

**Competition Clause:** We ask you for your understanding that participants of competing companies cannot take part in the Bausch + Lomb site visit on 23 May 2019.

**Wednesday, 22 May 2019**

**9:00 – 17:00**

**9:00**      **Welcome and Introduction**

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**9:15**      **Target Product Profile and Container Closure System – From Drug to Packaging and Usability**

- Formulation
    - ▷ Compendial compliance
    - ▷ Properties e.g. viscosity
  - Processability
    - ▷ Aseptic filling
    - ▷ Thermal sterilization
  - Usability
    - ▷ User needs
    - ▷ Administration routes
    - ▷ Application systems
    - ▷ Single/multidose
    - ▷ Environmental conditions
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**9:55**      **Primary Container Closure Systems, Part I: Bottles, Vials, Ampoules, Cartridges, Syringes**

- Requirements
  - Advantages and disadvantages
  - Overview about available systems
    - ▷ Glass (bottle, ampoules, vials, cartridges, syringes)
    - ▷ Polymers (vials, syringes)
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**10:15**      **Primary Container Closure Systems, Part II: Blow-Fill-Seal Containers**

- Requirements
  - Advantages and disadvantages
  - Overview about available systems (external sources)
    - ▷ Bags
  - Overview about available systems (internal manufacturing)
    - ▷ Blow-fill-seal containers
    - ▷ Bottles
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**10:35**      **Coffee Break**

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**11:05**      **Basics of Blow-Fill-Seal Technology**

- From polymer granulates to filled and sealed containers
  - Traditional BFS-process
  - Multilayer options
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**11:35**      **Interactive Exercise 1:**

Impact of drug formulation and application on primary packaging and container closure system

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**12:30**      **Lunch Break**

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**13:30 Dosage Forms, Designs and Usability of BFS Containers**

- Ophthalmics
- Inhalation
- Parenterals
- Terminal sterilization
- User acceptance and usability
  - ▷ Optimized application of infusions
  - ▷ Easy empty containers

**14:00 Recent Innovations in Blow-Fill-Seal**

- Cool-BFS for temperature sensitive formulations
- Increased functions by inserted parts
- Adapters/closures for minimizing administration errors and increasing safety

**14:30 Coffee Break**

**15:00 Interactive Session 2:**

Impact of drug formulation and application on selection of primary packaging and container closure system and on manufacturing of primary packaging

**16:30 Summary Day 1 and Q & A**

**17:00 End of Day 1**

**Thursday, 23 May 2019**

**9:00 – 17:15**

**09:00 Primary Packaging Materials, Part I: Glass, Polymers**

- Glass
  - ▷ Glass types
  - ▷ Basic properties
  - ▷ Advantages, limitations
  - ▷ Novel compositions, trends
  - ▷ Manufacturing
    - Tubing
    - Converting
    - Molding
    - Surface treatment
- Polymers
  - ▷ PE, PP, COP/COP
  - ▷ Basic properties
  - ▷ Advantages, limitations
  - ▷ Trends
  - ▷ Manufacturing
    - Molding
    - Surface treatment

**9:40 Primary Packaging Materials, Part II: Elastomers**

- Elastomers
  - ▷ Butyl, halobutyl, synthetic polyisoprenes, SBRs
  - ▷ Basic properties
  - ▷ Advantages, limitations
  - ▷ Trends
  - ▷ Manufacturing
    - Surface treatment

# TWO-DAY TRAINING COURSE

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<b>10:00</b>	<b>Coffee Break</b>
<b>10:30</b>	<b>Practical Considerations During Development/Selection of Packaging System</b> <ul style="list-style-type: none"><li>• Interaction of packaging materials with drug product</li><li>• Closure system</li><li>• Impact of storage/transportation temperatures</li><li>• Container closure integrity test methods</li></ul>
<b>11:30</b>	<b>Interactive Session 3:</b> Risk Analysis of material selection (glass or COC/COP) for pre-filled syringes during development of new biopharmaceutical drug product
<b>12:30</b>	<b>Lunch Break</b>
<b>13:15</b>	<b>Bus Transfer to Bausch + Lomb</b>
<b>14:00</b>	<b>Introduction to Facility Tour</b> <ul style="list-style-type: none"><li>• "Virtual" tour through facility: what will be seen</li><li>• Different type of BFS technology</li><li>• CCIT</li><li>• Inspection systems</li></ul>
<b>14:30</b>	<b>Facility Tour at Bausch + Lomb</b> <ul style="list-style-type: none"><li>• BFS machines types in production</li><li>• CCIT in operation</li><li>• Inspection systems in operation</li></ul>
<b>15:30</b>	<b>Summary Day 1 &amp; 2 and Q &amp; A</b>
<b>16:00</b>	<b>Farewell Coffee</b>
<b>16:30</b>	<b>Transfer to Training Course Hotel</b>
<b>17:15</b>	<b>End of Training Course</b>

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