Career opportunities in Regulatory Affairs

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AGENDA

1. About me
2. Regulatory and Safety department
3. Requirements
4. Other opportunities

ABOUT ME

Pharmacist

Master´s degree in Clinical Analysis

Master´s degree in Regulatory Affairs

2015

Regulatory and Safety department

REGULATORY&SAFETY DEPARTMENT (1/2)

Development of a MEDICINE:

- A molecule shows good results in clinical trials: **safety, efficacy and quality**
- Registration: Dossier is prepared, and it is submitted to the competent HA
  - Medicine registration procedures in the EU framework (Pharmaceutical Companies decide or depends on the type of medicine)
    1. Centralized
    2. Mutual recognition / Decentralized
    3. National

- Marketed: all the product information is summarized in leaflet and SmPC

Development (clinical trials…) → Registration → Marketed

Dossier Submission by RA Leaflet/SmPC

REGULATORY&SAFETY DEPARTMENT (2/2)

- The dossier is evaluated and approved by Health Authorities
  - ✓ EMA European Medicines Agency (EU)
  - ✓ FDA Food and Drug Administration (USA)
  - ✓ PDMA Pharmaceutical and Medical Devices Agency of Japan (JP)
  - ✓ AEMPS Spanish Agency (Spain)
- Regulatory department tasks
  - ✓ **Point of contact with Health Authorities**
  - ✓ **Submit** the dossier
- **BUT…**

  After the marketing of the medicine the process does not end →**LCM (life cycle of medicine)**

- We must continue **updating** the information of the medicine registration:
  - ✓ SmPC/Leaflet (variations, line extension, revalidations)
  - ✓ Labelling materials
  - ✓ Recalls
  - ✓ Safety: surveillance of the drug in the market
- Other responsibilities and opportunities
  - ✓ Pharmacovigilance responsible
  - ✓ Technical Responsible person
  - ✓ Reviewer of promotinal materials
  - ✓ Quality
  - ✓ Market Access
  - ✓ Compliance

REQUIREMENTS

Degree in Science (pharmacist, chemist, biologist biochemist…)

Specialist postgraduate in Regulatory Affairs like a Master with the possibility of internships in a pharmaceutical laboratory

OTHER OPPORTUNITIES

Novo Nordisk offers multiple individual development plans

Inside the affiliate: move temporally to other departments related or not with RA

Outside affiliate: move to HQ in Demark

Global vision of the business → Cross functional with other departments: Market Access, Logistics department, Quality, marketing, compliance

Thank you!

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