Preconference Workshop
2021 PDA Combination Products and the Regulatory Framework Workshop,
A Hands-on Journey to MDR Article 117 – A License (not) to Kill your Products Market Access
4 October 2021, ONLINE

Monday, 4 October 2021		**12:00 – 17:00 CEST**
12:00	Welcome & Introduction	Egmont Semmler, *TÜV Süd*
Session 1 Overview and Introductory Talks		
12:10	Overview: Current Status of Devices and their Regulatory Framework	Michael Karl Ledinegg, *Sandoz Novartis*
12:30	Notified Body Opinions - Lessons Learned and How to Satisfy the Notified Body to Avoid Delay in Time-To-Market	Mike Wallenstein, *Novartis*
12:50	Overcoming the Regulatory Pitfalls – Expectations and Future Outlook from a Notified Body Perspective	Christiana Hofmann, *TÜV Süd* Egmont Semmler, *TÜV Süd*
13:10	Usability, the Impact of Human Touch and Risk Management for Combination Products	Stephanie Göbel, *Beyond Conception*
13:30	Q&A for Immediate Questions	
13:45	**Break**	
Session 2 Interactive Working Groups		
After parting in 2 groups, the participants will enter a moderated discussion on administrative and content related questions. Facilitated by a table moderator each group is introduced to the topic and will have a set amount of time to discuss and gather key points on each topic. The results will be documented for further discussion and groups will switch midway through the session, so everyone will address all questions. A concrete take-home-message will be shared after the event with all attendees.		
14:00	**Introduction to the Working Group Format**	Michael Karl Ledinegg, Sandoz Novartis

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14:05	Addressing Regulatory Challenges – The Notified Body Opinion • Which GSPR are applicable for your device part - how do you decide and when? • What is needed to provide sufficient evidence? Are summary reports acceptable? • Labeling considerations: What is required and what is not allowed? **Moderators**: Michael Karl Ledinegg, *Sandoz Novartis* Mike Wallenstein, *Novartis* Jonathan Sutch, *BSI*	Addressing Content Related Challenges – Usability and Risk management • Which difference exists between patient/user/other persons – is there any at all? • Do I have to consider post-market information within the risk management activities: yes, no, maybe and why? • Do I have to consider the disposal after use within usability testing: yes, no, maybe and why? **Moderators**: Stephanie Göbel, *Beyond Conception* Egmont Semmler, *TÜV Süd* Ninette Genster, *Novo Nordisk*
14:35	Groups will switch after 30 min	Groups will switch after 30 min
15:10	**Break**	
Session 3 Open Group Discussion		
15:40	Summary of the Working Groups by the Table Moderators	Michael Karl Ledinegg, *Sandoz Novartis*

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		Mike Wallenstein, *Novartis* Stephanie Göbel, *Beyond Conception* Egmont Semmler, *TÜV Süd* Jonathan Sutch, *BSI* Ninette Genster, *Novo Nordisk*
16:00	Final Group Discussion • Addressing questions raised in the working groups • Discuss different stakeholders' perspectives • A checklist will be compiled based on conclusive results from the group work and discussions	Michael Karl Ledinegg, *Sandoz Novartis* Mike Wallenstein, *Novartis* Stephanie Göbel, *Beyond Conception* Egmont Semmler, *TÜV Süd* Christiana Hofmann, *TÜV Süd* Ninette Genster, *Novo Nordisk*
16:55	Farewell	Egmont Semmler, *TÜV Süd*
17:00	**End of Workshop**	