

# Invitation



## Medical Software

### Going beyond theory of market access

Medical software is omnipresent both as part of networked medical devices and as independent medical device. In all sectors of healthcare, numerous complex product types and diverse manifestations of medical software are used. This results in very different regulatory requirements, which must be considered during product development to gain access to international markets.

In our event we provide you exclusive knowledge and networking opportunities in the field. This year our speakers share with you their knowledge on the topics post-market clinical follow-up, risk management, quality management, technical documentation, and cybersecurity in the U.S. healthcare!

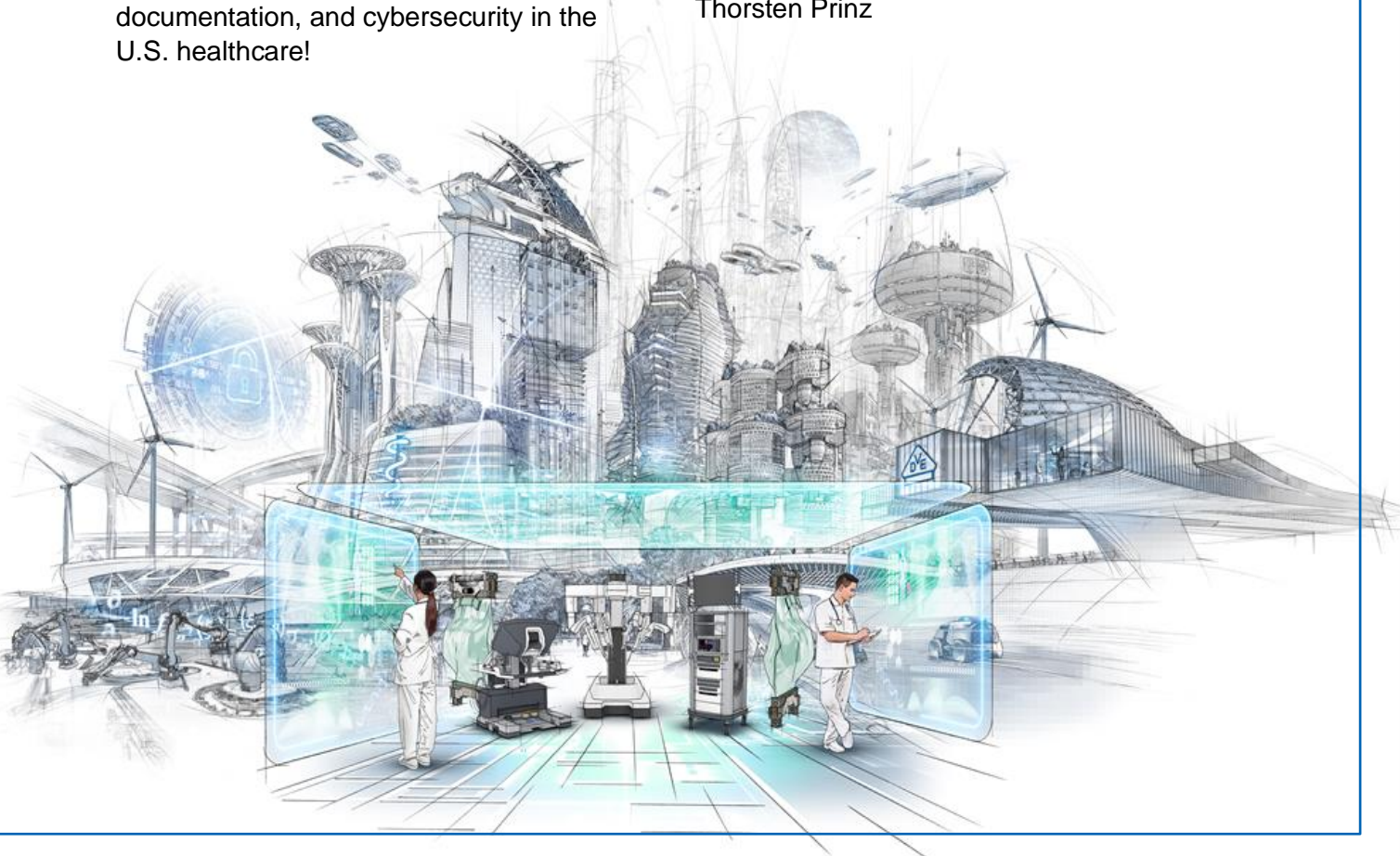
**May 15, 2019**  
**Frankfurt / Main, Germany**

Learn at Medical Software 2019

- which future regulatory requirements you will have to meet,
- how to deal efficiently with them, and
- what the brand-new digital platform VDE Medical Software offers to you!

We would be pleased if you forwarded this invitation to all your colleagues.

See you in Frankfurt,  
Thorsten Prinz



## Program

- 10:00 Welcome and start of event
- Register and get your USB-Stick with the new White Paper
  - Learn more about the new digital platform "VDE Medical Software"
  - Network with other experts while enjoying coffee and snacks
- 11:00 Post-Market Clinical Follow-Up for Medical Software  
Dr. Manuela Schwegler,  
Expert Scientific & Regulatory Affairs,  
i.DRAS GmbH,  
Planegg/Martinsried
- 11:30 Developments in Risk Management: the new ISO 14971  
Hans Wenner,  
Owner,  
Engineering Office Wenner,  
Rüsselsheim
- 12:00 Lunch break at the exhibition
- 13:30 Challenges in Quality Management for Medical Software  
Prof. Dr. Mark Hastenteufel,  
Owner,  
dr-hastenteufel.de,  
Heidelberg
- 14:00 The Technical Documentation as central Element for Market Access  
Isabella Lehner  
Senior Manager Regulatory Affairs,  
Croma Pharma GmbH,  
Vienna (Austria)
- 14:30 Networking break at the exhibition with coffee and snacks
- 15:15 Cybersecurity in U.S. Healthcare  
Axel Wirth  
Distinguished Technical Architect,  
Symantec Corporation,  
Boston (USA)
- 15:45 Panel Discussion  
With VDE Medical Software partners,  
speakers and the audience
- Before and during the event, you can ask questions interactively on the new digital platform.
- 16:30 End of event

The organizer reserves the right to modify the program. Conference languages are German and English. All presentation slides will be in English.

## Organizer

VDE Medical Software  
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## What we do

VDE Medical Software provides an expert platform. Use it to

- Get relevant expertise by reading our Blog, using the Q/A and browsing through the medical software Glossary.
- Connect with international medical software experts in our Community and benefit from the experience of others.
- Receive customized training and guidance from our Partners to implement all regulatory requirements for your project.

## Registration

Please note our special early bird deal: If you register on our new digital platform [VDE Medical Software \(meso.vde.com\)](http://VDEMedicalSoftware.meso.vde.com) and book your ticket until April 15, 2019, admittance is free and no fee will be charged. Registering or booking your ticket later, the regular fee of 290 EUR will apply.

In addition, all participants registered on [meso.vde.com](http://meso.vde.com) will receive an exclusive copy of the new VDE Medical Software Whitepaper on the day of the event! Find further information at: [meso.vde.com/event-2019](http://meso.vde.com/event-2019)

## Venue

The event will take place in the "Haus am Dom", right next to Frankfurt's Kaiserdom, the Römer and the "new" Old Town. The address is Domplatz 3, 60311 Frankfurt am Main. Get yourself oriented here: [tinyurl.com/ycbg2ye3](http://tinyurl.com/ycbg2ye3)