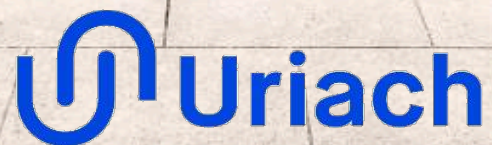




# University joins Industry: R&D

Dr. Ester Masllorens

R&D Manager



# 1. WHAT IS R&D?

## R&D definition



Systematic activity combining both basic and applied research, and aimed at discovering solutions to problems or creating new goods and knowledge. R&D may result in ownership of intellectual property such as patents.  
*<http://www.businessdictionary.com/definition/research-and-development-R-D.html>*

R&D is therefore a business tool for product development.

# 1. WHAT IS R&D?

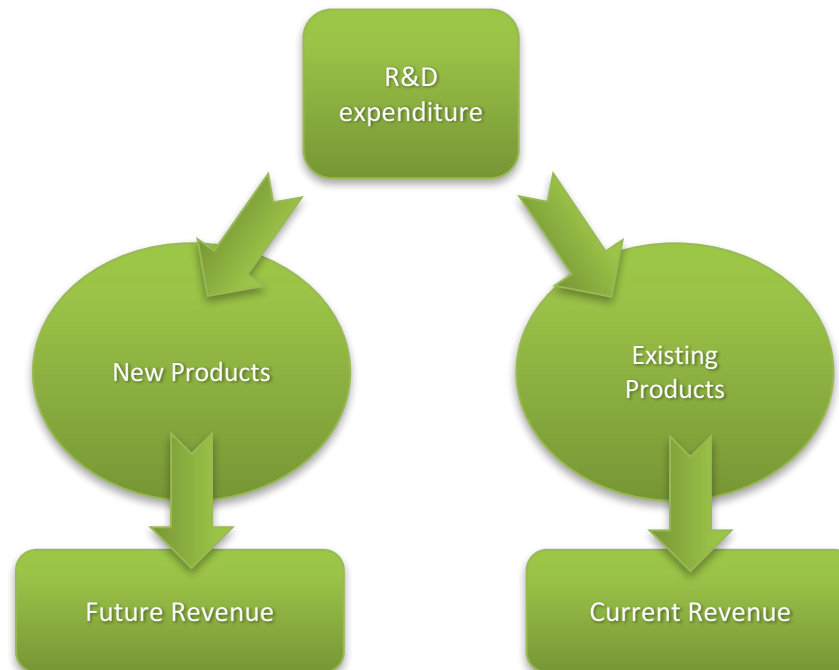
## R&D role in Pharma development

Main role:

- **Development of New Products.**

Secondary Objectives:

- Improvement of existing products (Lifecycle Management).
- Supporting the organisation on scientific and technical aspects (marketing, regulatory, manufacturing, quality, etc).



# 1. WHAT IS R&D?

## Scope of Pharma R&D



“New Chemical/Biological Entities”

- Novel Active Ingredients
- Investment of hundreds of Million€
- 8-10 years long development

“New Therapeutical Entities”

- Existing Active Ingredients
- Efficacy improvements without detriment to Safety
- New dosage, route of administration, repositioning.
- Typical 4-8 years long development

Generic and OTC drugs

- Existing Active Ingredients
- Same dosage and route of administration. Formulation can be different.
- 1,5-3 years long development

**Innovation**  
**Technical risk**

# 1. WHAT IS R&D?

How important is it?

## How important R&D is in Companies? It depends.....

The relevance (and therefore the level of investment) is related to the intended level of innovation in the company.

- Companies focused in the development of NCEs/NBEs spend in R&D approximatey 12 % of revenues.
- Generic drugs developers spend in R&D approximatey 5-7 % of revenues.

## Is it possible for a Company to exist without R&D activities?

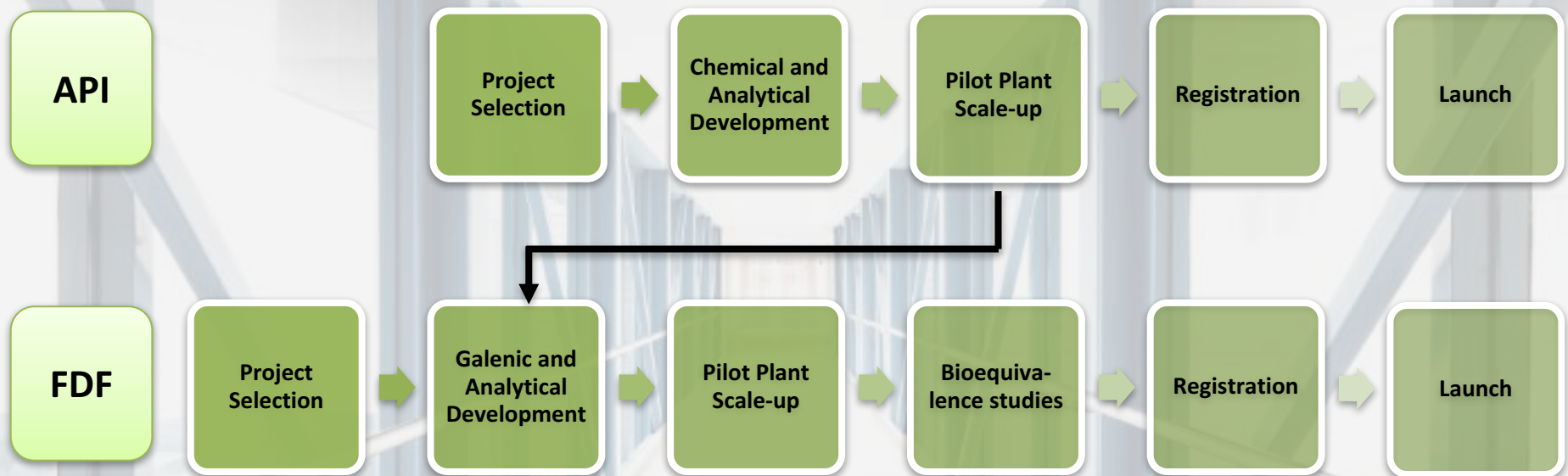
- It is crucial to survival
- Competition has made R&D important
- Adaptation to continuous change in consumer trends, needs, demands





## 2. ONE DAY IN THE OFFICE

## Generics Drug Development



## 2. ONE DAY IN THE OFFICE

## R&D Responsibility



## 2. ONE DAY IN THE OFFICE

What do we have to deal with?

R&D differs from the vast majority of corporate activities in that it is not often intended to yield immediate profit, and generally carries greater risk and an uncertain return on investment. (Wikipedia)

2 + 2 not always = 4

Very tight timelines to have products on time. If not on time, opportunity could be lost. PRESSURE.



But.....

.....CREATIVE

.....YOU DISCOVER

.....EVERY DAY DIFFERENT

.....INNOVATION

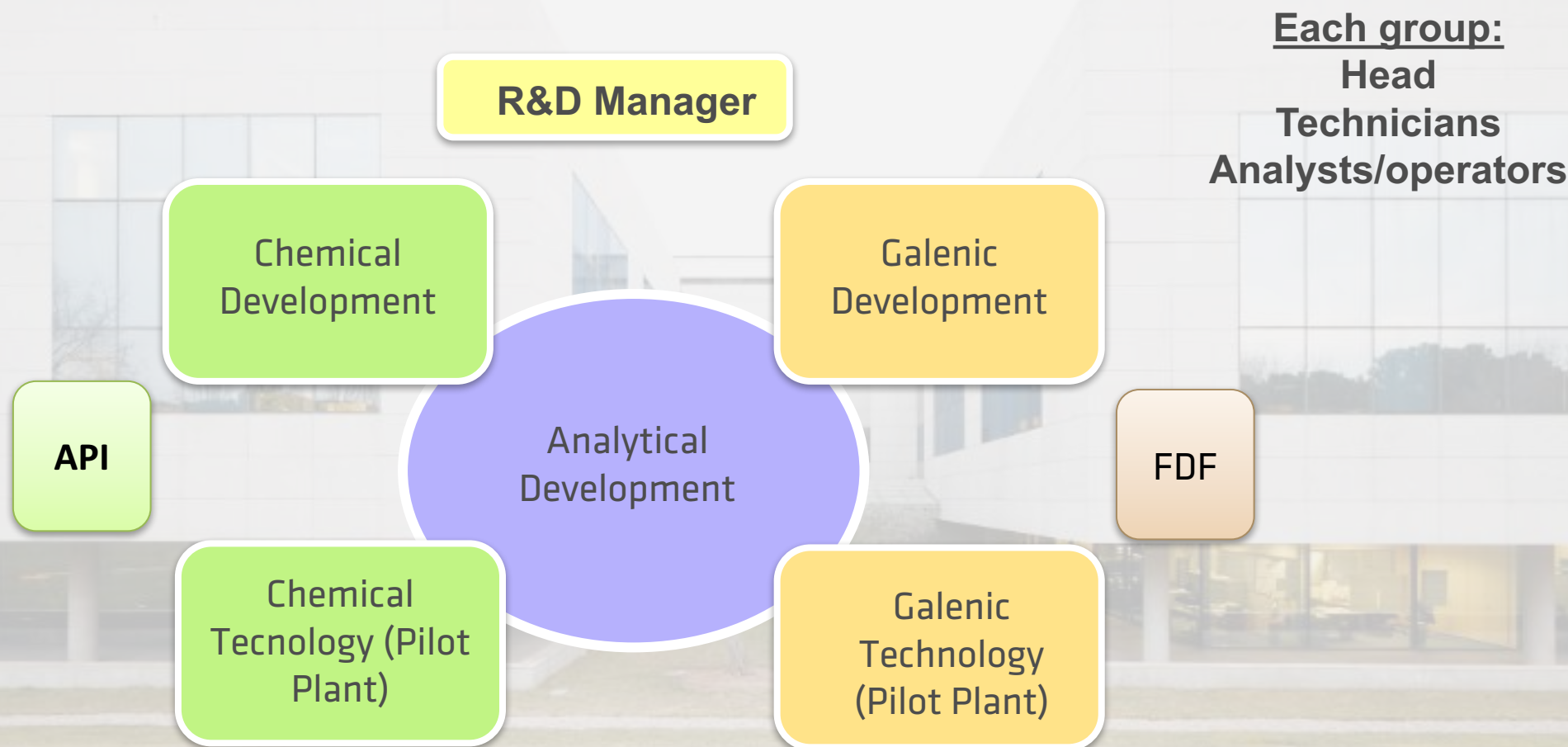
.....YOU SEE REAL APPLICABILITY





## 2. ONE DAY IN THE OFFICE

## R&D sections – work positions



## 2. ONE DAY IN THE OFFICE

## R&D sections – work positions

### API

### Chemical Development

Design of synthetic route to prepare an API (literatura/know-how).  
Organic synthesis / purifications  
Optimization of steps (Quality by design, QbD = statistics).  
Verification batches.  
Preparation of impurities to control API quality/safety.  
Structural elucidation.  
Compilation of documentation for Technology Transfer.  
Support to pilot plant and production.  
Support to regulatory affairs/customers ....



Confidential  
For academic purpose only





## 2. ONE DAY IN THE OFFICE

## R&D sections – work positions

Pilot Plant reactors

API

Chemical  
Technology (Pilot  
Plant)



Reception of Tech Transfer from Chemical Dev.  
Adaptation to pilot plant equipment, prevision for production.  
Production of pre-validation and validation batches (if small scale).  
Technology Transfer to production.  
Support to production (troubleshooting).  
Support to regulatory affairs/customers. ....

## 2. ONE DAY IN THE OFFICE

## R&D sections – work positions

Design of formulation to prepare an FDF (literature/know-how).  
Formula development.  
Optimization of formula (Quality by design, QbD = statistics).  
Optimization of process steps (QbD).  
Verification batches.  
Compilation of documentation for Technology Transfer.  
Support to pilot plant and production.  
Support to regulatory affairs/customers. ....

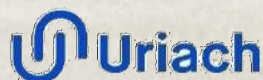
FDF

Galenic  
Development

*Equivalent to Chemical Development but for FDF*



High speed granulator



Desintegration test



## 2. ONE DAY IN THE OFFICE

## R&D sections – work positions



Mill

Tabletting machine



FDF

Galenic  
Technology  
(Pilot Plant)

Reception of Tech transfer of processes from Galenic Dev.  
Adaptation to pilot plant equipment, prevision for production.  
Production of pre-validation and validation batches.  
Technology Transfer to production.  
Support to production (troubleshooting).  
Support to regulatory affairs/customers. ....

*Equivalent to Chemical Development but for FDF*



## 2. ONE DAY IN THE OFFICE

## R&D sections – work positions

Development of analytical methods (HPLC, UPLC, GC, DT...).  
Validation of analytical methods.  
Characterization of compounds.  
Analysis of verification batches.  
Analysis of validation batches.  
Analytical transfer to QC, CMOs.  
Qualification of analytical equipment. ....  
Support to Chemical Dev, Galenic Dev, Pilot Plants, Production, QC....

API

Analytical  
Development

FDF



## 2. ONE DAY IN THE OFFICE

## R&D sections – work positions

### Head

Planification of technical daily work to accomplish timings (people and equipments)  
Guidance of technicians / analysts.  
Feasibilities of new selected projects. Control of timings.  
Follow-up meetings.  
Revision of Tech Transfer documentation.  
Motivation of people. Training.  
Patentability opportunities.  
“Browns management” .....  
Support to production / regulatory affairs / customers....



## 2. ONE DAY IN THE OFFICE

## R&D sections – work positions

### R&D Manager

Take part in Business Strategy.

Take part in evaluation and selection of new projects.

R&D Innovation options.

Planification of API-FDF projects / timings along the year.

Preparation and monitoring of Budget (people dedication / external costs)

Investments planning (innovation)

Optimization of resources in each area.

Leadership. Motivation of people. Training plan.

“Bigger browns management” .....





### 3. WHAT IS THE MARKET LOOKING FOR?

---



The most common qualifications in Pharma R&D are degree holders from the following disciplines:

Biology  
Chemistry  
Pharmacy  
Medicine

**HARD**

But recruitment from other backgrounds are also such as: maths (statistics), veterinary, computer science, process engineering.

And.... is it necessary to hold a PhD degree?

## 4. ARE YOU THE PERSON?

---



what competencies make a competent scientist into a exceptional R&D professional?

- Team-work
- Attention to detail
- Problem Solving
- Personal development
- Communication Skills

**SOFT!!!!**

And also....

...those other competencies and values that are specific to each company.





## 5. CAREER DEVELOPMENT

---

### **Future opportunities / knowledge development:**

Different profiles in all sections. Polivalency via continuous training.

R&D scope gives a wide business knowledge due to interaction with almost all business sections -> Future work opportunities in other company departments also.

Internal promotions.