



Mediteq Forum Seminar

MDSAP – Who is it for?

Mediteq Forum is visited by Derek Nagelkerke from BSI Group who will share his and BSI view on MDSAP with us. MDSAP – Medical Device Single Audit Program – has been the talk of the town during a longer time. Right now, it is a bit unclear what impact MDSAP will have on the medical device industry.

The pilot program, that include the countries USA, Brazil, Canada, Japan and Australia, ended more than one year ago. Some companies have already performed revisions according to MDSAP but is it a demand to participate in MDSAP? Will more countries participate in the program? How will the result from these revisions be accepted and handled by the authorities?

Time: 4 October 2018, 13:00 -17:00

Place: ATWORK in Gårda

Sign up: [Here](#)

- 13.00 Introduction and presentation
- 13.20 Background and purpose with MDSAP
- 14.00 How do you do it?
- 14.30 Coffee break
- 15.00 Advantages, disadvantages and experiences
- 16.00 Questions
- 16.30 Summary and evaluation

If you have questions about the subject that you would like to discuss or that you want to have answered at the seminar? Please add them when you sign up for the seminar.

If you wish there is a possibility to start the seminar with a lunch, at own cost, together. Gathering for lunch is 12 o'clock on ATWORK's restaurant Hildas.

Welcome!

Helen Sandelin

Facilitator, **Mediteq Forum**





Presentation of today's guest



Derek Nagelkerke is responsible for the business development in the Netherlands, Belgium and Nordics countries including Iceland for BSI Notified Body.

He holds a Bsc. Science degree and has over 10+ years' experience in project management and business development with several Notified Bodies and certification bodies.

The activities range from being a lead auditor for ISO 9001, key account

management of multi-national companies in Food safety and Healthcare and support the business by setting up new offices. The last 4 years have been with BSI in with a strong focus on business development in the Nordic countries.