Teva is looking for

Regulatory Affairs Associates/ Senior Regulatory Affairs Associates

to join our expanding team in Athens

The main work of the **RA Associates/Senior RA Associates** will be the dossier preparation for new applications and the maintenance of the quality section (module 3) of our dossiers for existing MAs.

Qualifications:

- Greek or foreign University degree in Pharmacy, Chemistry or related subjects
- Excellent English oral and scientific writing skills
- **RA Associates:** Relevant Experience in Drug Regulatory affairs and/or Analytical will be an asset (for the RA Associates)
- **Senior RA Associates:** At least 3-5 years' Experience in Regulatory Affairs (preferably in CMC positions) and/or Analytical (for the Senior RA Associates)
- Capability in problem-solving and co-ordination of regulatory issues
- Analytical thought needed to resolve issues in a variety of complex situations
- Knowledge of EU regulatory framework, ICH and EU requirements of GMP & GLP
- Very good computer skills (working with specialized computer software and resources)
- Excellent organizational skills
- Must have good communication skills (both written and verbal) and interpersonal skills, since he/she has to coordinate the tasks between various departments of the site, as well as with suppliers and departments from other sites within the company.
- Must have an eye for detail and a methodical approach to work
- Must be able to work under pressure and on own initiative
- Military obligations should be completed (by male candidates)

Main tasks and key responsibilities:

- Assist in the collection and evaluation of data for inclusion in marketing authorization dossiers
- Prepare the variation and post-approval change packages and other necessary documents as required by the variation process
- Respond to queries (from regulatory authorities or clients) concerning dossiers, manage the process to respond to the CMC questions by involving all stakeholders both within and outside the company and following up agreed actions in order to respond as rapidly and completely as possible
- Assist in keeping the dossier (Module 3 and corresponding QoS) fully up to date during registration procedures and as a consequence of a variation or of a site transfer
- Respond to queries (from regulatory authorities or clients) concerning potential changes.
- Ensure that the documentation of the Active Substance Master Files is appropriate for the required purpose and targeted countries
- Review for regulatory compliance the Stability protocol and compile raw data
- Participate in meetings related to registration procedures or when the CMC expertise is needed.
- Review regulatory compliance protocols and/or reports, as requested