

REGULATORY SCIENTIFIC ADVICE SEMINAR

19 December 2019 15:00-17:00 in the
Mærsk Tower of Copenhagen

Invitation to an evening seminar followed by reception

When developing new medicines, companies will experience great value from receiving scientific advice from a regulatory authority. The assessors of regulatory authorities often have a broad view of similar medicinal candidates. The scientific advice helps to ensure that developers perform the appropriate tests and studies, so that no major objections regarding the design of the tests, and the development programme in general, are likely to be raised during the evaluation of clinical trial applications and the marketing authorization application. Questions during scientific advice can relate to all aspects of the development programme. E.g. manufacturing, toxicological and pharmacological tests designed to show the safety and activity of the medicine in non-clinical studies, appropriateness of studies in patients or healthy volunteers, selection of endpoints, i.e. how best to measure effects in a study, and methodological issues such as statistical tests, modelling and simulation. Thus, this also helps avoid patients taking part in studies that will not produce useful evidence!

Programme

- Welcome and setting the scene. **Per Spindler**, Biopeople
- Preparation, execution and follow-up of scientific advice – perspectives from inside the company. **Nicklas Lindland Roest**, Lindland Roest Consulting and Chief Regulatory Officer, Scandion Oncology A/S
- The scientific advice in the overall strategic plan of the company. How to phrase the specific questions and what is beyond the guidelines? **Steffen Thistrup**, NDA Advisory Services Limited
- Network reception

Would you like to participate in the event?

Join us for sharing experiences and learn from real-life cases on top of the Mærsk Tower. The meeting is open for all interested, participation is free of charge, and we welcome companies and other professionals with special interest in seeking scientific advices for medicinal products. Registration is mandatory at www.biopeople.eu.

Contact for further information: Per Spindler at pesp@biopeople.ku.dk

“by Biopeople” is:

Learn the hands-on regarding scientific advice

Enjoy the informal exchange of experiences and ideas

Network and wish your colleagues a Merry Christmas!

When:

Thursday, 19 December
2019, 15:00-17:00

Location:

Maersk Tower
15th floor, room 7.15.92
Blegdamsvej 3B
2200 Copenhagen N

Organiser:

Biopeople