

Meeting MDR / IVDR Challenges Together - How to Successfully Implement IVDR

On February 19th, 2019, Kalms Consulting led the expert forum "How to successfully implement IVDR - case studies and practical questions" as part of the event "Meeting MDR / IVDR challenges together".

The event was conducted under the leadership of the cluster Health Capital Berlin and Brandenburg with the partner Spectaris German Industrial Association for Optical, Medical and Mechatronic Technologies e.V. (Spectaris e.V.) and Network Diagnostics Berlin-Brandenburg (DiagnostikNet-BB e.V.).



As part of the event, the initiated discussion with Lowri Evans and Günther Öttinger was presented as an interchange to the European Commission and the current implications of MDR and the IVDR on manufacturers in Germany was discussed.

Dr. Sinan Akdeniz, representative of Unit 124 - Medical Device Safety, provided in-depth insights into the background work of the responsible working groups in the Federal Ministry of Health.

With the words of welcome from Health Minister Susanna Karawanskij from the Ministry of Labour, Social Affairs, Health, Women and Family of the State of Brandenburg on the funding measure "Klinische Evidenz belegen - Medizintechnik in die Patientenversorgung überführen" of the BMBF was presented by the project sponsor VDI Technologiezentrum GmbH. Subsequently our consultants, Dr. Julia Knorr, Dr. Madeleine Künz and partner Dr. Maren von Fritschen successfully guided 26 participants through a five-hour workshop, where they excitedly discussed relevant challenges, progress, as well as legal innovations and regulatory uncertainties.

The extensive exchange revealed numerous new challenges as well as ambiguities in the dynamic IVDR sector, which are now being used in the hands of the partners for the preparation of a standpoint paper in order to further exchange and discourse with the European representatives.

Kalms Consulting is pleased to assist you and your company with our various expert teams as a strong partner for successful and seamless market access - feel free to contact us.

India Expanding 2019



For nearly two decades, India's advanced medical device market has been steadily growing by two-digit figures. The Indian government has firmly declared "healthcare for all" as one of the most important goals of Indian public policies. We are here to guide you through the process of market entry; with decades of experience that matter, and a network that delivers.

By 2020, India will be the most populated country in the world. Even today, it is the most populous democratic nation; with 1.36 Billion citizens as of 2019. Due to steady economic growth, the number of Indians entering the middle-class has reached around 250 million and continues to grow.

The demand for solutions in healthcare is massive and the market is ready to accept the latest technology, when introduced properly.

However, market entry is rather complex and requires in depth knowledge of both the administrative procedures and how the medical system functions. Unprepared market entry is very likely to fail and will be costly.

We will help you properly place your product / service in the market against existing players, jointly establish a realistic business plan and last, but not the least, introduce you to the network critical for your success. Our expert in India, Peter Laser, has lived and worked in India for more than 20 years, and as such, will guide you through the required steps with considerable ease.

COLLATERAL MARKETING – “Adapting marketing-material to be up to date for new market requirements?”

The medical device market has become more and more complex in the last decades and it is constantly necessary to adapt to these changes and innovations.

Regulations, legal requirements and the competitive business environment make it essential to review and refine marketing activities, like documents for internal or external marketing, marketing material or website-content such as:

- Topics, like formulating and proving claims, proper wording and / or qualified referencing may need to be checked.
- Material content, like flyers and brochures, may need to be updated, modified or adapted.
- Brand positioning may need to be reviewed for consequential differentiation and positioning in today's competitive business environment.

Kalms Consulting GmbH, supported by our partner Erxleben Consulting GmbH, can offer individual support for necessary adjustments and adaption for existing internal and external marketing material, in the areas of our expertise, to help prepare you for the market's future.

Please ask for details and an individual quotation.

US Roadshow: Spring 2019



Marco Kalms, CEO and Dr. Stephan Binder, COO are back home from their successful first roadshow of 2019.

Stephan started in San Francisco and the surrounding Bay Area; where he had amazing discussions with current, new and potential clients and business partners. After some productive days, Stephan headed to Minneapolis to team up with Marco for the second stage of our roadshow.

Stephan started in San Francisco and the surrounding Bay Area; where he had amazing discussions with current, new and potential clients and business partners. After some productive days, Stephan headed to Minneapolis to team up with Marco for the second stage of our roadshow.

In addition to the daily roadshow routine, they had the pleasure of giving an overview on European Healthcare systems and discussing their differences to the US system at the University of Minnesota. They presented this, together with our partner Edward Black (NAMSA), to the students of the Medical Device Innovation Program.

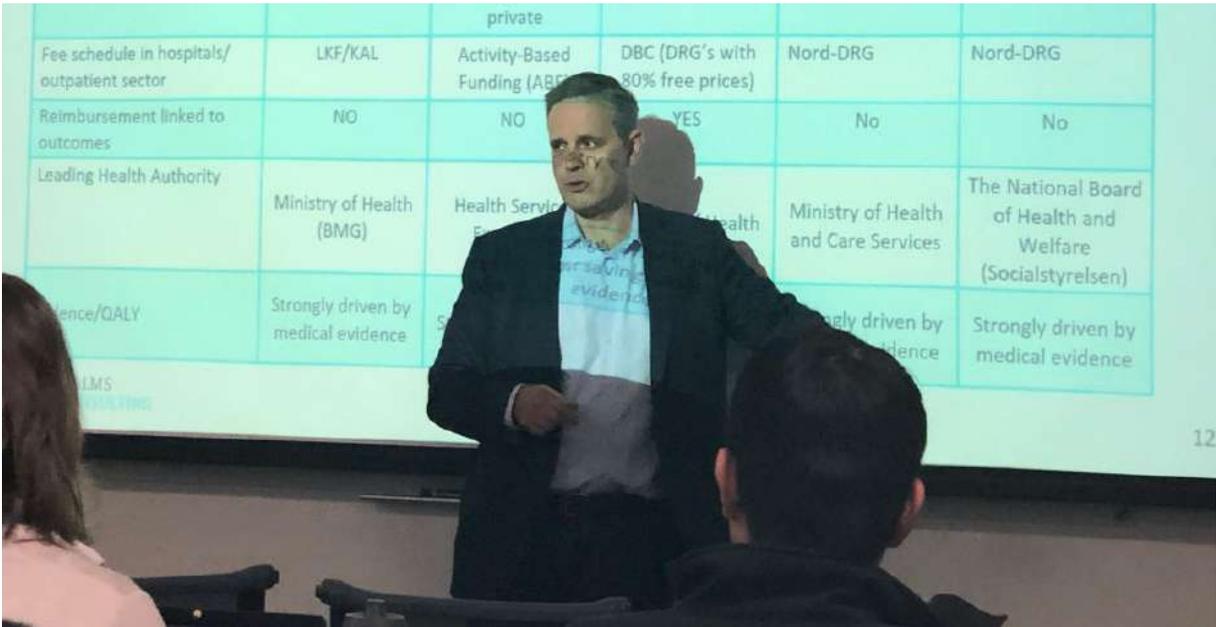
The last stage of our roadshow was the BIOMEDvice in Boston. Within this trade fair, the MassMedic association held its annual conference "Medtech Town Hall", where Stephan had the opportunity to discuss the future of the Biomed, MedTech and Life Science industries with Leaders from different fields in US Health Industry. The conference clearly showed that investors now have a more thorough understanding of reimbursement for the products they are investing in. Without a clear strategy for reimbursement in the world's key healthcare markets, it is significantly more difficult, if not impossible, to receive sufficient funding.

Thus, it is never too early to start talking about reimbursement opportunities. Make sure you are prepared for the next step in your company's growth.

Other topic of great interest in almost all of our discussions, were the services Kalms Operations is offering for warehousing, logistics and customer service. Due to Brexit, there is a strong and fast-growing demand for such services in continental Europe, and we are happy to support our clients with solutions specifically designed for small and fast-growing enterprises.

Finally, the field of in vitro diagnostics (IVD) is quickly growing, and the upcoming regulations (IVDR) raise concerns amongst almost all the companies active in this field that we spoke with. With a deep understanding of IVD and the regulatory environment, we are prepared to support our clients with all IVD inquiries.

If you would like to receive more information on the topics mentioned above or discuss your opportunities in the German or US marketplaces, please feel free to contact us.



Thank you to all of our friends and partners who made this roadshow a pleasant and successful experience. We are looking forward to seeing you again soon.
(Marco Kalms presenting at the University of Minnesota)

Arab Health 2019



For the second time, Kalms Consulting was present at the Arab Health in Dubai, where more than 84,500 participants from over 160 countries clearly showed the importance of emerging and established markets in the Middle East and Asia Pacific regions.

There, Kalms Consulting's COO Stephan Binder met with key industry players, manufacturers and distributors in the med-tech and life science markets.

In working with our consulting partners and other service providers, we were able to further extend our networks with the goal of providing solutions for our clients' success everywhere.

We were very pleased about the lively interest in our services and would like to thank all new contacts and partners for the new connections.

We are already looking forward to seeing you again next year!

Introducing Dr. rer. nat. Julia Knorr

Dr. Julia Knorr focuses on market access and reimbursement projects in bioscience and innovative interdisciplinary medicine.

She has worked for several years as a Project Manager in the pharmaceutical industry and has profound experience in the study lead of post-marketing studies from the early set-up phase to study start within Europe.

She has additional expertise in the study set-up in bioscience and pharmaceutical development including regulatory duties as well as in the study management of Investigator Initiated Trials throughout Europe and North America.

Julia has a degree in Biochemistry and holds a PhD in Drug Discovery and Biophysics. Besides her mother tongue German she speaks English and Spanish fluently and has considerable knowledge of French.



Dr. rer. nat. Julia Knorr

„I look forward to working on the success of pioneering technologies. Together, we can see the challenges of the market as opportunities and work on a successful path to the future.“

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