

Deep Dive - outsourcing R&D and the marketing authorization – the GxP perspective

19 March 2020

This event has been postponed due to the emerging situation of coronavirus/COVID-19 – new date will be announced at www.biopeople.eu

Outsourcing R&D and the marketing authorization – the GxP perspective

Ever increasing proportions of research & development activities are conducted by contract-research-organizations (CROs) on behalf of biotech and pharma companies. However, what are the specific regulatory requirements and considerations to subcontracted data when being assessed for marketing authorization of medicinal products. This event sets out to provide a practical guide to industry on how to manage the interface between CROs and sponsors. Guidelines and regulatory considerations concerning the interface will be presented and discussed.

Programme 14:30 Registration opens

15:00 Welcome, **Houman Pourhassan** and **Per Spindler**

- *Take the myths out of regulatory requirements of inspections and QMSs in the interface between CRO and sponsor! How are inspections of laboratory and analytical data managed, including analysis of human specimens?*
Lene Bjerring Bork, the Danish Medicines Agency, Denmark
- *Inspections of laboratory and analytical data.*
Chris Rothwell, Covance, United Kingdom

Panel discussion and a light reception, farewell at approx. 17:30.

Would you like to participate in the event?

Join us for a great afternoon on top of the Mærsk Tower, with great talks, conversations and networking. We will serve a network reception to complete this network meeting. You are welcome! It is free, but [registration is mandatory at www.biopeople.eu](http://www.biopeople.eu).

For further information, please contact:

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Biopeople events are:

- Your scientific & regulatory brains boost
- Your place for informal exchange of ideas for both academia and industry
- Networking reception expanding your network

When:

19 March 2020
15:00-17:30

Location:

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

Organisers:

