

## IMP TRAINING PLACEMENT OFFER



## **PARTNER**

Name Asphalion S.L.

**Description** Asphalion is an international scientific and regulatory affairs consultancy

firm. The company offers comprehensive services for drug development and regulatory affairs to pharma, biotech and medical devices companies.

**Web** www.asphalion.com

## **PLACEMENT**

**Area** Regulatory Affairs

Name Regulatory Affairs Officer

**Description** The role offers an excellent opportunity for career development in an

international, dynamic and flexible environment.

Key responsibilities:

• Support the preparation of submissions which may include, but are not restricted to, new license applications, variations, PSURs;

 Use of internal electronic systems for planning, preparing, tracking and storing submissions to regulatory agencies;

 Evaluation and revision of non-clinical and quality documentation, and participation in drug development programmes in collaboration with R&D and CRO groups;

 Liaise directly with local Affiliates, distributors or agents to define/clarify submission requirements, and follow up on submissions, requests for supplementary information and approvals, in designated markets of responsibility.

Provide support in pharmacovigilance projects.

**Location** Barcelona, Spain

**Duration** 6-12 months

Salary 600 EUR/month (net) + bonuses

Start date Flexible

Mandatory qualifications

University degree in Pharmacy;

Very good written/spoken English;

Motivated by challenges, proactive, flexible, curious and willing to learn;

• Effective communication and interpersonal skills. Team player;

• Excellent attention to detail.

Preferable qualifications

 An understanding of the role of regulatory affairs in the preparation of MAA submissions;

• Knowledge of Spanish language or any other language highly valued.

**Reception** Handled by National IMP Coordinator

## **APPLICATION**

More info David Kološić

Central IMP Coordinator central.imp@epsa-online.org