

**Insights from
Johannes Bacher
former Managing Director
and Chief Operating Officer**



Edition Focus: IVD R&D and Regulations

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By Lydia van der Meulen, Client Partner, Global Head of Life Sciences & Healthcare Practice Group, and Michael Ade, Client Partner:

Pedersen & Partners conducts regular interactive sessions for its global team, bringing in senior executives from the Life Sciences & Healthcare ecosystem to update all team members on developments that impact the global industry.

In our ongoing Market Pulse symposium series, we invite industry leaders to share insights on current market trends. We are committed to enhancing our knowledge of the industries with which we work, positioning us optimally to serve our global clients in 50 countries, spanning all domains of Life Sciences innovation.

During the October Market Pulse symposium, we had the privilege of hearing from Johannes Bacher, who shared insights into past and current challenges of In-Vitro Diagnostics (IVD) companies with a special focus on product development in the light of ever-increasing regulatory approval requirements.

As an electrical engineer with a longstanding medical device and IVD career, Johannes Bacher is a distinguished authority in the field. Following prior placements at Hewlett Packard, Agilent Technologies and Philips Medical Systems, he was one of the co-founders of German based Curetis in 2007, where he was instrumental in growing the start-up to a publicly listed company developing,

manufacturing and selling rapid infectious disease diagnostics in more than 40 countries worldwide. Johannes recently left Curetis, where he had been serving as Managing Director and Chief Operating Officer, responsible for global R&D and operations.

During his talk, Johannes painted a vivid picture of the IVD industry, and discussed broader trends and changes in regulatory pathways worldwide. As well as assessing the EU's In-Vitro Diagnostic Regulation EU 2017/746 and its latest applicable timelines, he gave the Pedersen & Partners team a valuable overview of the diverse regulatory pathways applicable for IVD products in the USA, ASEAN, China and several LMICs. The complex range of different regulatory routes and approval pathways is an increasing burden in terms of development cost and timelines.

Back in 2018, Johannes and his team were responsible for the first ever FDA De Novo request granted for an automated high-multiplex rapid PCR test after a multi-year clinical trial and FDA submission process. In the symposium, he explained that regulatory requirements must be integrated early and throughout the whole development process, highlighting the increasing importance of clinical trials for successful regulatory approval submissions.

Johannes Bacher concluded his presentation with a summary of his personal "lessons learned" during the last two decades, and his best practice recommendations based on the latest regulatory and industry trends.