



Swiss Cleanroom Community Event 08. April 2019

Case Study Corden Pharma Lab Containment

Speaker

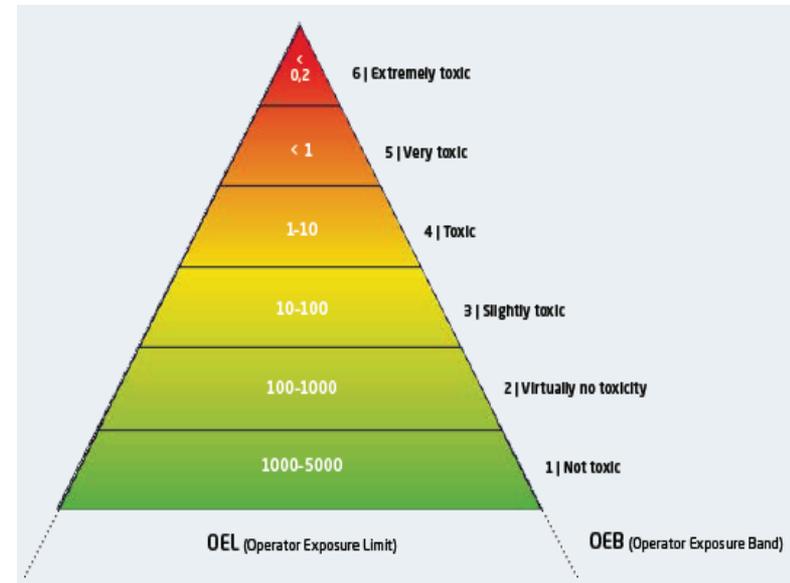
- Dipl. Ing (FH) Rainer Hundekiker
E-Mail: rainer.hundekiker@weiss-technik.com
- Rainer Hundekiker is Product Manager Containment and Areas Sales Manager at Weiss Pharmatechnik GmbH; Germany
 - He is working more than 20 years for the company developing the international market, introducing new technologies for Weighing, Dispensing and Sampling Units as well as Containment Solutions.
 - The system called WIBObarrier is tailor-made manufactured according to the needs of the customer and their procedures.
 - Containment solution for APIs could also be developed together with the customer.
 - The realization of turnkey projects with cleanroom environment together with the required equipment is one of our goals.



TEST US!!

Containment Requirements.

- **OEL (Occupational Exposure Limit - $\mu\text{g}/\text{m}^3$)**
 - Average airborne concentration of a medium $\mu\text{g}/\text{m}^3$ to which exposition of a worker is permissible over a certain period of time (8hours day 5 days a week) over a working life time.
- **OEB (Occupational Exposure Band - $\mu\text{g}/\text{m}^3$)**
 - Product classification class 1-6:
(classification differs depending on the company)
 - OEB 1: > 1'000 $\mu\text{g}/\text{m}^3$
 - OEB 2: > 100 – 1'000 $\mu\text{g}/\text{m}^3$
 - OEB 3: > 10- 100 $\mu\text{g}/\text{m}^3$
 - OEB 4: >1 – 10 $\mu\text{g}/\text{m}^3$
 - OEB 5: >1 $\mu\text{g}/\text{m}^3$
 - OEB 6: > 0,2 $\mu\text{g}/\text{m}^3$
- **STEL (Short-Term Exposure Limit)**
 - OEL for short time exposure (15-30 minutes) can exceed the OEL 3-8 times of the OEL.
 - The exposure to the operator is never permitted to be higher than the STEL
- **PDE (Permitted Daily Exposure)**
 - Maximum exposure to the API without (adverse) effect.



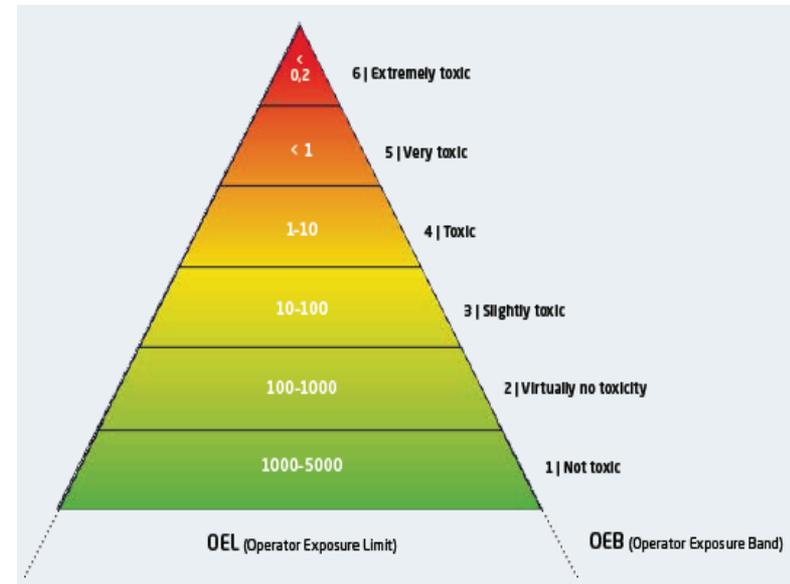
Regulations which need to be followed.

Occupational Health:

- 29CFR1910 (USA)
- 89/391 EWG (Europe)
- TRGS 900 (Germany)
- ILO / OSH (Swiss)
- many others.

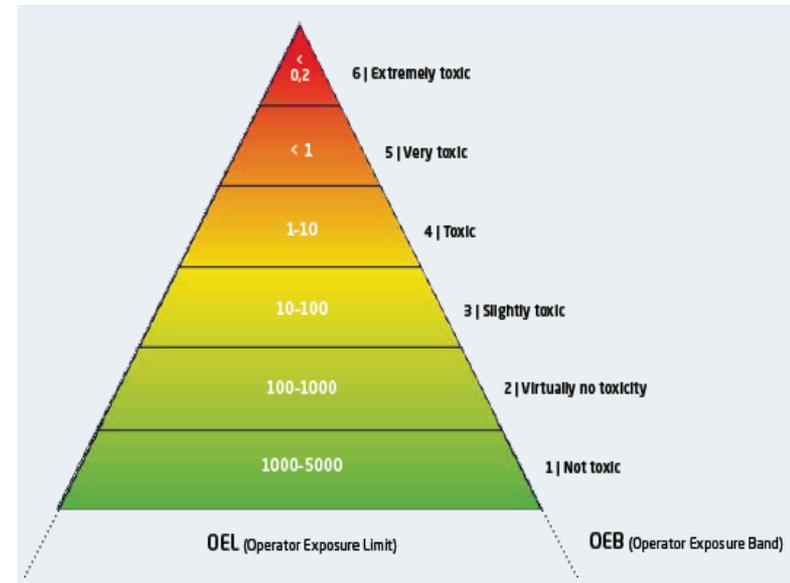
Pharmaceutical Quality:

- ICH Q7 (GMP Guideline)
- ICH M7 (Genotoxic Impurities)
- ICH Q9 (Quality Risk Management)
- ICH Q10 (Pharmaceutical Quality System)
- EMA 169430 / 2012 (Health based exposure limits in shared facilities)
- and many others.



Regulations Cleaning.

- Few criteria on cleanliness since 1995:
 - Max. 10 ppm carry over
 - 1/1'000 therapeutically dose
 - 1/50'000 LD 50
 - Visual Clean -> not specific to the pharmaceutical characteristics of the actual drug
- EMA Guidline since mid 2015:
 - Cleanliness is now based on scientific observation
 - Toxicologists identify the PDE of each specific component of a pharmaceutical product (API's and Excipients) based on the OEL and the max. carry over are defined



„EMA 169430/2012 GUIDLINE ON SETTING HELTH BASED EXPOSURE LIMITS FOR USE IN RISK IDENTIFICTION IN THE MANUFACTURE OF DIFFERNET MEDICAL PRODUCTS IN SHARED FACILIITIES“

Small Laboratory Scale

General Concept

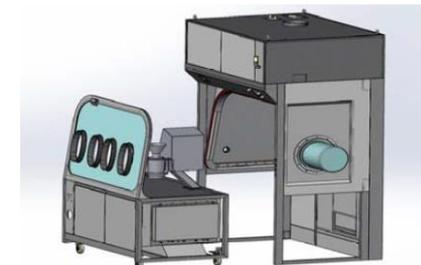
- Containment is achieved with Containment Systems (OCS Open Containment Systems) WIBObarrier OEB 4: >1 – 10 µg/m³ up to OEB 5: >1 µg/m³
- Processing equipment (units) are mounted on movable trolley, removable from the Containment System. Exchangeable movable trolley with other processing equipment (unit).
- Control modules, inlet air handling are placed outside the Containment System to avoid contamination and to reduce cleaning.
- Before removing the movable trolley it must be cleaned or washed down manually together with the Containment System with water to achieve SHE-Cleanliness (Safety-Health-Environmentally clean)
- GMP cleanliness is achieved by washing the processing equipment manually in a separate GMP washing area.



Small Laboratory Scale

— Tailored OEB in the WIBObarrier System

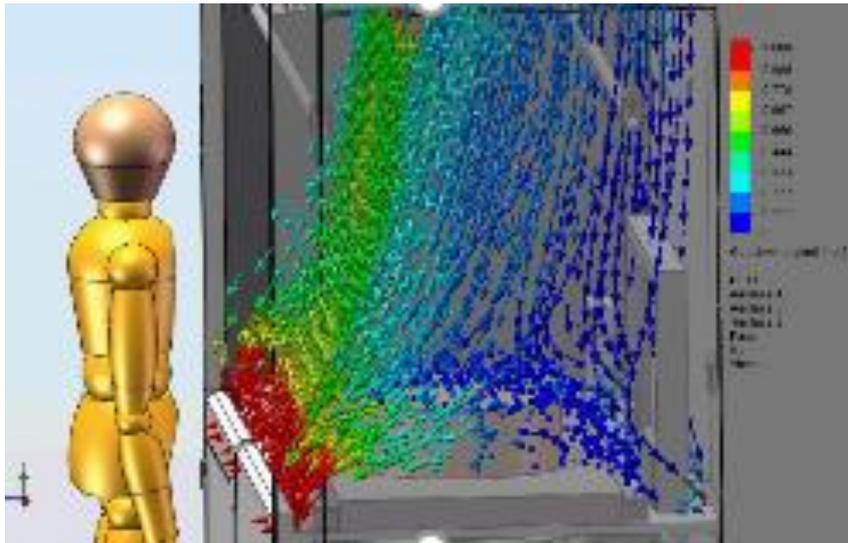
- OEB 4 => OCS Open Containment System
- OEB 4 / 5 => OCS^{plus} Open Containment System^{plus}
- OEB 5 => CCS Closed Containment System
- OEB 5 => CCS^{plus} Closed Containment System^{plus}



Small Laboratory Scale

→ The WIBObarrier System

- Unidirectional air flow inside of the barrier system captures dust and collect this at the integrated HEPA H14 filter in the movable trolley.
- Air curtain protects the operator form dust inside, and the inner part from particles outside.
- Optionally available with window pane or and closed window gives additional protection.



Concept of Corden Pharma Small Laboratory Scale

- 5 Units of Containment Systems: 4 of them with movable trolley and two additional trolley without process equipment; one unit as weighing unit.



Concept of Corden Pharma Small Laboratory Scale

- Weighing Unit with scales



Concept of Corden Pharma Small Laboratory Scale

- Left Fluid Bed Dryer, Pass-Box, Blending and Dry Milling



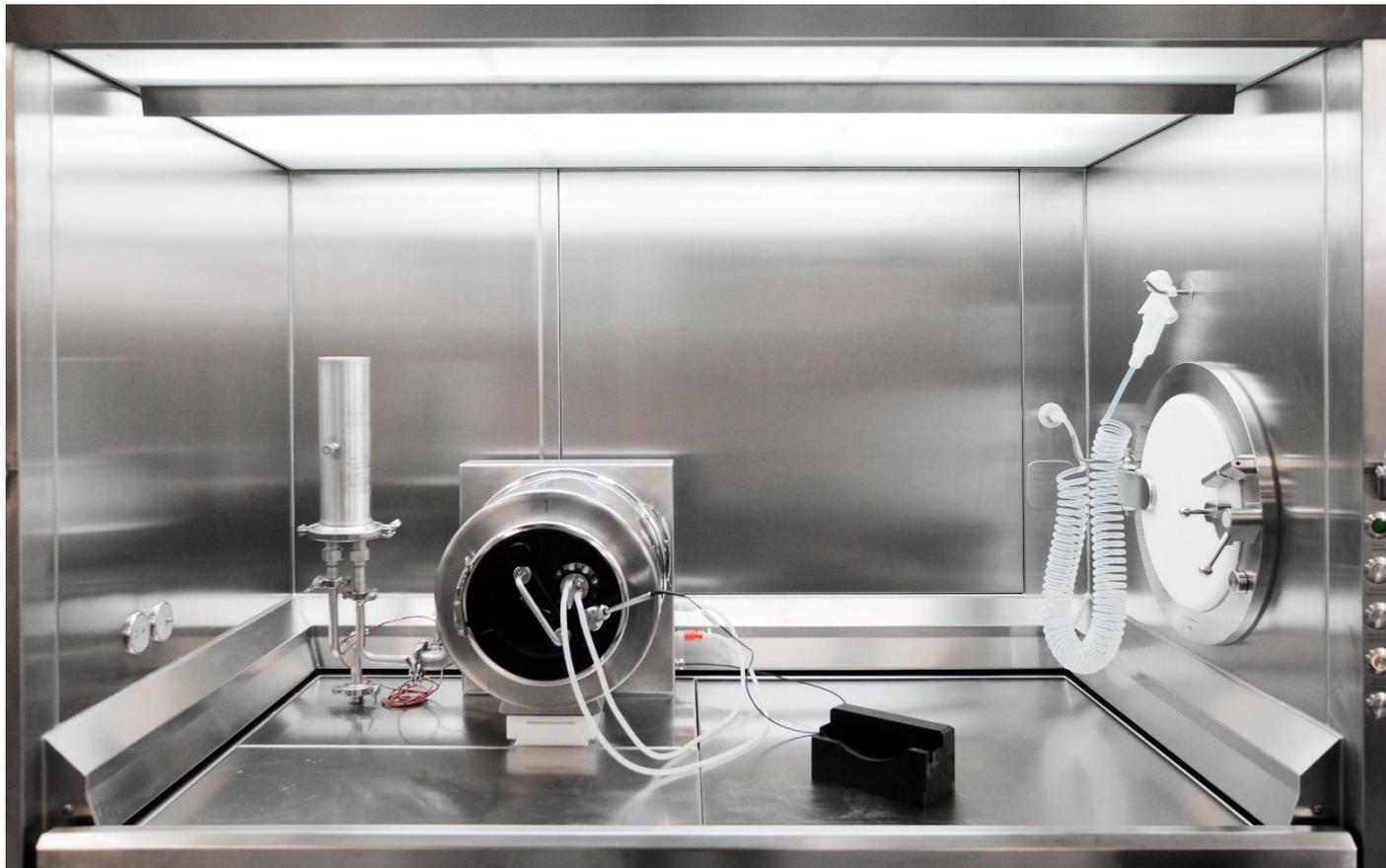
Concept of Corden Pharma Small Laboratory Scale

- Granulation and Wet Sieving



Concept of Corden Pharma Small Laboratory Scale

- Tablet Coating



How could be checked the WIBOBarrier System:

- According to surrogate test / SMEPAC “ISPE Good Practice Guide 2005” the test has to be performed at customer site; regularly the customer is conducting and performing the test.
- ANSI / ASHRAE 110 - 1995 with a Gas SF₆
- DIN EN 14175-3 with a Gas SF₆



Infraserv GmbH & Co. Höchst KG

Business segment Environment, Safety, Health

4.1.3 Measuring and calculation results

See appendix 1, analysis reports and calculation logs

1. Test series (With front pane)

- **Measuring point 4** person-related measurements < 0,032 - 0,59 µg/m³
- **Measuring point 2** inside the WIBOBarrier unit 20,2 – 99,0 µg/m³
- **Measuring point 1** outside the WIBOBarrier unit, left < 0,12 – 0,20 µg/m³
- **Measuring point 3** outside the WIBOBarrier unit, right < 0,047 – 0,22 µg/m³





Thank you for your attention!

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