DCVMN training – Hanoi

Agenda
# Gap Analysis

**Presentation**

- **Gap Analysis**
  - Presentation on conducting a Gap Analysis in relation to readiness for a Pre-certification Inspection.
  - Elements/Scope of the Gap Analysis
  - Rating for gaps
  - How to identify weaknesses

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## Preparing the site for External Inspection – Inspection Readiness

**Presentation**

- **Preparation**
  - This session presents how to prepare for an external inspection – how to plan, set up and manage a regulatory inspection using a “packages approach.”

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## Quality Systems

**Presentation**

- **Quality Systems**
  - Topics covered:
    - How does a QS fit together?
    - Risk Management
    - Internal Audit Programs

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## Quality Systems (continued)

**Presentation**

- **Management of Deviations/Investigations and CAPA**

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## Workshop #1 – Developing a Gap Analysis check sheet

**Workshop**

- **Designing a comprehensive Gap Analysis check sheet**

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## Workshop #2 - Deviations

**Workshop**

- **Preparing and analysing examples of GMP Deviations**

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## Workshop #3 - Investigations and Corrective / Preventive Action

**Workshop**

- **Developing Investigation and Corrective Action plans**

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## Workshop #4 – Risk Management

**Workshop**

- **Developing impact (equipment) and risk (product**
Cleanrooms and Aseptic Practices Workshop  
25th and 26th November 2015 (Paul Fletcher and Steve Williams)

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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| 8:00  | **Cleanroom Management and Qualification:**  
Presentation on the current basic requirements for Cleanroom Layout, GMP Standards, Grades (ISO5, 7, 8 and 9) WHO expectations on HVAC system.  
Focus will be on:  
- Particulate and microbial standards  
- Entry of materials and personnel (flows) into ISO 7 (Grade B) and ISO5 (Grade A) space  
- Qualifying cleanrooms and Grade A space  
- Industry movement toward RABS and Isolators |
| 10:00 | Refreshment break                                                                             |
| 10:30 | Small group review of a cleanroom plan where participants will be asked to decide the product, materials and personnel flows for an aseptic cleanroom and appropriate locations of inlets and returns. |
| 12:30 | Lunch break                                                                                  |
| 13:30 | **Aseptic Processing Practices and Process Validation of Aseptic Operators:**  
This presentation will discuss cleanroom gowning and behaviours within Grade A and Grade B space, including a summary of good and poor aseptic practices in and around Grades A/ISOS/Class 100 and Grade B space. |  
**Presentation**  
**Workshop**  
15:30 Refreshment break  
16:00 Small group review of aseptic practices, Grade A interventions, operator behaviours and gowning programs, including review of airflow studies in Grade A space.  
<p>| 17:30 | Adjourn                                                                                      |</p>
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Description</th>
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<tbody>
<tr>
<td>8:00</td>
<td><strong>Key Concepts for Sterilization and Validation:</strong></td>
<td>This presentation will focus on the GMP requirements for steam, dry heat and filtration sterilization. The presentation will review the requirements for validation and what inspectors look for under cGMPs.</td>
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<td>10:00</td>
<td>Refreshment break</td>
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<tr>
<td>10:30</td>
<td>Small group review of sterilisation validation protocols and data with a focus on steam sterilisation.</td>
<td>Workshop</td>
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<td>12:30</td>
<td>Lunch break</td>
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<tr>
<td>13:30</td>
<td><strong>Cleanroom Microbiology Controls and Environmental Monitoring Programs</strong></td>
<td>This presentation will include a review of:</td>
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<td>• Fundamental EM Program – what to monitor:</td>
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<td>• frequency, location and methods for monitoring</td>
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<td>• setting appropriate limits</td>
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<td>• monitoring of water systems.</td>
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<td><strong>Presentation</strong></td>
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<tr>
<td>15:30</td>
<td>Refreshment break</td>
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<tr>
<td>16:00</td>
<td>Small group review of EM programs and evaluation of results from example monitoring data.</td>
<td>Workshop</td>
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<td>17:30</td>
<td>Adjourn</td>
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