

Tuesday, 2 June

CEST Daylight Time (UTC +2:00)

09:00 – 09:30	Welcome and Collection of Participants' Expectations
09:30 – 10:15	Contamination Control Strategy as the Basics for Aseptic Processing <ul style="list-style-type: none">• Introduction and basics of the CCS• Regulatory requirements and expectations• Maintaining an effective CCS Tarik Cheema PhD , Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i>
10:15 – 11:00	Fundamentals of Microbiology and Aseptic Processing <ul style="list-style-type: none">• Background on key concepts of microbiology• Regulatory requirements and expectations• Overview of environmental monitoring programs (air, surfaces, personnel) Tarik Cheema PhD , Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i>
11:00 – 11:30	Coffee Break
11:30 – 12:30	Fundamentals of Cleaning and Disinfection <ul style="list-style-type: none">• Key elements for cleaning & disinfection in cleanrooms• Regulatory requirements and expectations• Hazard scenarios in cleaning and disinfections• <i>Practical Part: Disinfection with UV & GMP-conforming cleaning</i> Hussein Bachir PhD , Senior Scientist - GMP Compliance, <i>Franz Ziel GmbH</i>
12:30 – 13:30	Lunch Break
13:30 – 14:15	Glove Disinfection and Disinfection Agents Hussein Bachir PhD , Senior Scientist - GMP Compliance, <i>Franz Ziel GmbH</i>
14:15 – 14:45	Coffee Break
14:45 – 15:15	Considerations & Pitfalls in <ul style="list-style-type: none">• Cleaning and Disinfection• Environmental Monitoring Tarik Cheema PhD , Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i> Hussein Bachir PhD Senior Scientist - GMP Compliance <i>Franz Ziel GmbH</i>
	Fundamentals of Gowning in Cleanrooms and Personnel Transfer

15:15 – 16:45	<ul style="list-style-type: none"> • Key elements for gowning in different cleanroom grades • Demonstration of risks and possible errors during gowning • <i>Practical Part: Correct Gowning</i> <p>Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></p>
16:15 – 16:45	<p>Cleanroom Controls, Operations and Behavior</p> <ul style="list-style-type: none"> • Background on key concepts on cleanroom controls • Introduction to correct cleanroom behavior • Regulatory requirements and framework <p>Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></p>
17:15 – 17:45	Attendee Questionnaire Day 1 & Round Table Discussions with participants
17:45 – 17:45	End of Training Course Day 1

Wednesday, 3 June

CEST Daylight Time (UTC +2:00)

09:15 – 09:45	<p>Introduction to Barrier Systems (Isolators, RABS) and Material Transfer</p> <p>Hussein Bachir PhD, Senior Scientist - GMP Compliance, <i>Franz Ziel GmbH</i></p>
09:00 – 09:15	Recap of Day 1
09:45 – 10:45	<p>Fundamentals of First Air and Smoke Studies</p> <ul style="list-style-type: none"> • Key elements of first air and how it protects critical process areas • Rules for maintaining first air integrity • <i>Practical Part</i> <p>Hussein Bachir PhD, Senior Scientist - GMP Compliance, <i>Franz Ziel GmbH</i></p>
10:45 – 11:15	Coffee Break
11:15 – 12:00	<p>Practical Part</p> <p>Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></p> <p>Hussein Bachir PhD Senior Scientist - GMP Compliance <i>Franz Ziel GmbH</i></p>
12:00 – 12:30	<p>Fundamentals of Aseptic Processing</p> <ul style="list-style-type: none"> • Background on different cleanroom technologies (RABS; isolator, closed systems/robotics) • Principles of equipment setup • Regulatory requirements and expectations <p>Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></p>
12:30 – 13:00	<p>Risks during Aseptic Interventions and Equipment Setup: Theoretical Part I</p> <ul style="list-style-type: none"> • Risks and errors during material transfer and equipment setup • Background on common aseptic interventions • Regulatory requirements and expectations • Risks and errors during aseptic interventions <p>Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, <i>F. Hoffmann-La Roche AG</i></p> <p>Hussein Bachir PhD Senior Scientist - GMP Compliance <i>Franz Ziel GmbH</i></p>
13:00 – 14:00	Lunch Break

Continued Risks during Aseptic Interventions and Equipment Setup: Theoretical Part II and Practical Part

14:00 – 15:30

- Risks and errors during material transfer and equipment setup
- Background on common aseptic interventions
- Regulatory requirements and expectations
- Risks and errors during aseptic interventions
- *Practical part*

Tarik Cheema PhD, Asset Excellence Lead - Pre-Filled Syringe Line, *F. Hoffmann-La Roche AG*

Hussein Bachir PhD Senior Scientist - GMP Compliance *Franz Ziel GmbH*

15:30 – 16:00 **Coffee Break**

16:00 – 16:30 **Round Table Discussion**

16:30 – 17:00 **Wrap up, Q&A & Attendee Questionnaire**

17:00 – 17:00 **End of Training Course**