<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>9:00</td>
<td>Welcome and Introduction</td>
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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 |
| 9:55  | **Primary Container Closure Systems, Part I: Bottles, Vials, Ampules, Cartridges, Syringes**  
        - Requirements  
        - Advantages and disadvantages  
        - Overview about available systems  
            ▷ Glass (bottle, ampoules, vials, cartridges, syringes)  
            ▷ Polymers (vials, syringes) |
| 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 |
| 10:35 | **Coffee Break** |
| 11:05 | **Basics of Blow-Fill-Seal Technology**  
        - From polymer granulates to filled and sealed containers  
        - Traditional BFS-process  
        - Multilayer options |
| 11:35 | **Interactive Exercise 1:**  
        Impact of drug formulation and application on primary packaging and container closure system |
| 12:30 | **Lunch Break** |
### TRAINING COURSE AGENDA

**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

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**Thursday, 23 May 2019**

**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
<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>10:00</td>
<td>Coffee Break</td>
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<tr>
<td>10:30</td>
<td>Practical Considerations During Development/Selection of Packaging System</td>
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<tr>
<td></td>
<td>• Interaction of packaging materials with drug product</td>
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<tr>
<td></td>
<td>• Closure system</td>
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<td>• Impact of storage/transportation temperatures</td>
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<td>• Container closure integrity test methods</td>
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<td>11:30</td>
<td>Interactive Session 3:</td>
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<td>Risk Analysis of material selection (glass or COC/COP) for pre-filled syringes during development of new biopharmaceutical drug product</td>
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<td>12:30</td>
<td>Lunch Break</td>
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<tr>
<td>13:15</td>
<td>Bus Transfer to Bausch + Lomb</td>
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<tr>
<td>14:00</td>
<td>Introduction to Facility Tour</td>
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<tr>
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<td>• “Virtual” tour through facility: what will be seen</td>
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<td></td>
<td>• Different type of BFS technology</td>
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<td>• CCIT</td>
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<td>• Inspection systems</td>
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<tr>
<td>14:30</td>
<td>Facility Tour at Bausch + Lomb</td>
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<tr>
<td></td>
<td>• BFS machines types in production</td>
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<td>• CCIT in operation</td>
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<tr>
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<td>• Inspection systems in operation</td>
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<tr>
<td>15:30</td>
<td>Summary Day 1 &amp; 2 and Q &amp; A</td>
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<td>16:00</td>
<td>Farewell Coffee</td>
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<tr>
<td>16:30</td>
<td>Transfer to Training Course Hotel</td>
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<tr>
<td>17:15</td>
<td>End of Training Course</td>
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