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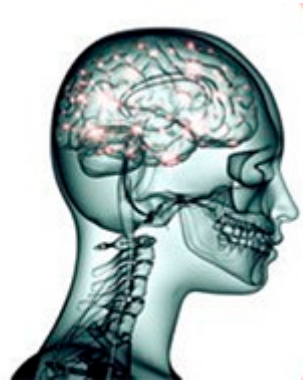


Regulatory review

Your monthly medical device update
December 2022

Featured in this Newsletter

- Clinical Masterclass Series 2023 - register now
- Dr Manuela Gazzard's, Group Director, end of year video
- On demand webinar: Article 54 – Understanding the Clinical Evaluation Consultation Process (CECP) and Expert Panel Roles
- Compliance Navigator client story
- Events for your calendar

Clinical Masterclass Series Webinars 2023

Due to popular demand, our clinical masterclass series of webinars is here again for 2023 with new and

exciting content for you.

These 5 webinars will help you focus on various aspects of the MDR, from preparing a Clinical Evaluation Plan, to supporting you with preparing a Clinical Evaluation Report, as part of an in-depth, 2-part webinar.
Additionally, we'll also provide guidance on preparing a Post Market Clinical Follow Up Plan and Evaluation Report (PMCF) as well as helping you to understand how best to produce a compliant Summary of Safety and Clinical Performance (SSCP) for both healthcare professionals and patients.

These webinars will be presented by Richard Holborow, Head of Clinical Compliance, along with various members of his team.

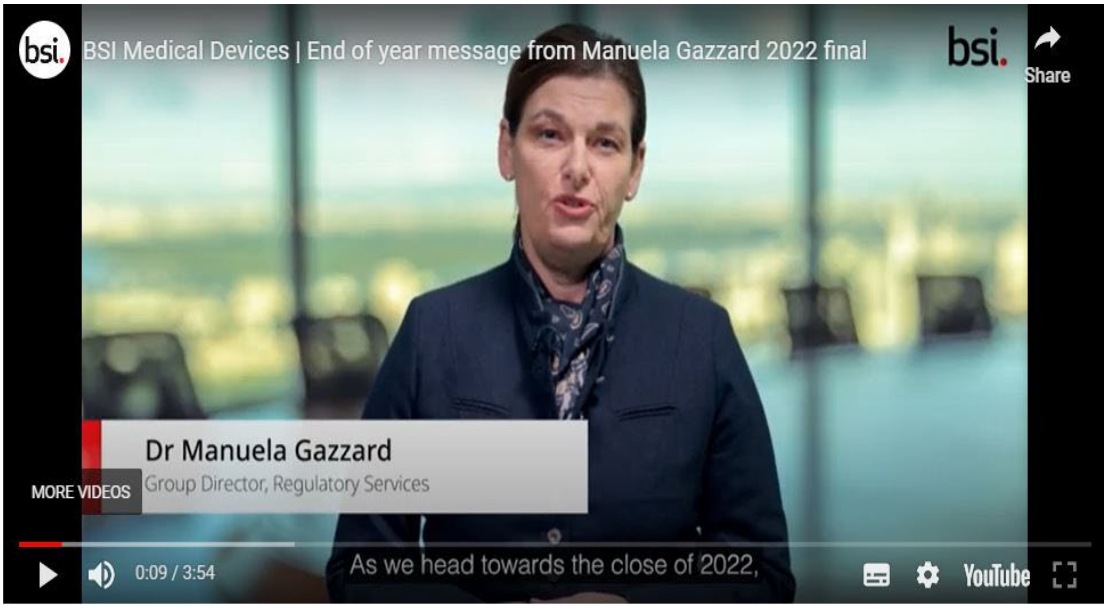
The full list of webinars and dates are below:

- **11 January** **Preparing a Clinical Evaluation Plan**
- **25 January** **Preparing a Clinical Evaluation Report (Part I)**
- **8 February** **Preparing a Clinical Evaluation Report (Part II)**
- **22 February** **Preparing a Post Market Clinical Follow Up Plan & Evaluation Report**
- **8 March** **Preparing a Summary of Safety and Clinical Performance (SCCP) Report**

To find out more and to register for all 5 webinars, click on the button below.

Register for the Clinical Masterclass Series

Dr Manuela Gazzard's, Group Director, end of year message



Watch this end of year video delivered by Dr Manuela Gazzard, Group Director, as she reflects on some of our key achievements of 2022.

As part of her end of year message, Manuela would also like to say; 'a huge and heartfelt thank you to our clients, industry partners and staff for your trust, flexibility, commitment and patience'.

Watch Dr Manuela's end of year message

On Demand Webinar - Article 54 – Understanding the Clinical Evaluation Consultation Process (CECP) and Expert Panel Roles

Listen back to the Article 54 - Understanding the Clinical Evaluation Consultation Process (CECP) and Expert Panel Roles webinar from Wednesday 23 November.

The webinar was run by Richard Holborow, Global Head of Clinical Compliance, and he talked about the MDR requirements in relation to Article 54. Richard was joined by Sheila Walsh, Clinical Regulatory Lead, Clinical Compliance Team

This webinar provided the required information to manufacturers of class III implantable, and class IIb active rule 12 administer or remove medicinal substances (ARMS) devices of the new clinical evaluation consultation procedure (CECP) in accordance with Article 54 of the Medical Device Regulations EU 2017/745.

Listen back to webinar

Have you read our medical devices blog?

The Compliance Navigator medical devices blog covers industry news on regulation, standards and technology. New posts are published bi-weekly and are written by industry experts. What's more, you can read the latest posts on the Compliance Navigator website today.

Read the Compliance Navigator blog

Events for your calendar

Take a look at our calendar of events for 2023.

Don't miss the opportunity to interact with BSI experts or connect with our commercial team to discuss your certification requirements. Find out more about our latest Events and Conferences.

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