



Elena Makarova

Consultant

EXPERIENCE:

Regulatory Affairs Consultant, Emergo Europe - 2008 to Present

Function as Regulatory Project Manager on assigned projects and mentor other Regulatory Project Managers, Co-ordinate and manage flow of information, document client and agency contacts. Design and complete regulatory deliverables, marketing applications, clinical trial applications etc for assigned projects; interface with company as appropriate during process. Conduct critical reviews of key technical documents including, pre-existing regulatory dossiers, non-clinical and clinical development plans, protocols and reports and related documentation aiming to ensure completeness, scientific accuracy, regulatory compliance, consistency with other key documents and ease of review. Provide general, development and regulatory advice for company. Arrange, participate in and report on meetings with regulatory authorities, with managerial supervision. Responsible for completion of assignments on time to cost and quality requirements, with a proactive approach to assignments. Contribute to time and cost estimates for projects. Follow company standards and policy.

Head of Regulatory Affairs and Pharmacovigilance Dept. in Russia and CIS, Baxter, USA, Moscow, RF - 2005 to 2007

Provide registration, re-registration of medicines and medical equipments and disposables in Russia and CIS countries. Preparing regulatory strategy documents based on detailed analysis of technical/scientific documentation and current knowledge of application regulations and conduct critical review of documents, ensuring completeness, fairness, scientific accuracy. Provide strategic and tactical advice to drug and equipment development staff to ensure projects are managed, proceeded on time, and within the designated budget whilst liaising with the appropriate regulatory body. Manage and conduct sample QA and verification checks on process deliverables to verify compliance to GCP; report the results of operational QA and compliance checks and quality gates to appropriate. Identify and manage initiatives to improve department capabilities. Initiate efforts to generate business leads. Maintain current knowledge of New regulatory requirements for all Baxter's products. Implement and develop according to new requirements Labels for all Baxter's products. Develop budget and reports

Regulatory Affairs Manager, IPSEN, France, Moscow, RF - 2002 to 2005

Develop and implement global regulatory strategy. Analyze laws, regulations and guidelines for compliance requirements of Authorities. Negotiate with Government Health Authorities during the regulatory procedures. Provide registration, re-registration and certification of medicines in Russia and CIS countries. Provide expert regulatory advice for assigned projects. Coordinate preparation, review and assembly for all documents, ensuring consistency with European standards. Provide clinical trial design (III, IV), conduct and documentation are in compliance with GCPs



Elena Makarova, continued...

Regulatory Affairs Manager, Merck Sharps & Dohme Idea, Inc . Moscow, RF - 2000 to 2002

Managed scheduling and submission of the regulatory documents to Government Health Authorities and other authorities. Coordinated with Government Health Authorities, preparation and implementation of controlled documents. Provided registration of medicines. Coordinated preparation, review and assembly for all documents, ensuring consistency with European and USA standards. Prepared the instructions for specialists and patients. Implemented and maintained labels and packs(packaging development) according to the requirements of the Authorities.

Regulatory Affairs Manager, Searle Pharma LLC factory - affiliation to Monsanto Corporation (Pharmacia), Moscow, RF - 1998 to 2000

Designed and implemented global file according to the standards and requirements of the Government Health Authorities. Provided registration of medicines in Russia and CIS countries. Prepared the instructions for specialists and patients.

Regulatory Affairs Manager, Hemofarm, Yugoslavian pharmaceutical company Moscow, RF - 1995 to 1998

Provided registration of medicines in Russia and CIS countries(implemented global file, submitted to Authorities, coordinated with Authorities) . Implement marketing research for new launch products in Russia. Develop supply and distribution chain for imported finished products. Organize Training for Medical Representatives on Sales and Introduction of New Launch Products.

TRAINING:

- Pharmaceutical Regulatory Training Course (arranged by FDA) RF, Moscow, June 2003
- Regulatory Affairs Managers EU Training Belgium, Brussels, May 2001
- Worldwide regulatory affairs training USA, Chicago, April 2000
- Presentations and negotiations skills RF, Moscow, November 1999
- Good clinical practice for investigators RF, Moscow, March 1999

EDUCATION:

- The Russian Academy of Foreign Trade, Moscow,RF, 2002-2003
- Management of foreign trade, specialize in management
- The Russian Academy of Foreign Trade, Moscow,RF, 2003-2004
- Master of Business Administration , Marketing
- I M Sechenov Moscow Medical Academy, Moscow,RF, 1985-1990
- Doctor of Pharmacy, Specialize in pharmacy and chemistry