



# Training Course Agenda

PDA 802.1 Risk-Based Approach to Airflow Visualization

## 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 Training Course**