U.S. FOOD & DRUG ADMINISTRATION

FDA-ASH Regulatory Science Workshop

Day 1 – September 29, 2026

9:00 am	**FDA-ASH Regulatory Science Workshop Welcome**
9:20 am	**Introduction**
9:30 am 9:45 am	**Investigational New Drug Application (INDs) & Early-Stage Clinical Trials** **Panel Discussion**
10:30 am	**BREAK**
10:45 am	**Expedited Programs, Marketing Applications and Regulatory Considerations**
11:00 am 11:20 am	**Considerations in Late-Stage Trials: Design and Endpoints** **Panel Discussion**
12:15 pm	**Lunch: Disease Interest Group Tables**
1:15 pm	**Case Study: Regulatory Topic #1** Breakout Groups
2:30 pm	**CAR-T and Cellular Therapy Considerations**
2:45 pm	**BREAK**
3:00 pm	**Case Study: Regulatory Topic #2** Breakout Groups
4:15-4:30 pm	**Closing Comments and Adjourn**

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Day 2 – September 30, 2026

9:00 am	**Summary of Day 1**
9:10 am	**Case Study: Regulatory Topic #3** Breakout Groups
10:30 am	**BREAK**
10:40 am	**Case Study: Regulatory Topic #4** Breakout Groups
12:00 pm	**Lunch** **Shaping the Future of Therapeutics in Hematology: A Fireside Chat with FDA Leadership**
1:15 pm	**Expanded Access Programs and Project Facilitate**
1:30 pm	**ASH Initiatives and Workshop Housekeeping**
2:00 pm	**BREAK**
2:15 pm	**Finding the Balance in Drug Development** **Panel Discussion**
2:45 pm	**Workshop Closing**
3:00 pm	**Adjourn**