DARE TO **FLY**

REGULATORY AFFAIRS

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Galenicum 20 YEARS

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?**

- Understand the regulatory guidance to ensure compliance
- Compile the product dossier in compliance with current regulations on Quality, Efficacy and Safety
- Submit the Dossier to Health authorities in order to obtain the Marketing Authorisation (MA) for medicinal products
- Maintain the MA for as long as the company keeps the product in the market (life cycle management), via submission of variations to the dossier, renewals, etc.
- Channel of communication between the company, customers and the regulatory authorities
- Important role in company’s strategic planning and decision-making

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.

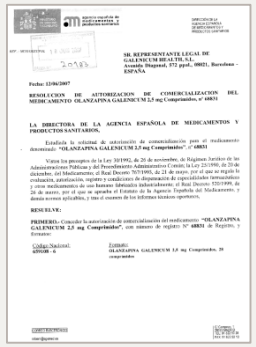
The interface between the pharmaceutical company and the regulatory agencies across the world.

3. HOW DO **WE DO RA?**

All medicinal products require 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 RA?**

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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. ONE DAY **IN THE OFFICE**

Regulatory compliance check, documentation review

Price and reimbursement, advertising materials

Emails, meetings, deficiency letters, tight deadlines

Compilation/Submission of initial dossiers, duplicates, variations

Registration strategies

Interdepartmental queries, quick turnover to customers and health authorities

Attention to customers, negotiation with health authorities and manufacturers

3. 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

Worst 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. WHAT IS THE **MARKET LOOKING FOR**

Soft Skills

- Accountable, organized, responsible, good team player
- Attitude: easy learning, focused, curious, critical-minded, eager to learn and think out-of-the-box, adaptable and flexible
- Negotiation, analytical & communication skills
- Time management, problem solving, resourceful, dynamic thinking, open-minded
- Understanding relevant legal, scientific, manufacturing guidances

Technical Skills

- Health Sciences, preferably Pharmacy, but also: Chemistry, Biochemistry, biotechnology, Medicine, etc.)
- Desirable post-graduate focused on Industry, including internship. Ex: CESIF, UB, etc.
- RA requires scientific, legal and business knowledge!!

Languages

- High quality communication in native language
- High level of English (both Oral and written communication)
- Other languages: Nice to have

5. CAREER **GROWTH OPPORTUNITIES**

Future opportunities

- RA senior role, progressing to regulatory coordinator, manager, Head, Regulatory Intelligence
- Develop your career into another area: QA, Clinical Affairs, Project Manager

Knowledge development in different areas

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

5. CAREER **GROWTH OPPORTUNITIES**

The Intern!

- 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

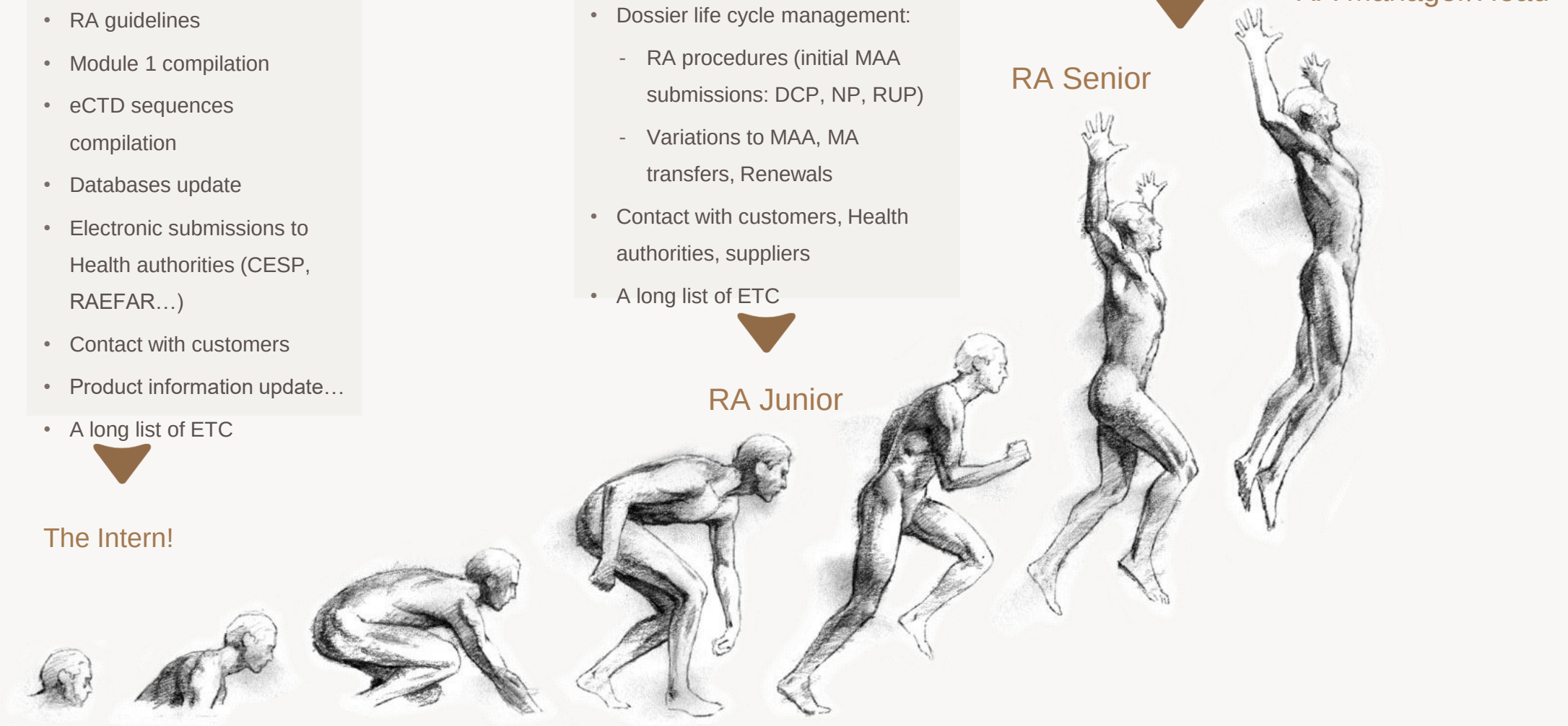
RA Junior

- 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 Senior

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

RA Manager/Head



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THANK **YOU**

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