

Trial Form Support AB

TFS Trial Form Support (TFS) is an FDA- and MPA-inspected full-service clinical CRO, operating in three independent business areas: Early Clinical Development, Project Delivery and Contract Placement Solutions. Founded in 1996 in Lund, Sweden, TFS has become the largest non-listed European CRO employing 480 highly competent and dedicated clinical research professionals working from offices across 16 countries in Europe, USA, Japan and India. The projected revenue for 2009 is 38 million EUR.

Regulatory Affairs Manager

TFS is now looking for a well-experienced Regulatory Affairs Manager who appreciates a flexible working environment filled with interesting and stimulating assignments.

TFS is working with both international and national projects within many therapeutic fields. The Regulatory Affairs department is involved in plenty of exciting projects in various phases, such as registration, strategy planning in early development phase, clinical trial application and marketing approval as well as maintenance after approval.

The main responsibilities of the Regulatory Affairs Manager will include:

- Preparation, review and compilation of regulatory submissions
- Liaison with authorities
- Advice/answers to regulatory issues/questions
- Preparation of prescribing documents (SPCs, Package insert labels)
- Maintain a high level of competence regarding international regulatory requirements and regulatory procedures

Requirements/qualifications:

- Suitable academic education in life science such as pharmaceutical science, medicine, biomedicine, biology or similar
- At least 3 years experience from working with regulatory affairs within the pharmaceutical industry or regulatory authorities
- Good communication skills in spoken and written Swedish and English
- Knowledge of Medical Device is an advantage

TFS Trial Form Support will offer:

A dynamic and growth-oriented organization with a work environment distinguished by professionalism, integrity and responsibility.

Welcome to join us and to contribute in placing TFS Trial Form Support among the top 10 worldwide CROs.

Your job **will** make a difference!



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For more information about this position please contact:

Cecilia Falkenberg, Unit Manager Medical Affairs at +46(46)280 18 06 or e-mail cecilia.falkenberg@trialformsupport.com

We are looking forward to receiving your application with included CV and a personal letter. We practice a continuous selection procedure, so please submit your application via the link provided on our website as soon as possible, however no later than the 31st of August, 2010.