Meet with ZWIERS! 2dayRA

**The essentials of Regulatory Affairs in two days**

Comprehensive and ready-to-use training course

Following three very successful previous editions, Zwiers Regulatory Consultancy, part of Product Life Group, is determined to keep offering yet again a two days regulatory affairs training. The training offers a quick start in understanding RA at a very comprehensive level and in a way readily applicable to daily practice.

In the dynamic environment of regulatory affairs, it is essential to have a solid understanding of the basics and be aware of opportunities. Starting with a quick overview of drug development and the involvement of RA experts in it, the 2dayRA course provides extensive insight in the contents and format of the regulatory dossier (eCTD) as well as EMA and FDA regulations, guidance and procedures to obtain, maintain and expand approval. Building to this basic knowledge, the course also addresses possibilities for early access, abridged dossiers and regulatory strategy options (e.g. conditional/accelerated approval, repurposing, generics). Apart from obtaining knowledge on key regulatory topics, participants will also apply this knowledge by performing practical tasks. Moreover, they will be treated to an interactive session on RA related pharmacovigilance activities.

The course is of value to all in pharmaceutical industry that deal directly or indirectly with regulatory affairs; to those already working on a subset of regulatory activities and wanting to broaden their understanding, but also to those working in a related position that would benefit from being acquainted with RA basics and options. Working onsite (Oss Offices, the Netherlands), in small groups of (max. 12) participants and with mixed backgrounds has previously proven to pleasantly add to the learning efficiency. Moreover, with all course materials being shared and the possibility of exchanging contact details, long lasting sources of information and networking are warranted.

Zwiers Regulatory Consultancy has an extensive track record of training programs which is recognised by clients, course participants and expert organisations like TopRA and supported by the solid organizational structure of Product Life Group. Its highly dedicated trainers rely on decades of experience in RA and are very keen on sharing knowledge. Moreover, as customer's needs are much valued, they will be as flexible as possible to adapt the training program putting focus on specific parts, as desired. For more information: contact the principal trainer Karin Ruijtenbeek (karin.ruijtenbeek@az-regulatory.com) or check https://www.az-regulatory.com/opportunities/2dayra.