ROLE: Regulatory Manager PLPI (Product Licence Parallel Import)
DEPARTMENT: PLPI
REPORTS TO: Clinical and Development Director
SITE: Ruislip

PRIMARY RESPONSIBILITIES

You will be involved in the submission and monitoring of successful pharmaceutical licence applications by liaising with various governing boards to obtain granted licences as soon as possible.

SECONDARY RESPONSIBILITIES

- Have detailed knowledge of the full licence application process for all the different Regulating Bodies and establish contacts/relationship with key people within these bodies.
- Going through all correspondences from the governing boards and logging them in the appropriate databases and looking at the issues raised.
- Maintaining and updating product samples and product files, to ensure applications are done in line with the regulatory requirement
- Proactive license checking and maintain the compliance
- Regular meetings on how things are developing in order to keep on target with the Team
- Keeping a track of Pending stock processing and informing appropriate department when products can be labelled.
- Continually review the PIL workload with a commercial focus and ensure work is prioritised in a way that will realise cash quickly.
- Coordinating with Eurobuyers, PI Assembly and QPs for current license compliance and new regulatory requirement
- Be proactive in reviewing all processes and procedures regularly, with a view to improving them.
- Take initiative to stay abreast of commercial changes by reading widely and seeking out relevant knowledge that may affect the way we work. And be proactive in sharing this with the senior team along with suggesting solutions on how we could minimise threats and optimise on opportunities.
- Managerial duties:
    - Coordinating with the team on any daily issues.
    - Organising daily objectives/tasks in line with KPI's
    - Conducting one to ones and team meetings regularly
    - Developing the teams' skills to ensure work is carried out as efficiently and accurately as possible
    - Identify skill shortfalls in team members and put in place development plans to address these.
- Provide holiday and absence cover when required, in other roles.
- Ad hoc projects when required

Any other duties as required.

KNOWLEDGE, SKILLS AND EXPERIENCE

- Previous experience in a similar role
- Excellent people management skills.
- Has good communication skills both written and verbal
- Can demonstrate excellent analytical skills
- A conscientious and innovative individual who shows attention to detail.
- Must computer literate and competent in MS Office.
- Ability to keep up-to-date with Pharmaceutical trends and developments within the industry.