

Venue: groninger & co. gmbH
 Sulzbrunnenstraße 1,
 74564 Crailsheim, Germany

Training Course Agenda

PDA EU00192 Manage Your Aseptic Filling Line

Day 1, 04 September 2024		
9:00	Welcome and Introduction <ul style="list-style-type: none"> • Introduction of all trainers • Brief introduction round of all students (name, company, expectation) • Presentation of the Agenda for the two training days • Collection of expectations • Security briefing for entrance to assembly halls 	
9:15	Lecture 1: Annex 1 Requirements on Aseptic Processing <ul style="list-style-type: none"> • Annex 1 and requirements for aseptic filling • Filling Line Set Up • What types of Barriers are available and what are their limitation? • Surface Decontamination • Gloves • Material Transfer overview in the Barrier System and Filling Line • Cleaning requirements and cross-contamination prevention 	Richard Denk, SKAN
10:15	Lecture 2: First Air <ul style="list-style-type: none"> • Explanation of first air • Where is first air important to consider • Examples of first air design • How to prevent to interrupt first air. 	Richard Denk, SKAN
10:35	<i>Coffee Break</i>	
11:00	Lecture 3: General Filling Line Design <ul style="list-style-type: none"> • General differentiation of primary packaging containers and corresponding filling line technology support by visual materials • Description of different filling technologies with a focus on single use systems vs. conventional filling systems incl. a pro and con overview • Explanation and distinguishing of indirect product contact parts based on visual materials. • General reference to current regulatory guidance documents 	Julian Petersen, groninger
12:00	<i>Lunch Break</i>	

<p>13:00</p>	<p>Exercise 2: Set-Up of the Indirect Product Contact Parts</p> <ul style="list-style-type: none"> • Short filling line walk through to identify points of interest from the theoretical training session incl. a short machine run to understand the process. • Hands on explanation and differentiation of the function of the indirect product contact parts • Understand hands on the different wrappings of the indirect parts incl. the sequence of unwrapping. • Installation of indirect parts as open-door intervention for bigger parts and closed-door interventions for smaller parts using barrier glove system • Perform sequenced unwrapping with barrier glove system. • Experience first air requirements 	<p>Julian Petersen, <i> Groninger</i> Bram Van Puymbroeck, <i> STERIS</i> Bianca Bohrer, <i> PSM</i></p>
<p>15:00</p>	<p><i>Coffee Break</i></p>	
<p>15:30</p>	<p>Exercise 1: Set-Up of the Filling Path (PP & RPP)</p> <p><i>Attendees will be separated into two groups, with no switching between Single-Use and RPP planned.</i></p> <ul style="list-style-type: none"> • Hands on explanation of the filling system peristaltic pump and rotary piston pump. • Hands on explanation of a SUS filling kit from needle to surge bag. • Installation of the filling path with closed doors and barrier glove system 	<p>Julian Petersen, <i> Groninger</i> Roland Schmelzle, <i> Groninger</i> Bianca Bohrer, <i> PSM</i></p>
<p>17:00</p>	<p><i>Q&A and Questionnaire</i></p>	
<p>17:40</p>	<p><i>End of Day 1 & Networking Event</i></p>	
<p>18:30</p>	<p>Meeting Point for Networking Event: in front of the Meisner Design Hotel</p>	
<p>Day 2, 05 September 2024</p>		
<p>8:30</p>	<p>Lecture 4: Environmental Monitoring Risk Analysis</p> <ul style="list-style-type: none"> • Presentation of the environmental risk analysis (EMRA) from the training machine • Understanding of the principles and execution of an EMRA for passive/active viable and total particle • Understand the principles of requirements to surface sampling and swapping incl. reference to respective surfaces. • References to current regulatory guidance documents • Execution of an own high-level EMRA 	<p>Robert Kibele, <i> Groninger</i></p>

<p>09:30</p>	<p>Exercise 3: Filling Line Set-up Monitoring Handling</p> <ul style="list-style-type: none"> • Handling of settle plates and active viable monitoring incl. opening of wrapping, positioning, opening, and closing as well as discharging it from the barrier. • Handling of contact plates incl. application on parts of the filling line. Closing of contact plates and discharging it from the barrier. • Handling of swabs incl. application on parts of the filling line. Closing of the swab tube and discharge from the barrier. 	<p>Julian Petersen, <i> Groninger</i> Robert Kibele, <i> Groninger</i> Bianca Bohrer, <i> PSM</i></p>
<p>10:10 <i>Coffee Break</i></p>		
<p>10:40</p>	<p>Exercise 3 (cont.): Filling Line Set-up Monitoring Handling</p> <ul style="list-style-type: none"> • Handling of settle plates and active viable monitoring incl. opening of wrapping, positioning, opening, and closing as well as discharging it from the barrier. • Handling of contact plates incl. application on parts of the filling line. Closing of contact plates and discharging it from the barrier. • Handling of swabs incl. application on parts of the filling line. Closing of the swab tube and discharge from the barrier. 	<p>Julian Petersen, <i> Groninger</i> Robert Kibele, <i> Groninger</i> Bianca Bohrer, <i> PSM</i></p>
<p>11:20</p>	<p>Lecture 5: Sterile Filtration</p> <ul style="list-style-type: none"> • Regulatory requirements for sterile filtration: Annex 1 is the baseline • Filter validation to ensure bacterial retention, to evaluate adsorption and leachables, to ensure compatibility • Filter integrity test: PUPSIT or risk assessment, bubble point or diffusion? • Filtration process considerations: is redundant filtration a must? • Keep it closed: the filter as part of a closed single-use system 	<p>Simone Biel & Marco Klatter, <i> Merck</i></p>
<p>12:30 <i>Lunch Break</i></p>		
<p>13:30</p>	<p>Exercise 4: Set-Up of Sterile Filtration <i>The group will be split in 2 groups</i></p> <ul style="list-style-type: none"> • Best design practice: build your filtration set • Handling of sterile connection device to connect to the filling operation • Handling of filtration process: wetting, flushing, filter integrity testing 	<p>Marco Klatter & Simone Biel, <i> Merck</i></p>

15:00	<i>Coffee Break</i>
15:30	Wrap up of the training course <ul style="list-style-type: none">• Questionnaire of the two training days and joined walk through of the answers.• Benchmarking of the expectations from day one• Completing of evaluation / feedback sheet• Hand out of certificates
16:20	<i>End of Training Course</i>