Training: Regulatory Affairs from A to Z

Why participate?

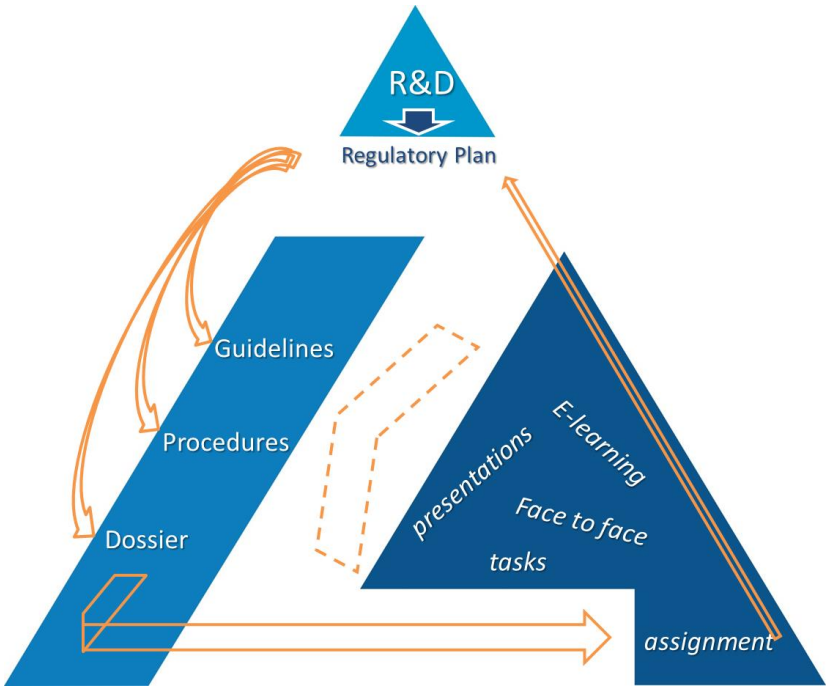
You will rapidly gain a lot of knowledge under supervision of experienced professionals. In this way, you will turn your career in to a new challenging direction.

"Exciting! A large variety of topics.

Efficiently and focused on daily practice."

What's the content?

After an introduction to research & development and regulatory strategy, you will dive into regulatory detail. Guidelines, procedures and the dossier will be explained in presentations, e-learning modules, meetings and tasks. This knowledge you will use to perform your own regulatory (coached) assignment.



Practical details

- Where? In the offices of Zwiers Regulatory Consultancy in Oss
- Duration? 4 weeks (4 days (of 8h) a week)
- Costs? €2995,- (excl VAT)
- Register? Send your CV and motivation* to info@az-regulatory.com

*We will check if your background matches and will ensure you gain as much as possible from the training.

Program topics

INTRODUCTION R&D AND REGULATORY STRATEGY

Introduction Zwiers Regulatory Consultancy, Pivot Park, programme, practical business
Drug development in overview
Essentials of EU and US Regulatory Affairs
Regulatory Strategy Plan
RA organisation
Introduction to individual assignment

Regulations

Guidelines
Regulatory Intelligence
Coaching on assignment
RA job roles
Medical devices

PROCEDURES

The European Centralised Procedure
The European Mutual Recognition Procedure
The NDA Process: Requirements for Obtaining Approval for a New Drug in the USA
Abbreviated procedures

DOSSIER

Preclinical
CMC
Clinical
Product information, module 1
Drug safety and pharmacovigilance
eCTD

Set up

Development is the keyword.
Regulatory affairs play a decisive role in the development and life cycle of drugs.
We show you the insights.
But above all we will also stimulate your personal development. Either by adding detail to your know-how (Which regulatory aspects are applicable to my business?) or by opening up new horizons (I have a pharmaceutical basis and would like to move towards a career in regulatory affairs). The assignment we will give you will match with your background and ambition.
You will learn and work in our offices in Oss. You will directly benefit from the coaching of our professionals.

Questions?

E-mail or calll: karin.ruijtenbeek@az-regulatory.com, 06-10488548