

Drug-Device Combination Products: Updates and Challenges with Demonstrating Generic Substitutability

Symposium I: Understanding the Landscape and Challenges for Development of Generic Drug-Device Combination Products

<i>Introductions:</i>	Karthika Natarajan, PhD	Staff Fellow, DTP I, ORS, OGD, FDA
<i>Presenters:</i>	Lisa Bercu, JD	Senior Regulatory Counsel, DPD, OGD, OGD, FDA
	Johannes Keuschnigg, PhD	Regulatory Devices Portfolio Head, Sandoz
	Tim Briggs, MSc	Senior Principal Human Factors Engineer, Global Device Development, Viatris
<i>Facilitator:</i>	Sarah Ibrahim, PhD	Associate Director for Stakeholder and Global Engagement, OGD, FDA
	Patient Speakers	
<i>Moderator:</i>	Karthika Natarajan, PhD	Staff Fellow, , Device Evaluation Team (Team D), DTP I, ORS, OGD, FDA
<i>Panelists:</i>	Lisa Bercu, JD	Senior Regulatory Counsel, DPD, OGD, OGD, FDA
	Tim Briggs, MSc	Senior Principal Human Factors Engineer, Global Device Development, Viatris
	CDR. Andrew Fine, PharmD, BCPS	Senior Advisor, DCR, OSCE, OGD, FDA
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	Patient Speakers	