

Tuesday, 2 June

CEST Daylight Time (UTC +2:00)

09:00 – 09:30 **Welcome and Collection of Participants' Expectations**

Contamination Control Strategy as the Basics for Aseptic Processing

09:30 – 10:15

- Introduction and basics of the CCS
- Regulatory requirements and expectations
- Maintaining an effective CCS

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

Fundamentals of Microbiology and Aseptic Processing

10:15 – 11:00

- Background on key concepts of microbiology
- Regulatory requirements and expectations
- Overview of environmental monitoring programs (air, surfaces, personnel)

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11:00 – 11:30 **Coffee Break**

Fundamentals of Cleaning and Disinfection

11:30 – 12:30

- Key elements for cleaning & disinfection in cleanrooms
- Regulatory requirements and expectations
- Hazard scenarios in cleaning and disinfections
- *Practical Part: Disinfection with UV & GMP-conforming cleaning*

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

12:30 – 13:30 **Lunch Break**

Glove Disinfection and Disinfection Agents

13:30 – 14:15 **Hussein Bachir PhD**, Scientist - GMP Compliance, *Franz Ziel GmbH*

14:15 – 14:45 **Coffee Break**

Considerations & Pitfalls in

14:45 – 15:15

- Cleaning and Disinfection
- Environmental Monitoring

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

Fundamentals of Gowning in Cleanrooms and Personnel Transfer

15:15 – 16:45

- Key elements for gowning in different cleanroom grades
- Demonstration of risks and possible errors during gowning
- *Practical Part: Correct Gowning*

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Cleanroom Controls, Operations and Behavior

16:15 – 16:45

- Background on key concepts on cleanroom controls
- Introduction to correct cleanroom behavior
- Regulatory requirements and framework

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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)

Introduction to Barrier Systems (Isolators, RABS) and Material Transfer

09:15 – 09:45 **Hussein Bachir PhD**, Scientist - GMP Compliance, *Franz Ziel GmbH*

09:00 – 09:15 **Recap of Day 1**

Fundamentals of First Air and Smoke Studies

09:45 – 10:45

- Key elements of first air and how it protects critical process areas
- Rules for maintaining first air integrity
- *Practical Part*

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

10:45 – 11:15 **Coffee Break**

Practical Part

11:15 – 12:00 **Tarik Cheema PhD**, Asset Excellence Lead - Pre-Filled Syringe Line, *F. Hoffmann-La Roche AG*

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

Fundamentals of Aseptic Processing

12:00 – 12:30

- Background on different cleanroom technologies (RABS; isolator, closed systems/robotics)
- Principles of equipment setup
- Regulatory requirements and expectations

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Risks during Aseptic Interventions and Equipment Setup: Theoretical Part I

12:30 – 13:00

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

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

13:00 – 14:00 **Lunch Break**

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

- 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*

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

14:00 – 15:30 **Coffee Break**

15:30 – 16:00 **Round Table Discussion**

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

16:30 – 17:00 **End of Training Course**