

2020 PDA Cell Therapy Control Strategy Workshop

June 23, 2020 | Washington Marriott Wardman Park | Washington, DC

TUESDAY, JUNE 23

7:15 a.m. - 4:45 p.m. | Registration Open

7:15 a.m. – 8:15 a.m. | Continental Breakfast

8:15 a.m. - 8:30 a.m. | Welcome and Opening Remarks from Workshop Chair

8:30 a.m. – 10:00 a.m. | Laying the Control Strategy Foundation

Interactive Discussion on Lifecycle, Target Product Profile (TPP), and Quality Target Product Profile (QTPP)

10:00 a.m. – 10:30 a.m. | Refreshment Break

10:30 a.m. – 11:00 a.m. | Defining Critical Quality Attributes (CQA)

11:00 a.m. – 11:30 a.m. | Control Strategy Development Hands-On Exercise 1

11:30 a.m. – 12:00 p.m. | Control Strategy Development Exercise 1: Report Out

12:00 p.m. – 1:00 p.m. | Lunch

1:00 p.m. – 2:00 p.m. | Developing the Control Strategy

Interactive Discussion on Critical Product Parameters (CPP), Critical Material Attributes (CMA), and Associated Risk Assessments

2:00 p.m. – 2:45 p.m. | Control Strategy Development Hands-On Exercise 2

2:45 p.m. – 3:15 p.m. | Refreshment Break

3:15 p.m. – 3:45 p.m. | Control Strategy Development Exercise 2: Report Out

3:45 p.m. – 4:45 p.m. | Workshop Close out and Final Thoughts