COMBINATION PRODUCTS SUMMIT

FT. WORTH, TX • NOVEMBER 28–30, 2023

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Use Of Emerging Digital Health Technologies For Combination Products

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE

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Use Of Emerging Digital Health Technologies For Combination Products

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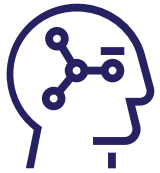
Session Overview:

1. Setting the Stage (Ryan Hoshi)
2. FDA Digital Health Center of Excellence (MiRa Jacobs)
3. FDA's Digital Health Technology Framework (Kristina Lauritsen)
4. Panel Discussion and Q&A

Digital Health Regulatory Landscape

Digital Health Technologies

- FDA Framework for the Use of DHTs in Drug and Biological Product Development
- Draft Guidance: Decentralized Clinical Trials for Drugs, Biological Products, and Device
- Draft Guidance: Digital Health Technologies for Remote Acquisition in Clinical Investigations



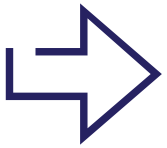
Artificial Intelligence & Machine Learning

- FDA Discussion Paper: Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products
- Draft Guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions

Software

- Guidance: Clinical Decision Support Software Guidance Document
- Guidance: Content of Premarket Submissions for Device Software Functions
- Draft Guidance: Regulatory Considerations for Prescription Drug Use-Related Software

Opportunities & Challenges



- Streamlined combination product development.

- Integration of patient support tools: Continuous monitoring, dose accuracy, medication reminders, enhanced safety.

- Assessment of novel endpoints collected using a DHT.

- Mechanisms for FDA Feedback

- Regulatory Classification

- Appropriate regulatory pathway