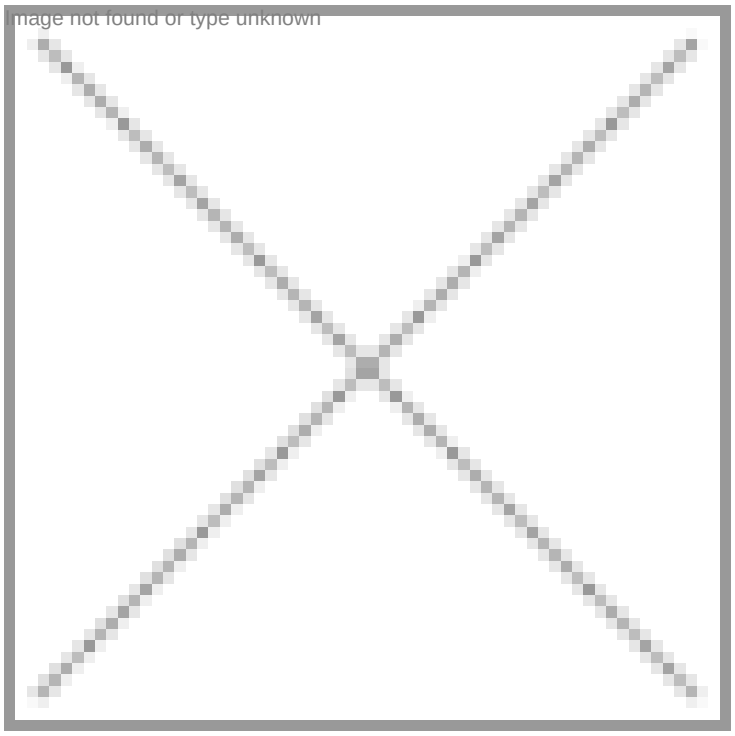
BioSpectrum the business of Bio & Health Sciences

# SIRO Clinpharm launches training center

13 September 2011 | News




SIRO Clinpharm announced its plans to launch the Center of Excellence for Medical Writing (CEMW), a first of its kind training institute in the field of medical writing in India. The center will offer a basic certificate and an advanced course in medical writing for duration of three months each. Emphasizing on quality training, the number of seats will initially be restricted to only 30.

Eligible candidates should have at least a degree in the medical profession (MBBS, BAMS or BHMS). Postgraduates in pharmacy and life sciences may also apply.

â€œWe are excited about launching this one of a kind institution in India. The faculty of CEMW will include the best trained and qualified industry experts in medical writing from SIRO's SBU, SCEDAM (The Strategic Center of Excellence for Data, Analysis and Medical Writing),â€? said Nimita Limaye, PhD, VP and global head â€“ SCEDAM and CEMW.

â€œIndia is a key destination for outsourcing of medical writing, owing to its large scientific and medical community and the command over the English language. There is a paucity of professionally managed quality training solutions in the industry.

Also, since medical writing is a niche domain, there is a huge demand-supply gap of trained medical writers. The CEMW will not only fill the need for a high quality training institution but will also act as a springboard for candidates aspiring to join the medical writing industry,â€? said Mr Ajit Nair, president, Asia operations at Siro Clinpharm.

---

## 'Govt should speed up approval process'

In light of the current controversies surrounding clinical trials and increasing competition from China and Latin American countries, the clinical research industry in India has called for various measures to maintain India's image as an attractive

destination for conducting clinical trials.

Speaking to BioSpectrum, Dr KH Ramanjaneya, managing director, SMO Clinical Research (SMO-India), a privately owned site management organization offering comprehensive services from Bangalore, asked for better training at the site level and stringent checks on smaller unregulated companies carrying out trials. â€œOnce the basic set-up of the clinical trials adheres to strict guidelines not only will it improve the overall environment of conducting such trials, but also encourage investment from foreign companies,â€? he said.

â€œCurrently, India has various appealing features such as a large ethnically and culturally diversified pool of an English speaking population. We should take advantage of this situation,â€? he said.

Lamenting the slow rate of approvals from the regulatory agencies, he added, â€œThe general perception is that approvals come very slowly in India and is one of the reasons why foreign companies are hesitating to invest here. The government should take the necessary measures to address this issue.â€?

---

## Phase IIb trials begin for Revamilast

Glenmark Pharmaceuticals has initiated phase IIb human dose range finding trials globally for its novel chemical entity Revamilast (GRC 4039). Revamilast is an orally active, potent and selective inhibitor of phosphodiesterase 4 (PDE 4) that is currently being developed by Glenmark for the treatment of chronic inflammatory disorders such as asthma, rheumatoid arthritis and other inflammatory diseases.

The phase IIb studies will help establish the efficacy and safety of the molecule and will also provide dose range finding data for Revamilast.

â€œThe clinical trials and the animal studies data for Revamilast are promising for both asthma and rheumatoid arthritis. There is a huge unmet need for both these chronic medical conditions globally. For Glenmark, this is a significant development as we have built on more than a decade of experience in the PDE 4 space to progress an exciting molecule to phase II human trials,â€? said Dr Steffen Stuerzebecher, president and chief medical officer, Glenmark Pharmaceuticals.

Glenmark has already received approval from respective authorities in the UK, Poland, India and Czech Republic to conduct phase IIb studies. Regulatory submissions have also been completed in Russia.

Glenmark has also initiated another global phase IIb trial with Revamilast in patients with rheumatoid arthritis.

It has already received approval from the MHRA, UK, India, Poland and the Philippines to conduct the phase IIb studies. Regulatory submissions have also been completed in Sri Lanka.