EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Reflections on academic path and career opportunities

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An agency of the European Union

European Medicines Agency (EMA)

- EMA was founded as a 'coordinating body' to manage the centralised procedure
- Decentralised networking administration. It utilises and coordinates the existing scientific resources of Member States
  - Network of 48 Agencies (32 Human and 16 Veterinary)
  - > 4900 experts
- EMA is a service provider for the network
  - *E.g. Network IT and Databases*

Centralised Procedure

Company Dossier → Evaluation → Scientific Opinion → EC → **Commission Decision** to grant a Marketing Authorisation

Legally binding to all MS

- 1 Invented Name
- Identical product information, in all EU languages:
  - Summary of Product Characteristics (SPC)
  - Package Leaflet
  - Package Labelling
- European Public Assessment Report

CHMP: Committee for Medicinal products for Human Use

- Appointed for three years (renewable)
- 1 member (and 1 alternate) for each of 28 EU countries
- Norway, Iceland
- Up to 5 co-opted members
- Meets monthly for 4 days

Evaluation assigned to Rapporteur/Co-Rapporteur teams

- Contract basis
- Typically use resources of national regulatory authorities
- National Experts nominated by Member States

Scientific Committees
WPs, SAGs

- Overall co-ordination and scientific support
- Peer Review
- Quality of opinion
- Legal scrutiny
- Regulatory advice

European Commission

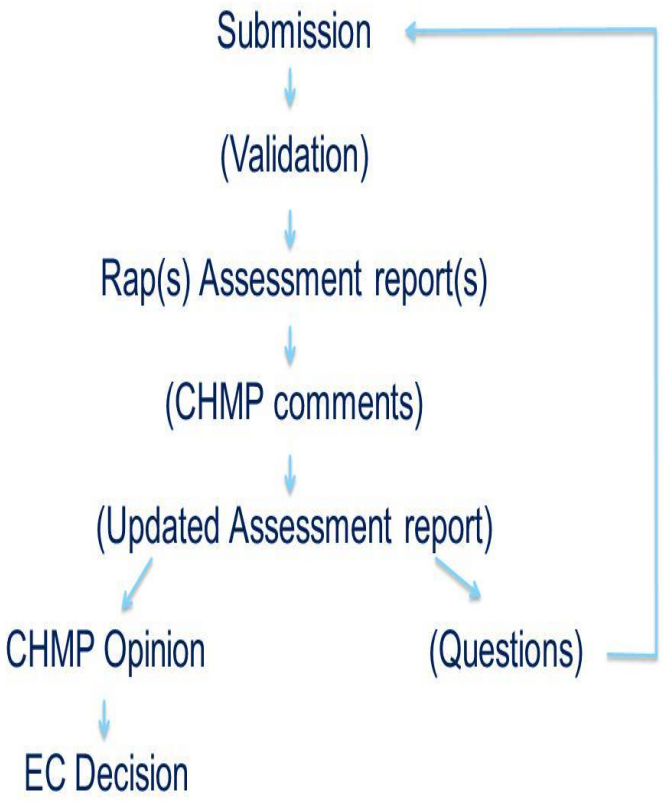
EMA secretariat
Scientific support+
Coordinating role

Rapporteurs + Assessors

Company

Centralised Evaluation System

- Upon submission of an application
- The CHMP appoints two of its members to act as "Rapporteurs" who will do the evaluation .
- The Rapporteurs' assessment is a recommendation to CHMP and forms the basis of the discussion
- The decision to grant an authorisation is taken by All CHMP members
- For "complex" cases the CHMP may seek the advise of specialised experts (Working Parties, SAGs)



EMA Product Team

The EMA product team: Role

- Set up for each medicinal product submitted through the centralised procedure.
- Responsible for providing support to the evaluation activities of the EMA scientific committees.
  - The responsibilities are based on the ones already described in Notice to Applicants Volume 2A, Chapter 4 "Centralised procedure", April 2006

EPL/ PM in the context of handling evaluation procedures

Procedure Manager (PM)

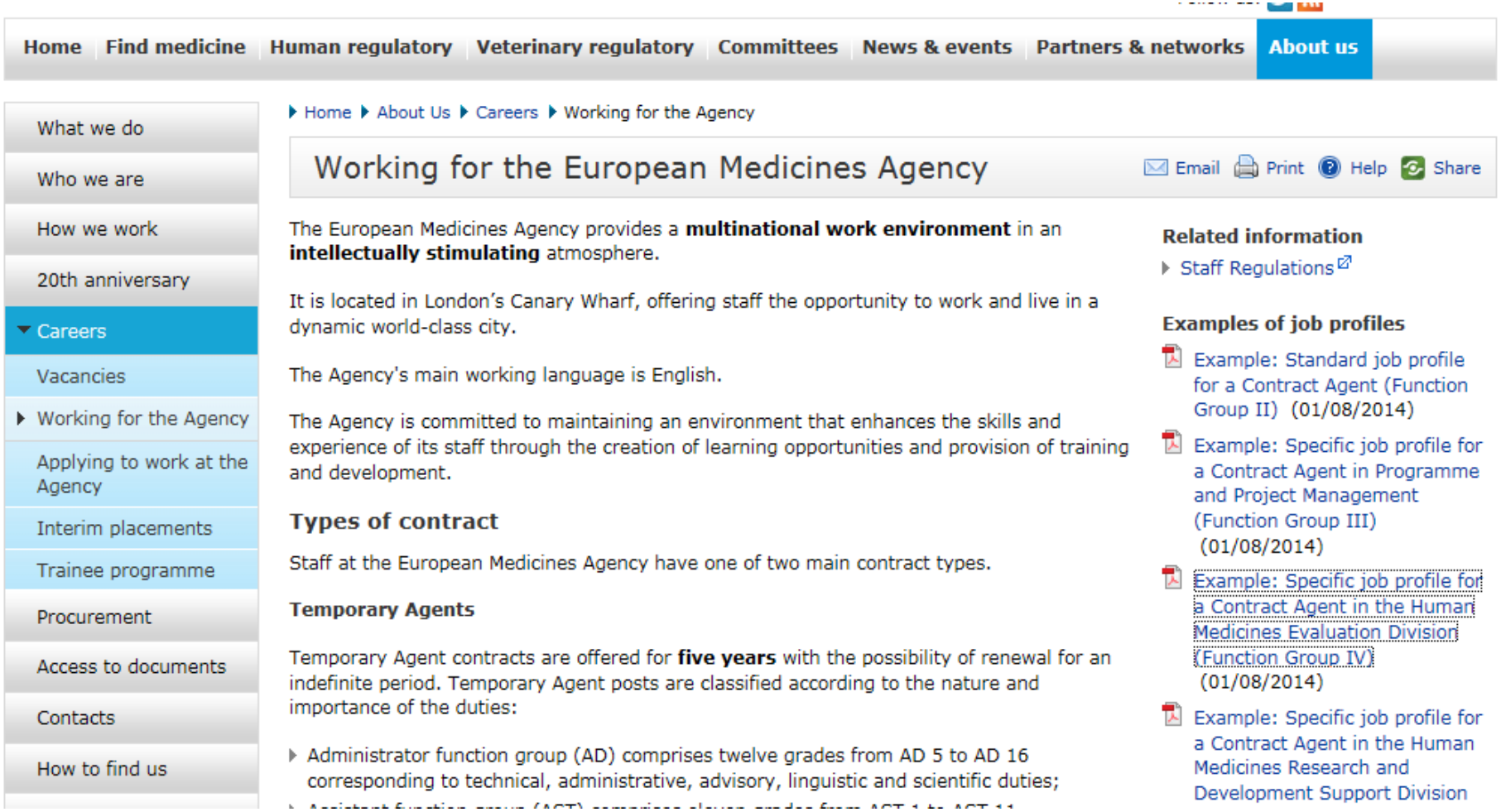
⇒ **Applicant's primary contact during the course of all evaluation procedures**

- Provision of regulatory procedural guidance
- Ensures adherence to procedural guidelines and timelines
- Regulatory scientific support in simpler procedures
- Maintains process performance metrics

EMA Product Lead (EPL)

- Leads the EMA product team
- Accountable for overall product knowledge
- Provides clinical and regulatory science input
- Supports consolidation of a committee position
- Facilitates cross-committee discussions
- Reference for the defined products/ disease area

Role profiles



Competences (examples)

- Qualified experience as an assessor in regulatory authorities or in Research & Development in Industry
- General knowledge of EU institutions including the Agency
- Knowledge of the pharmaceutical legal framework
- Experience in working in a multicultural environment

Skills (Example)

Skills:

- Excellent organisational skills
- Strong ability to follow detailed processes and procedures
- Precision in execution of work with attention to detail
- Initiative, diplomacy and good judgement
- Good written and oral communication skills
- Good interpersonal skills and team spirit
- Tact and discretion in the handling of confidential files and information

EMA trainee programme

The European Medicines Agency operates a trainee programme. The programme gives trainees an understanding of the Agency and its role within the activities of the European Union (EU) and provides professional experience in a working environment.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000321.jsp


UoA Pharmacy Degree, MSc, PhD
Industry experience
Training
Coaching
European Medicines Agency- Quality
European Medicines Agency Managerial roles
Life-long learning and Self-development
OPEN
SALE
SALE

Reflections

Enablers

- Pharmacy studies provided a good all around basis for the future career path
- Erasmus studies, MSc and PhD opened up the possibilities for a European career
- Soft skills

Reflections

- Fast changing working environment- Mobility
- Modern workforce takes responsibility for their self-development, i.e. identify areas of development and put in place development plans to address those needs.

- Increased demand and use of online and part-time courses