# REGULATORY AFFAIRS

## STAR PROGRAMME

How to start your career in regulatory affairs

STAR PROGRAMMES

**Benedikt Van Nieuwenhove**

Managing Director

Regulatory Affairs is a crucial area to ensure that pharmaceutical products can be manufactured, authorised and maintained on the market, as well as guarantee that they are aligned with all applicable regulations and legislation.

This is a fascinating field with numerous career opportunities. With our STAR Programme you will get acquainted with the job positions available and will understand the different players involved in regulatory affairs.

If you are looking for a way to enter in this area with the knowledge and experience required to start your career, then this Programme is for you!

Become a regulatory affairs professional now!

# MEET OUR CEO

Obtained a Pharmaceutical Sciences degree in 1991 and finished his PhD in 1997 while working as a quality assurance manager at a laboratory for medical biochemistry & clinical analysis in Ghent.

- Started his career as a CRA
- In 2000 created ECCRT (Managing Director)
- 2008-2011 Vice President Global Operations of the Harrison Clinical Research group.
- 2011-2014 Chief Executive Officer of Harrison Clinical Research
- 2016 Professor at the University of Gent
- 2021 President of BeCRO
- 2023 - Current CEO of Artialis

# REASONS TO ATTEND

## EXPERTISE

Very complete course about regulatory affairs from A to Z, delivered by experts in this field
*(9 trainers for this Programme)*

## PERSONALISED

Personalised approach for each participant
*(limited number of registrations and internship according to your location)*

## PERFECT CV

The Programmes gathers everything you need to match the qualifications for regulatory affairs job positions
*(knowledge and experience)*

BECOME A REGULATORY AFFAIRS PROFESSIONAL

# STAR PROGRAMME

## ABOUT

This STAR Programme is a must for anyone wanting to start a career in regulatory affairs as it will grant you the knowledge, skills, competencies and expertise required to become a regulatory affairs professional.

This Programme consists of 2 parts:

1.Theoretical part
2.Practical part

**1.Theoretical part:** A full-week training covering the different areas and activities within regulatory affairs and associated regulations and guidelines.

**2.Practical part:** 6-months internship to provide you with the experience most employers are looking for in this area.
The internships are customised upon your needs, expectations and location.

**NEW**
STAR PROGRAMME

**9**
Experts in their fields covering the theoretical part

**6**
Months international internships

THEORETICAL PART

# PROGRAMME AGENDA

**DAY 1**

## INTRODUCTIONS + LIFE CYCLE OF A PHARMA PRODUCT

Find your way in the regulatory space, discover the processes from drug discovery to clinical development as well as the medicinal product development processes to the authorisation and introduction in the market.

**DAY 2**

## SUBMISSION FOR MA IN EU AND NON-EU/US

The steps-by-steps to obtain marketing authorisation (MA), in the EU and Non-EU, with a focus on the US.Particular applicationtypes will be reviewed (such as Orphan Drugs).

**DAY 3**

## CMC & GMP, LABELLING

Clear overview of the Chemistry, Manufacturing & Controls (CMC) in drug development and for licenced medicines, and the Good Manufacturing Practices (GMP) enforcement and labelling.

**DAY 4**

## GDP GUIDELINES AND REGULATORY POLICY & INTELLIGENCE

Understand what Good Distribution Practices (GDP) are and who is responsible, as well as the difference between regulatory policy and intelligence.

**DAY 5**

## PHARMACOVIGILANCE & INFORMATION AND PUBLICITY

Gain a good comprehension on the pharmacovigilance system in the EU and of the promotion of prescription-only medicines to HCPs.

PRACTICAL PART

# INTERNSHIPS

The internships will take place to help you have a complete overview of the actual duties and number of areas within regulatory affairs, as well as to help you know which **environment to pursue your career in the future**:

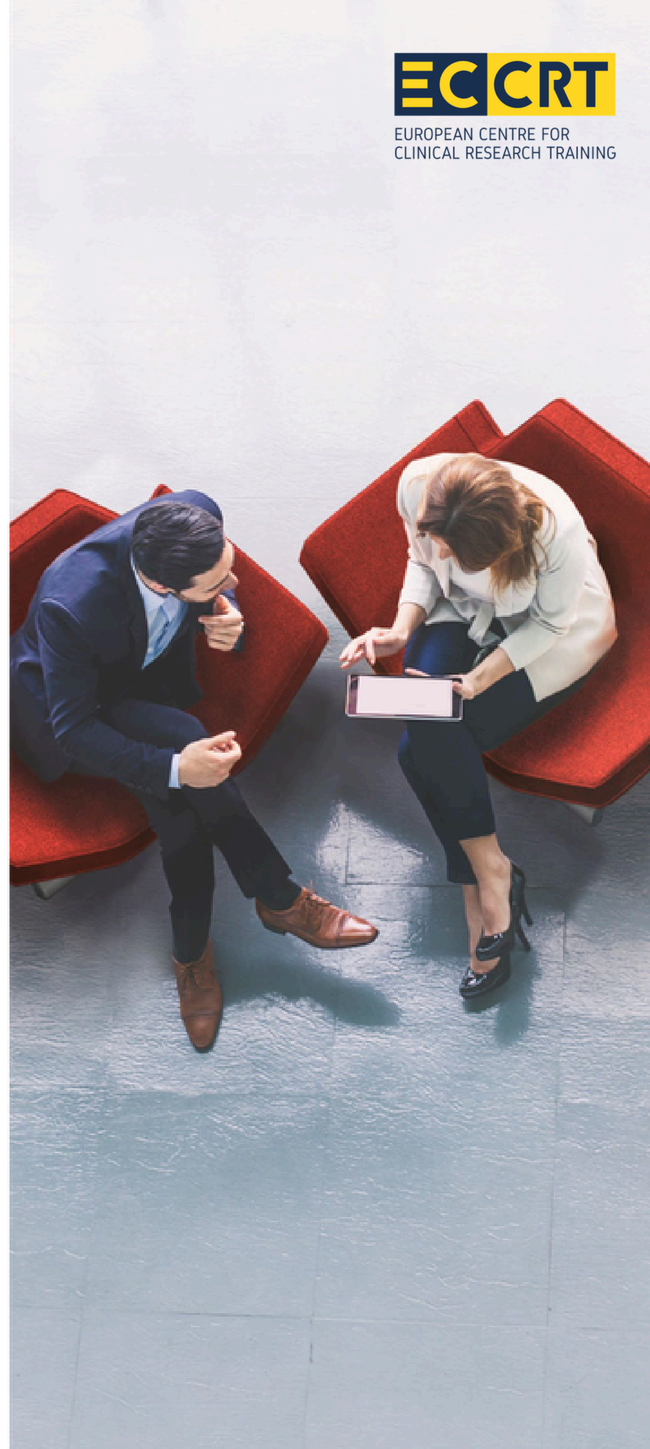
**6 months in**

**PHARMA COMPANY**

**OR**

**CONSULTANCY COMPANY**

These internships will help you to acquire knowledge and hands-on experience in regulatory affairs regulations, processes and related activities.



ECCRT
EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

# TESTIMONIALS

**Michela Lisjak**
Regulatory Affairs Trainee

The ECCRT Regulatory Affairs programme was a great experience in my career transition from academia to the pharmaceutical industry. The course content is designed for individuals from diverse backgrounds, with no prior regulatory experience required, and offers personalized guidance to help secure an internship that matches with personal skills and background. In addition, the programme offers networking opportunities with industry professionals and peers, helping build a professional network that is crucial for career advancement.

**Mopelola Adegun**
Regulatory Affairs Specialist

It has been really interesting right from the first day of our meeting face to face in Belgium Being in a room with trainees from diverse scientific backgrounds and experienced Regulatory Affairs expert in the field enhanced productive and interesting conversation. Not a boring moment!
Learning is not enough to have knowledge, ability to practice is key, the RA STAR Programme gave me the opportunity to have much needed practical exposure to the industry. I was able to do my internship in Janssen Pharmaceuticals, a top global pharmaceutical company.
I also I would like to appreciate Virginie Hamtiaux for her kind support and follow-up all through the programme.
I would really recommend RA STAR Programme to everyone interested in building a career in Regulatory Affairs!

HOW TO PARTICIPATE?

# APPLICATION PROCESS

## APPLICATION

Fill out the **application form** & submit *(this does not mean you are registered for the Programme and will have to pay the Programme's fee).*

## REVIEW

Your application form *(including CV and motivation letter)* will be reviewed by ECCRT and your Mentor.

## INTAKE CALL

An intake conversation with your Mentor will be organised shortly after the submission of your application.

## REGISTERED

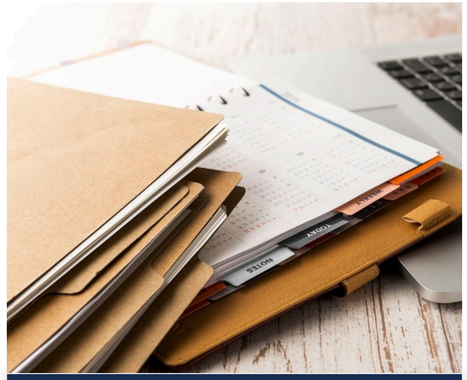
After the intake call, if accepted, you can proceed with your registration by booking the STAR Programme session you want to attend.

WHAT

# JOBS AREAS CAN YOU GO

AFTER THE PROGRAMME?

EUROPEAN CENTRE FOR CLINICAL RESEARCH TRAINING

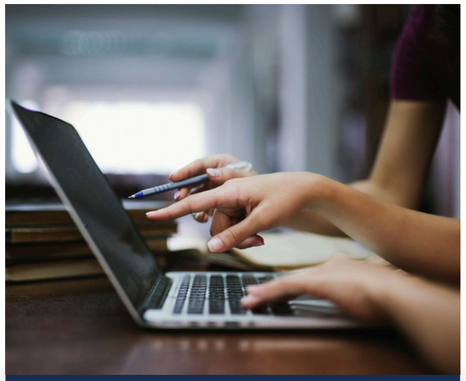


MARKET AUTHORISATION

CHEMISTRY, MANUFACTURING CONTROLS

LABELLING

POLICY & INTELLIGENCE



INFORMATION & PUBLICITY

GOOD DISTRIBUTION PRACTICE

# TRAINERS

Pieter Vancaeneghem

Saskia De Haes

Dr. Evren Henslegers

Aurélie Auger

Solange Corriol-Rohou

Thierry Dedecker

# ABOUT ECCRT

*Key player in clinical research training*

*The European Centre for Clinical Research Training (ECCRT) will help you excel in your competencies and knowledge to start and advance your career in regulatory affairs and other related fields.*

- OPEN COURSES
- STAR PROGRAMMES
- CAREER COACHING

*AND MANY OTHER SERVICES…*



https://eccrt.com/ +32 (0)25040720 info@eccrt.com