

## ***Job Description***

---

**Job Title:** Junior Regulatory Affairs Project Manager Medis - France

---

**Division/Department:** Medis France

**Location:** Regulatory Affairs Department - Medis France - 15 rue Taitbout, PARIS 9ème.

**Contact person:** Cécile CLERC - Tel 01 73 02 89 88 - [cclerc@medis.is](mailto:cclerc@medis.is)

Web sites: [www.medis.is](http://www.medis.is) (and [www.actavis.com](http://www.actavis.com))

---

**Reporting to:** Regulatory Affairs Manager Medis-France.

---

**Valid from:** March 2009

---

### **Main responsibilities:**

Supporting the regulatory activities in France

---

### **Main projects:**

1. To support the Regulatory Affairs Manager in its activities
2. Preparing dossiers from own R&D for submission into France (Hardpaper and eCTD)
3. Submission of Marketing Authorization Application, responses to deficiency letters if any, and subsequent Variations in France
4. Follow up of submissions and registrations activities
5. Pharmacovigilance support
6. Surveillance of Regulatory Requirements

## Communication

Medis and Actavis group

Experts, Regulatory consultants

Clients and regulatory counter part

AFSSAPS

## Technical Competence

1. University degree in the fields of Pharmacy, Chemistry or any related scientific field
2. Work experience with drug registration procedures in France or related university education
3. Experience with drug registration procedures in EU is desirable, or related university education
4. Good English language skills (spoken and written)
5. Good computer skills

## Personal Competence

1. Good organization skills
2. Good communication skills and ability to work cooperatively with different people
3. Ability to take initiatives and to work independently when needed
4. Ability to prioritize and to respond logically and in an understandable manner
5. Good problem solving and brainstorming skills
6. Ability to handle and to work under pressure