REGULATORY AFFAIRS

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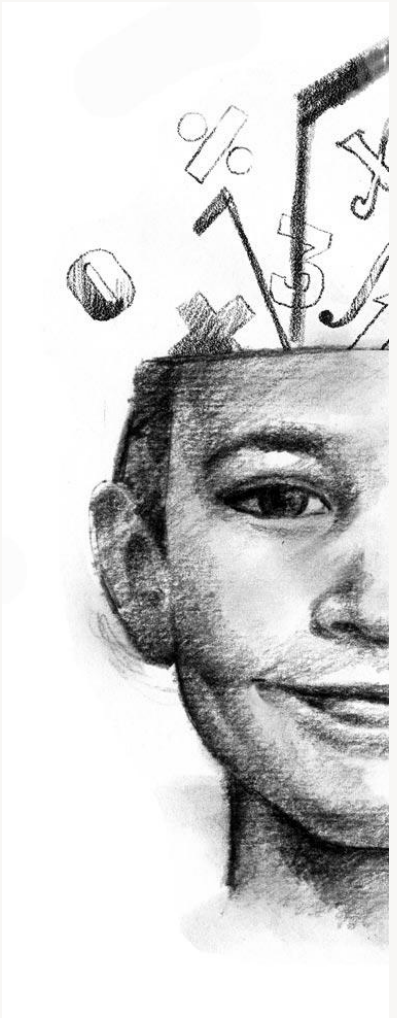
Regulatory Affairs – University Joins Industry

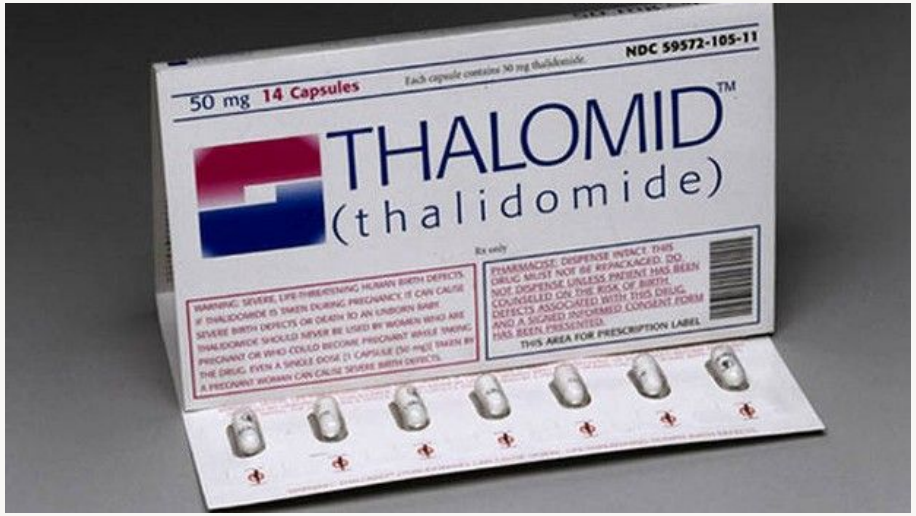
- **WHY REGULATORY AFFAIRS?**
- **WHAT IS IT ABOUT?**
- **HOW DO WE DO IT?**
- **WHO IS IT FOR?**
- **WHERE DO WE GO FROM HERE?**



1. WHY REGULATORY AFFAIRS?

Healthcare industry regulation has stemmed from avoiding the repetition of disasters

Elixir Sulfanilamide
1937 US Antibiotic
Prepared with diethylene glycol caused >100 deaths.
Food, Drug & Cosmetic Art Regulation in 1938 requiring animal safety test & pre-approval of FDA



1957-1962 DE (EU, Australia, US, Canada)
OTC 1960 DE
Antiemetic for pregnant woman.
Caused > 10,000 birth deformities cases.
Tougher rules for the testing and licensing of drugs were applied in all countries

2. WHAT IS "REGULATORY AFFAIRS" ABOUT?

- **Compile the product dossier** in compliance with current regulations on Quality, Efficacy and Safety
- **Obtain the Marketing Authorisation** for medicinal products
- **Ensure MA maintenance** for as long as the company keeps the product in the market (life cycle management)
- **Channel of communication** between the company, customers and the regulatory authorities
- **Interpret the regulatory guidance to ensure compliance**

2. WHAT IS "REGULATORY AFFAIRS" ABOUT?

- Regulatory Affairs is involved in the development of new medicinal products from early on, by interpreting legal requirements and integrating regulatory principles, leading to prepare and submit the relevant regulatory dossiers to health authorities

The interface between the pharmaceutical company and the regulatory agencies across the world.

3. HOW DO WE DO IT?

All medicinal products require prior authorization to be marketed. For that, a dossier registration is performed, which documents assure product's quality, safety and efficacy

DOSSIER compilation

SUBMISSION to Health authorities
(Marketing Authorisation Application)

MARKETING AUTHORIZATION

PRICE & REIMBURSEMENT

MEDICINAL PRODUCT

Registration procedure **Marketing Authorisation**

COVID-19

3. HOW DO WE DO IT?

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MARKETING AUTHORIZATION DOSSIER

Batch size increase

Changes of Manufacturer

MA Renewal after 5 years

PRODUCT LIFE CYCLE MANAGEMENT AND CONTINUAL IMPROVEMENT

MA Withdrawal

MA transfer

Shelf-life increase

Update product information

Change of specifications or methods

Submission to Health authorities for approval

3. HOW DO WE DO IT? - ONE DAY IN THE OFFICE

Emails, meetings, deficiency letters, deadlines, doubts, variations to dossier

New initial MA submission, price and reibursement,

Compilation of dossier, interdepartmental queries, advertising materials

Search for updated legislation…

Registration strategies, difficult customers, negotiation with health authorities and manufacturers

And… Coffee please!!!

3. HOW DO WE DO IT? - ONE DAY IN THE OFFICE

- **Best of the job position**
  - Compilation of a registration dossier
  - Getting the approval of a MA or a difficult variation
  - Key player in decision making of the company

- **Worse of the job position**
  - Administrative work

- **Interdepartmental relations**
  - Provide support to all departments in the company: R&D, Supply Chain, Quality Assurance, Sales
  - Close interaction with Finance for fees and invoices

- **What do you have to deal with?**
  - Tight deadlines.
  - Work under pressure.
  - Liaising and negotiating with regulatory authorities, customers, suppliers and colleagues
  - Constant feedback request from nameless and countless sources

4. WHO IS REGULATORY AFFAIRS FOR?

- **Degree**

  - Health Sciences, preferably Pharmacy, but also: Chemistry, Biochemistry, biotechnology, Medicine, etc)
  - Desirable post-graduate focused in Industry, including internship. Ex: CESIF, UB, etc
  - High level of English (both Oral and written communication)

- **Personal skills for the job**

  - Organised, responsable, good team player
  - Attitude: easy learning, multi-tasking, focused, problem solver, curious, critical-minded
  - Negotiation, analytical & communication skills.
  - Time management, problem solving, resourceful, dynamic thinking, open-minded
  - Understanding relevant legal, scientific, manufacturing guidances

RA requires scientific, legal and business knowledge

5. WHERE DO WE GO FROM HERE?

Future opportunities

- ✔ RA senior role, progressing to regulatory coordinator, manager, Head
- ✔ Develop your career into another area: QA, Clinical Affairs, PM…

Knowledge development in different areas:

Type of products	Markets
Human Medicines:	EU and UK
• Generic medicinal products	FDA – USA, Canada
• New Chemical Entities	Latin America
Veterinary medicines	MENA market
Medical devices	Africa
Cosmetics	ASEAN
Food supplements	Russia and CIS

5. WHERE DO WE GO FROM HERE?

SOP training
RA guidelines
Module 1 compilation
eCTD sequences compilation
Databases update
Electronic submissions to Health authorities (CESP, RAEFAR…)
Contact with customers
Product information update…
A long list of ETC

The Intern!

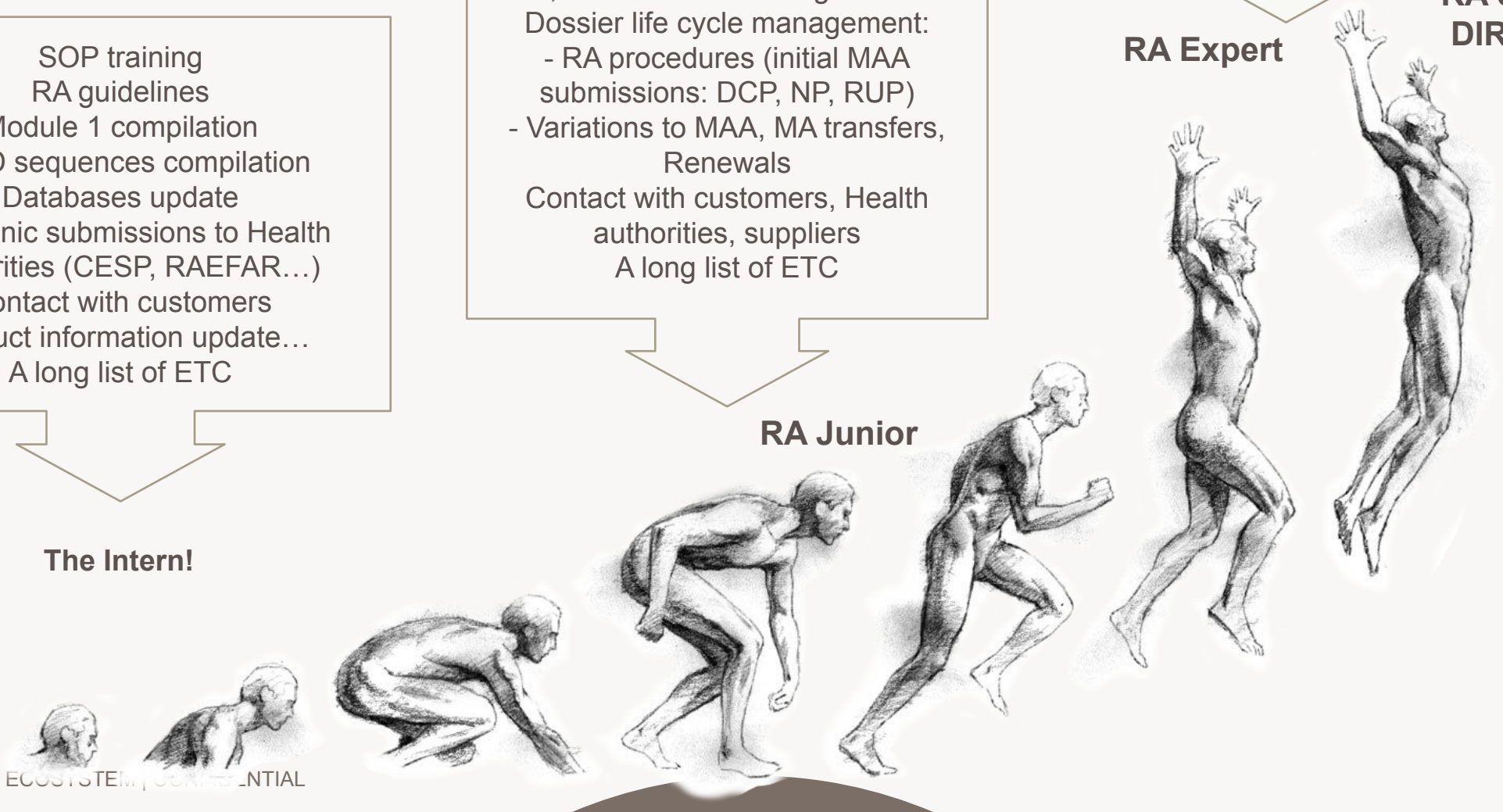
RA, scientific Module 3 guidelines
Dossier life cycle management:
- RA procedures (initial MAA submissions: DCP, NP, RUP)
- Variations to MAA, MA transfers, Renewals
Contact with customers, Health authorities, suppliers
A long list of ETC

RA Junior

Product development
New dossier compilation
RA strategy for submissions
Decision making
Worldwide registration
Training, Audits
A long list of ETC

RA Expert

RA SENIOR/ DIRECTOR



5. WHERE DO WE GO FROM HERE?

- Expected salary for junior/senior positions

✔ **Junior or RA Officer:** Up to 28,000€

✔ **Specialist, Expert, Senior:** 40,000 - 50,000€

✔ **RA Manager:** 45,000 – 70,000€

✔ **Head of RA:** 75,000 - 83,000€

✔ **Average base income in Spain:** 41,600 €/year

THANK **YOU**

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