



27 November 2020  
EMA/128303/2020  
Task Force Digital Business Transformation

## Agenda – Webinar to support implementation of Article 117 of the MDR on drug-device combinations

27 November 2020, 13:00-17:00 CET, virtual meeting

Item	Agenda	Time
1.	<b>Welcome / Introductions</b> Opening remarks and objectives of the meeting <i>Zaide Frias, EMA</i>	13:00-13:05 5 min
2.	<b>Overview of the agenda</b> <i>Armin Ritzhaupt, EMA</i>	13:05-13:10 5 min
3.	<b>Lessons learned from Notified body opinion process</b> <ul style="list-style-type: none"><li>The Notified Body Opinion - Industry Experience <i>Bjorg Hunter, EFPIA (NovoNordisk)</i></li><li>Team-NB Feedback on NBOps to date <i>Jonathan Sutch, BSI and Julia Frese, TÜV SÜD Japan</i></li><li>The Notified Body Opinion – Regulatory Assessor View <i>Maeve Lally, HPRA</i></li></ul>	13:10-14:00 50 min
	<b>Panel discussion</b> All speakers plus representatives from EC, medical device authorities and industry <i>Session Chairs: Armin Ritzhaupt (EMA), Mike Wallenstein, Medtech &amp; Pharma Platform (Novartis)</i>	14:00-14:50 50 min
	<b>Coffee break</b>	<b>14:50-15:00</b> <b>10 min</b>



4.	<p><b>Lifecycle Management: Considering 'Substantial Design Changes'</b></p> <ul style="list-style-type: none"> <li>Lifecycle Management: 'Substantial and Non-Substantial Changes' for Drug-Device Combinations <i>Amanda Matthews, EFPIA (Pfizer)</i></li> <li>TEAM-NB Perspective on Life Cycle Management under Article 117 / MDR <i>Petra van Leeuwen, DEKRA Certification BV and Colm O'Rourke NSAI</i></li> <li>EMA considerations on lifecycle management in the context of Article 117 <i>Pascal Venneugues, EMA</i></li> </ul>	15:00-15:50
	<p><b>Panel discussion</b></p> <p>All speakers plus representatives from EC, medical device authorities and industry</p> <p><i>Session Chairs: Ilona Reischl, AGES, Tim Chesworth, Vaccines Europe (AstraZeneca)</i></p>	15:50-16:45 55 min
5.	<p><b>Concluding remarks and next steps</b></p> <p>Quality of Drug-Device Combination Products - Current status <i>Nick Lee / Maeve Lally, Rapporteur / DG member, BWP (HPRA)</i></p> <p>Close of meeting <i>Armin Ritzhaupt, EMA</i></p>	16:45-17:00 15 min
	<b>Close of Webinar 17:00</b>	