

## Event Agenda

Risk-Based Approach to Airflow Visualization Training Course (PDA 802)

DAY 1	
8:30	Welcome, Introductions, and Objectives
9:00	Purpose, Fundamentals, and Regulatory Considerations for Airflow Visualization Studies
10:15	Break
10:30	Introduction to Lifecycle Approach and QRM Basics
12:00	Lunch
13:00	Prerequisites, Materials and Equipment, Velocity/Leak Testing (Lecture/Activity)
14:30	Break
14:45	Airflow Visualization Basics – Conventional Filler (Activity)
16:00	End of Day 1
DAY 2	
8:30	Day 1 Recap/Questions
8:45	Airflow Visualization in Barrier Systems (Activity)
10:15	Break
10:30	Airflow Visualization QRM Initiation – Case Study Introduced/Process Description/Interventions Defined
12:00	Lunch
13:00	Airflow Visualization QRM Finalization – Aseptic Manipulations Scored Using Methodology, Overall Risk Levels Determined
14:30	Break
14:45	Airflow Visualizations (Activity)
16:00	End of Day 2



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DAY 3	
8:30	Day 2 Recap/Questions
845	Airflow Visualizations (cont.) (Activity)
10:15	Break
10:30	Airflow Visualization Study Documentation
12:00	Lunch
13:00	QRM – AREM Strategy Development to Address Unacceptable Risks and Path Forward
14:30	Break
14:45	AVS/QRM Risk Review Process Overview/Lifecycle and Implementing Change
16:00	End of Event