lifesciences@work

Health~Holland

Expert Class 3 • 22 September 2017

[Update 8 September 2017]

Learn from experts on Clinical Trials

Programme • Information

Expert Class3/2017 • Clinical Trials • Regulatory Affairs

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Introduction

Clinical Trials: Getting a clinical trial underway is no simple task. From patient recruitment to study completion, the drug maker or med tech developer must undertake a wide array of complex, and closely monitored operations, complying with regulations all the way. Trials become more global, patient groups more targeted, and investigator sites more widespread.

- **Where to begin and how to set it up.**

Regulatory Affairs: The final hurdle – getting your drug, therapy or medical device approved and on the market. Regulatory requirements in Europe and the rest of the world are continually evolving and further more vary from one country to another.

- **What does it take to navigating through the different regulatory landscapes?**

Date	**22 September 2017**
Time frame	**13:30 - 19:00 hrs.**
Programme Features	Mini-Masterclass/Workshops, Free Consultations, Networking
Audience	Exclusively organized for Venture Challenge/Value Voucher/MedtechPartners/ BiotechPartners Alumni and new LS@W startups
Venue	BioPartner Leiden www.biopartnerleiden.nl

biopartner
center Leiden

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Time Schedule

13:30-14:00 Ready to welcome our participants

14:00 –14:30 **Start Expert Class 3/2017**

- Words of Welcome

Entrepreneurship in Leiden
Bart Hoenen, Entrepreneurship Advisor Luris

Entrepreneurship in West Holland
Stefan Ellenbroek, Senior Business Developer LifeSciences and Health, InnovationQuarter

- Programme details

Ellen de Waal, LifeSciences@Work Accelerator Partner, Mentor

14:30-15:00 **Workshop 1 | Clinical Trials: a general introduction**
(Lecture and Q&A)

Marcel Kenter, Director, Paul Janssen Futurelab Leiden

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15:00-15:30 **Workshop 2 | Perspective from a life sciences company**
(Lecture and Q&A)

Sandra van Wetering, Chief Operating Officer, DC Prime

15:30-16:00 **Break & Networking & Free consultations** (2 rounds x 10 min)

16:00-16:30 **Workshop 3 | Perspective from a med tech company**
(Lecture and Q&A)

Eline van Beest, Founder and CEO, Nightbalance

16:30-17:00 **Workshop 4 | Perspective from a medical center**
(Lecture and Q&A)

Speaker invited

17:00-17:30 **Workshop 5 | Regulatory Affairs and Clinical Trials: a quick tour**
(Lecture and Q&A)

Bas Megens, Attorney at Law, Loyens & Loeff

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17:45 –19:00 **Free consultations and 'borrel'**

- Further interaction with mentors and contributors about participant's questions and challenges. Approx. 4 'rounds' of 10 minutes each
- Including refreshing drinks and tasty snacks

19:00 Wrap- up and ending.

Registration

We sure hope to welcome you (again) at the 3rd Expert Class. The set up is very informal and personal. We highly value the contribution of our experts.
With this Expert Class we hope to give you a brief overview, since 'Clinical Trials' is a difficult and broad topic. Let us know what the issues and challenges are for you.

Participation is free of charge, provide you match our profile.
To register, send an email to Ellen de Waal: dewaal@lifesciencesatwork.nl, adding the following details:

- First name – suffix -last name - email - phone and/or cell phone - name of startup
- Website – Twitter - LinkedIn
- Status startup
- Questions for contributors

LifeSciences@Work Accelerator

Heath~Holland, Top Sector Life Sciences & Health
Laan van Nieuw Oost-Indië 334
2593 CE The Hague, The Netherlands

More information | www.lifesciencesatwork.nl

Join our community

- On Twitter: @lsatw
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- Email info@lifesciencesatwork.nl