



TRIAL FORM SUPPORT

Regulatory Affairs Specialist

The Regulatory Affairs Specialist works with other units within the company and with our clients to ensure that all TFS Trial Form Support trials meet regulatory requirements. The work often involves cooperating with other colleagues within the company.

Principal duties relate to:

- Providing advice or managing submissions to regulatory agencies including registration files, applications for clinical files, etc.
- Providing support to currently marketed products including updating SPCs (Summary of Product Characteristics), labelling updates and submitting variations, etc.
- Supporting the development of applications for clinical studies to the regulatory authorities
- Generating documentation required for regulatory agencies
- Providing regulatory guidance and training to employees
- Maintaining a professional and credible image with MPA (Medical Product Agency) and other regulatory agencies
- Planning, participating and leading meetings with clients

Desirable qualifications and background:

- Suitable academic education in life sciences or equivalent experience
- At least three years experience with regulatory affairs
- Good organisational skills
- A service-minded approach to clients and your work
- Good teamwork, communication and teaching skills
- Ability to prioritise and handle simultaneous work tasks
- Experience with IT aids and PCs
- Good ability to express yourself both verbally and in writing