University Joins Industry: R&D

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R&D from a financial viewpoint

- Feasibility
- Proof of Concept
- Prototype
- "Break even point"
- Launch
R&D in new medicines

- Identification of business opportunities (medical needs)
- Registration and authorisation
- Technology Transfer
- Project Proposals
- Development
- Proof of Concept
- Product Launch
- Lifecycle Management
R&D in the pharmaceutical industry

Mission: Development of New Medicines

Includes:

Discovery/ invention of new Active Ingredients (chemical substance with therapeutic uses)

Clinical and pre-clinical studies to demonstrate Efficacy (therapeutic benefit) and Safety (risk-benefit balance)

All development activities related to the Physical Product (Chemistry, Manufacturing and Controls). This includes all activities related to Chemical Development and Pharmaceutical Development.
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 and risk in Pharma R&D

- Novel target NCEs/NBEs
- Me too NCEs/NBEs
- Fixed Combinations
- Novel delivery Systems
- New routes of admtn
- Novel OTC formulations
- New physical Properties of APIs
- Generics
- “plain” OTC´s

Higher innovation

Higher technical risk
New Chemical Entities

Discovery Phase

- Target Discovery
- Lead Discovery
- Lead Optimisation
- Preclinical evaluation

Development Phase

- Proof of Concept
- Human clinical Trials
- Launch

Biology and Medicinal Chemistry

Pharmacology and Pharmacokinetics
Toxicology
Clinical Trials

Chemical Development
Pharmaceutical Development
Process Engineering
Not only Products… …..also PROCESSES

In parallel to Product Development, the industrial processes need to be developed
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).
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R&D in the Pharmaceutical Industry

How important is R&D for Pharmaceutical companies

It depends........

The relevance (and therefore the level of investment) in R&D is related to the intended level of innovation in the Company.

- Companies focused on the development of NCEs/NBEs spend in R&D approximately 12% of revenues.

- Generic Drug developers spend in R&D approximately 5-7% of revenues.

Is it possible for a Pharma Company to exist without R&D activities?
There are many Pharma Business models…

… so there are many ways to use R&D activities in Pharma companies.

– Only large multinationals carry out most R&D internally.

– There are companies specialising only in the Discovery phase to “sell” the projects before entering the costly Clinical Trials phase (license-out).

– There are companies very strong in marketing/sales “buying” the developed products (license-in).

– It is common that only the strategic R&D activities are carried out in-house, externalising the non-strategic activities to Contract Research Organisations.

….but the good news is that there is normally high profesional mobility within this business “ecosystem”. Scientists are recruited from pharma companies with different models and other companies with R&D and/or technical teams, such as other healthcare companies, scientific instrumentation makers, etc.
Professional profiles in Pharma R&D

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

- Biology
- Chemistry
- Pharmacy
- Medicine

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?
Professional profiles in Pharma R&D

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

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

And also....

...those other competencies and values that are specific to each company.
And Thank You for your attention!