

**FDA Public Meeting
Enhanced Drug Distribution Security Under the Drug Supply Chain Security Act (DSCSA)
December 5-6, 2017**

**Agenda
Day 1: December 5, 2017**

Time	Activity	Speaker/Moderator
8:00 – 9:00 am	Registration	
9:00 – 9:10 am	Welcome and Opening Remarks	Donald Ashley FDA/Center for Drug Evaluation and Research (CDER)
9:10 – 9:20 am	Goals of the Meeting	Ilisa Bernstein FDA/CDER
	Meeting Logistics	Connie Jung FDA/CDER
9:20 – 10:15 am	Standards for Data Exchange	Connie Jung FDA/CDER
	OPEN-Serialization Communication Standard – Overview	Dirk Rodgers OPEN-Serialization Communication Standard (SCS)
	Enhanced Drug Distribution Security under the DSCSA – EPCIS	Peter Sturtevant (Invited) GS1 US
10:15 – 10:30 am	Break	
10:30 – 12:00 pm	Standards for Data Exchange (continued) <ul style="list-style-type: none"> • <i>Breakout Sessions</i> • <i>Large Group Discussion</i> 	
12:00 – 1:00 pm	Lunch	
1:00 – 2:30 pm	Data Architecture	Dan Bellingham FDA/CDER
	Enhanced Drug Distribution Security under the DSCSA – GDSN	Peter Sturtevant (Invited) GS1 US
	HDA Verification Router Service – Overview	Perry Fri Healthcare Distribution Alliance (HDA)
	NCPDP DSCSA Efforts	Michele Davidson National Council for Prescription Drug Programs (NCPDP)

Understanding Blockchain and
DSCSA

Robert Celeste
Center for Supply Chain Studies

- *Breakout Sessions*

2:30 – 2:45 pm

Break

2:45 – 3:45 pm

Data Architecture (continued)

- *Large Group Discussion*

3:45 – 4:00 pm

Closing Remarks

FDA/CDER

4:00 pm

Adjourn

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**Agenda
Day 2: December 6, 2017**

Time	Activity	Speaker/Moderator
8:00 – 9:00 am	Registration	
9:00 – 9:15 am	Opening Remarks	Ilisa Bernstein FDA/CDER
9:15 – 9:45 am	A Safer Europe Without Falsified Medicines	Lorenzo Terzi Delegation of the European Union to the United States of America
9:45 – 10:15 am	Aggregation and Inference	Abha Kundi FDA/CDER
	Aggregation: Principles, Challenges and Solutions	Adriano Fusco OPEN-SCS
	Inference – Overview	FDA/CDER
10:15 – 10:30 am	Break	
10:30 – 12:00 pm	Aggregation and Inference (continued)	
	<ul style="list-style-type: none"> • <i>Supply Chain Sector Breakout Sessions</i> • <i>Large Group Discussion</i> 	
12:00 – 1:00 pm	Lunch	
1:00 – 2:30 pm	2023 Scenario Exercises	Eleni Anagnostiadis FDA/CDER
	<ul style="list-style-type: none"> • <i>Breakout Sessions</i> • <i>Large Group Discussion</i> 	
2:30 – 2:45 pm	Break	
2:45 – 3:45 pm	Large Group Discussion (continued)	
3:45 – 4:00 pm	Closing Remarks	Ilisa Bernstein FDA/CDER
4:00 pm	Adjourn	