

AGENDA

CBER Sentinel Program

February 12, 2018 | 1:00 p.m. – 5:00 p.m. | Industry Day

U.S Food and Drug Administration
White Oak Campus, Building 31, Great Room A

Biologics Effectiveness and Safety (BEST) Initiative Industry Day

Check-in begins at 12 pm

Time	Agenda Item	Presenter
1:00 p.m.	Welcome and Review of Logistics	Joyce Obidi , CBER Sentinel Central Team, OBE (<i>Facilitator</i>)
1:05 p.m.	Opening Remarks <ul style="list-style-type: none">❖ Overview of RFI and Industry Day❖ Overview of CBER Sentinel	Nick Sartain , Contract Specialist, OAGS Steve Anderson , Director, OBE
1:30 p.m.	Scientific Presentations <ul style="list-style-type: none">❖ Data, Tools and Infrastructure for Surveillance of Biologics❖ Innovative Methods for Automated Reporting for Biologics	Azadeh Shoaibi , CBER Sentinel Lead, OBE Alan Williams , Associate Director, OBE
2:30 p.m.	Break	
2:45 p.m.	BEST Sources Sought Submission Requirements	Nick Sartain , Contract Specialist, OAGS
2:55 p.m.	Questions and Answers Panel <ul style="list-style-type: none">❖ Review of Questions Submitted in Advance <p><i>Panel Members: Steve Anderson, Azadeh Shoaibi, Alan Williams, Michael Fischer, Nick Sartain</i></p>	Richard Forshee , Associate Director, OBE (<i>Moderator</i>)
3:30 p.m.	Open Questions and Answers Session <p><i>Questions from the audience (in person and online) will be answered by panel members.</i></p> <p><i>Panel Members: Steve Anderson, Michael Fischer, Richard Forshee, Nick Sartain, Azadeh Shoaibi, Alan Williams</i></p>	Joyce Obidi , CBER Sentinel Central Team, OBE (<i>Moderator</i>)
5:00 p.m.	Adjournment	