New Laboratory for PBOEL4 Handling at Cilag

Michael Justus
New Laboratory for PBOEL4 Handling at Cilag

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Introduction

Reasons for the need of a high containment laboratory in Cilag WWCP:

- Need for the handling of high potent compounds in Cilag WWCP (analytics: QC, CARD; chemical R&D for new projects)
- Gap: High containment pilot plant (HCPP) for highly potent compounds, but no laboratory equivalents
- Interim solution: Handling of those compounds in existing laboratories
  - Dedicated area in one R&D laboratory (limited access control)
  - Small laboratory for analytics (former isotope laboratory)
  - Several measurements had to be done in standard labs
- Moving of compounds and people between these places
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Introduction

Location of the new PBOEL4-laboratory at Cilag:
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General Concept of PBOEL 4 Unit

One unit for laboratory work (preparative synthesis, analytical development and quality control) and small GMP-production

Advantages:
- Separate ventilation of the whole area
- Access via the same airlock
- Same or similar equipment, same containment, no upscaling problems
- Direct contacts/information between R&D, QC, and scale-up staff
- Short transportation ways within designated area
Concept of PBOEL4 Laboratory

PBOEL4 laboratory is shared between three groups:
- Chemical R&D
- Chemical Analytical R&D
- Quality Control Chemistry

Advantages:
- Same containment concept for all laboratory co-workers including monitoring/sampling, engineering controls, administrative controls, work practice controls and personal protective equipment
- Same safety standards / safety education preventing inappropriate work practices
- No fixed staff, no desks, no personal drawers
- Identical / equal equipment for all groups
- Mutual assistance
- Short transportation of samples within the same laboratory
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- General Risk Analysis

Risk analyses for PBOEL4 compounds and the high potent laboratory are available:
Individual Risk Analyses

An individual risk analysis is made for every single high potent compound:
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- Work Practice Control - Access

Only educated staff (educated in the general risk analysis, the individual risk analyses, and practical training) is allowed to enter the laboratory.
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- Engineering Control - Solid Handling I
  - Handling of potent solids only in laminar flow devices:
    Vented balance safety enclosure
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- Engineering Control - Solid Handling II

Handling of potent solids only in laminar flow devices
Biological safety cabinet (e.g. preparation of solutions)
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- Engineering Control - Solid Handling III

Isolators:
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- Engineering Control - Liquid Handling I
  Local ventilation – Avoidance of vapours and aerosols:
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- Engineering Control - Liquid Handling II

Skan work stations:
(less potent compounds)
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- Engineering Control - Liquid Handling III

Skan work stations - Ventilation:

![Diagram showing ventilation system for Skan work stations with airflow rates and dimensions]
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- Engineering Control - Liquid Handling IV

Waste solvent containment:
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- Engineering Control - Liquid Handling V

General containment of HPLC-solvents:
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- Engineering Control – Further Devices
  Local vacuum systems – Control of possible contamination:
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- **Work Practice Controls**

  All infrastructure in the laboratory – Very limited transportation:
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- Safety Infrastructure – Emergency Exit
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- Safety Infrastructure – Shower and Eye Shower
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- Safety Infrastructure – Spill Kit
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- Administrative Controls

Most of the paper work is transferred to the office outside the laboratory – no entrance to the laboratory necessary:
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Summary

- A new laboratory for the handling of high potent compounds was designed in close vicinity with the small GMP-production
- The new laboratory integrates preparative (chemical R&D) and analytical (CARD, QC chemistry) operations
- Concept: Suitable containment for all handling steps of high potent compounds, short ways, minimum locking operations
- Appropriate work practices, protective equipment, and cleaning/maintenance ensured by risk analyses and education
- The new laboratory went active 2nd of August, 2006 for analytic purposes
- After delivery of the first isolator preparative work will start