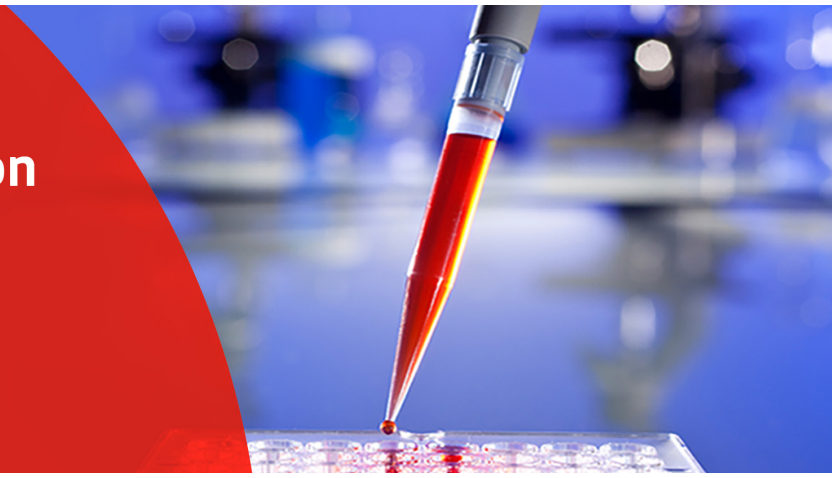
bsi.

...making excellence a habit.™

2019 **EU In Vitro Diagnostic Regulation** Roadshow



22 October 2019
Radisson Blu Hotel - Berlin

The IVD industry is undergoing significant change – Are you prepared?

BSI is proud to announce the upcoming EU In Vitro Diagnostic Regulation (IVDR) Meeting in Berlin, a full day event for the IVD device manufacturer regulatory affairs, quality assurance and related consulting community. Join our experts and guest speakers to learn about some of the most significant changes to the European Regulatory and Compliance Expectations for CE marking.

Topics will include

- IVDR Overview, Classification, Grouping Devices
- Technical Documentation Requirements
- New Requirements for Performance Evaluation
- Post-launch Requirements
- Market Access and Reimbursement*
- Workshop: Using the Remaining Transition Period Effectively
- Interacting with the Notified Body

* Session by Guest Speaker, Kalms Consulting GmbH

Our unique EU IVDR event is exclusively focused on addressing the European IVDR. BSI will be sharing our current view on the new regulation and the expectations from the perspective of the leading global medical device Notified Body, ISO 13485 registrar, MDSAP Auditing Organization and world's first national standards body.

BSI Speaker

Dr. Heike Möhlig Zuttermeister

Technical Specialist & Scheme Manager – IVD EMEA, BSI

Dr. Heike Möhlig Zuttermeister holds a PhD in Molecular Immunology. Prior to joining BSI in 2014, Heike worked for nine years as Head of Research and Development in life science and in-vitro diagnostic companies.

Registration Fee: EUR 175
Registration Page: bsigroup.com/euivdr2019

For more information
Call BSI: +49 69 2222 89 222
Email: charlotte.hess@bsigroup.com
or visit: bsigroup.com/IVDR-Revision