Learn and Work program

Goal:
All-round regulatory knowledge and ability to fullfill specific regulatory tasks
→ regulatory job (at Zwiers or mediated by Zwiers)

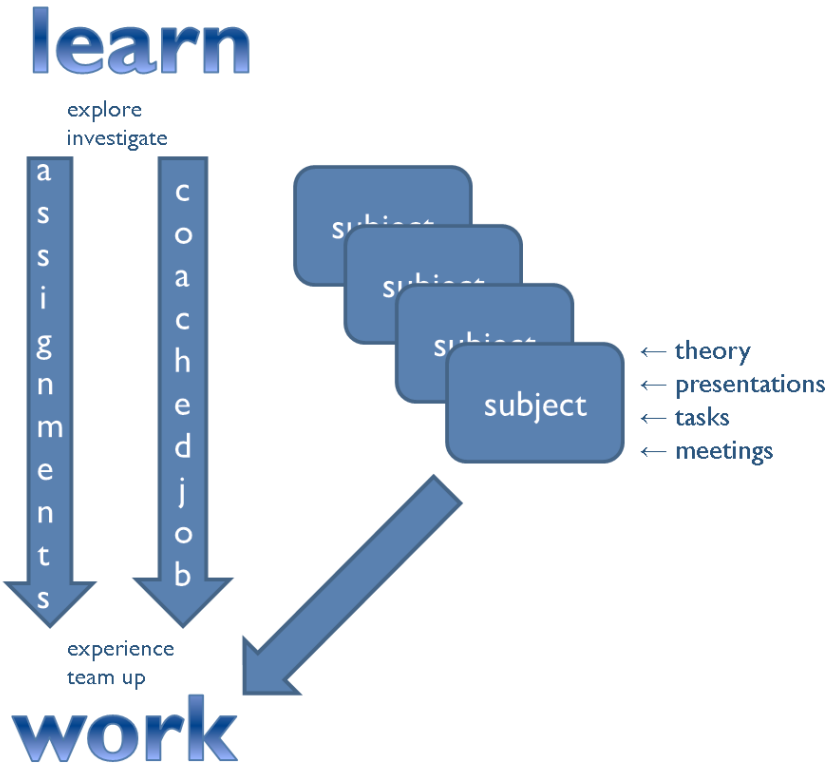

Figure 1 Schematic presentation of Learn & work program

Methods:
In the Learn part the trainees get acquainted with regulatory subjects (explained in more detail in the next page) by using:

- E-learning + explanations by Zwiers professionals.
- Presentations (by Zwiers professionals, guests or webcasts)
- Conversations, meetings with the Zwiers professionals
- Tasks; small assignments related to the "Learning" subject being addressed.

The Work part of the program consist of a regulatory strategy assignment and a hands-on job, coached and supervised by a Zwiers professional. During the program focus will move from Learn to Work. The trainee will have meetings with CEO Alex Zwiers and will join team meetings.
The assignment and coached job are further explained to the trainees at the start of the program.

Conditions:
Zwiers Regulatory Consultancy offers a fulltime trainee position and will invest in training and coaching. No salary is offered. However, travel expenses of the trainee will be covered.

INTRODUCTION

Subject	Content
Introduction to program and company	Content, planning
Introduction to drug development	Basics of drug development
Essentials of EU and US Regulatory Affairs (RA)	e-learning
RA jobs/organisation	How is RA organized? Which RA positions?
Introduction to RA assignment and coached job	Regulatory strategy and hands-on

REGULATORY STRATEGY

Subject	Content
Regulatory Strategy Plan(RSP) -task	Contents of RSP
Regulatory Intelligence and information	Which info and where to find?
Regulatory Intelligence in practice	Cases and focus on RA assignment

PROCEDURES

Subject	Content
The European Centralised Procedure (CP)	e-learning
The Mutual Recognition Procedure (MRP)	e-learning
The Decentralised Procedure (DCP)	Presentation/discussion
The New Drug Application (NDA) in the USA	e-learning
Generics/Abbreviated NDA	Procedures, comparison with innovative pharma
Accelerated approval	Possibilities, examples

PRODUCT INFORMATION

Subject	Content
Company Core Data Sheet	Explanation and practical examples
Task: readability	Readibility of patient information,QRD
Variations to Marketing Authorisations in Europe	e-learning
RA Chemistry Mnaufacutring and Control	Explanation and practical examples

DOSSIER

Subject	Content
Preparing Submissions in the (electronic) Common Technical Document (CTD) Format	Content and format
Local RA	Explanation and practical examples
RA coordinator/ liaison	Job role explanation

CLINICAL TRIALS

Subject	Content
Clinical Development/medical writing	Explanantion and practical examples
How to Obtain Approval to Conduct Clinical Trials in the EU	e-learning
The IND: How to Gain Approval for Clinical Trials in the USA	e-learning
Health Authority meetings	Case/task: preparation of Scientific Advice
Pediatric Investigational Plan	pediatric regulations/ development plans

MISCELLANEOUS

Subject	Content
Pharmacovigilance	Explanation and practical examples, job roles
Orphan drugs	Explanation, cases
Medical devices	Requirements, dossier content
CV update	Make CV "regulatory-attractive"
Vacancy analysis	Trainees and Zwiers check and evaluate opportunities

ZWIERS
Regulatory Consultancy