

Thursday, 27 February 2020 9:00 – 17:30

09:00	Welcome and Introduction
09:15	Regulatory Requirements <ul style="list-style-type: none"> • USP<1207> • EU Annex 1 • ICH Q9
09:45	Technology Overview <ul style="list-style-type: none"> • Differential pressure • High voltage • Headspace analysis
10:30	Coffee Break
10:45	Test Method Selection <ul style="list-style-type: none"> • Understanding and application of relevant criteria • Adapted feasibility approach
11:15	QC Lab or 100% Inspection <ul style="list-style-type: none"> • Differences in scale-up • Risk assessment • 2 views: technological (capabilities), external or internal requirement
11:45	Positive Controls <ul style="list-style-type: none"> • Types • Preparation • Pros and Cons • Verification with He Mass spec.
12:15	Lunch Break
13:15	Method Development <ul style="list-style-type: none"> • Feasibility • Fixture qualification • Method qualification • Test method validation
13:45	Lab Session 1 (Hands-on) <ul style="list-style-type: none"> • Operation of lab equipment • Daily business considerations • Considerations on installation site • Method development
14:45	Coffee Break
15:00	In-line Operation Session 1 (Hands-on) <ul style="list-style-type: none"> • Operation of inline equipment • Daily business considerations • Considerations on installation site • Method development
16:00	Facility Tour
17:00	Wrap-up Day 1

Friday, 28 February 2020 8:30 – 15:30

08:30	Recap Day 1 & Open Questions
08:45	Lab Session 2 (Hands-on) <ul style="list-style-type: none"> • Operation of lab equipment • Daily business considerations • Considerations on installation site • Method development
09:45	Coffee Break
10:00	In-line Operation Session 2 (Hands-on) <ul style="list-style-type: none"> • Operation of inline equipment • Daily business considerations • Considerations on installation site • Method development
11:00	Interactive Workshop on Best Practices <ul style="list-style-type: none"> • Feasibility trials • Implementation • Day to day use • Maintenance • Change Control
12:00	Lunch Break
13:00	Lab Session 2 (Hands-on) <ul style="list-style-type: none"> • Operation of lab equipment • Daily business considerations • Considerations on installation site • Method development
14:00	In-line Operation Session 2 (Hands-on) <ul style="list-style-type: none"> • Operation of inline equipment • Daily business considerations • Considerations on installation site • Method development
15:00	Wrap-up
15:30	End of Course