

	FORMULAIRE	Référence : F-AQ-P-007F Version n° : V01
FICHE DE POSTE – JOB DESCRIPTION		Date de rédaction : 22/01/2019 Page : Page 1 sur 1

POSITION:

- Regulatory Affair Officer
- Line Manager: Regulatory Affair Director

MISSIONS:

- Realise all the activities related to the registration and the maintenance of the marketing authorisation in accordance with the legislation.

ACTIVITIES:

- Assist the Regulatory affairs Director;
- Coordinate the content of the registration dossiers;
- Redaction of the administrative and/or pharmaceutical part of the registration dossiers;
- Submission of the registration dossiers;
- Follow the application, answer the authorities questions, and collect the necessary complements;
- Redaction, follow-up and/or review of the variation and renewal dossiers;
- Redaction, submission and follow-up of economic dossiers;
- Audit of dossiers;
- Preparation, submission, and follow-up of CEP dossiers to EDQM;
- Translation of documents between French and English;
- Contact with partners for all questions related to regulatory affairs;
- Management of a database and archiving of the dossiers;
- Regulatory intelligence.

MINIMUM GRADUATION AND EDUCATION REQUIREMENTS:

- Master II public health care;
- Minimum 3 months in regulatory affairs
- French and English spoken