Dissolution Disintegration</td>
<td>Control of Torque</td>
</tr>
</tbody>
</table>
Technical Evaluation

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

- Manufacturing
- Quality Assurance
- R&D
- Project Management

TECH
THANKS FOR YOUR ATTENTION!!!