



## **ANNEX 1 implementation** *Challenges & Lessons learned*

**With table top exhibitions and UCB site visits**

**When**      **Thursday 23 November 2023**

**Location**    UCB - Braine-l'Alleud

*A visit of UCB in Braine-l'Alleud will be organised in the afternoon*

*Table tops will be accessible during the seminar*

# Annex 1 Implementation Challenges & Lessons Learned

- 8:00 - 9:00 Registration and coffee
- 9:00 - 9:10 Welcome  
*(Wim Steenackers, President ISPE Belgium Affiliate)*
- 9:10 - 9:45 Annex 1 implementation strategy, impact and key implementation plan  
*(Christophe Haenzler, GSK)*
- 9:45 - 10:15 Annex 1: New requirements on Barrier and Transfers  
*(Richard Denk, SKAN) Remote presentation*

## 10:15-10:45 Coffee break with table top & networking

- 10:45 - 11:25 Annex 1 implementation, sterilization requirements of direct and indirect product contact parts and Biodecontamination of RABS gloves  
*(Nico Schillebeekx, Benedicte Filez & Liselotte Vandenbussche, J&J)*
- 11:25 - 12:00 Environmental Monitoring and Contamination Control Strategy (CCS).  
*(Alain Deloof & Nathan Decoster, Advipro)*

## 12:00-13:30 Lunch with table top & networking opportunities

- 13:30 - 14:05 Engineering and Facility Design: Practical Case Studies with Application of Annex 1  
*(Sylvie Alexandre & Paul Gillain, Ekium)*
- 14:05 - 14:40 Challenges and opportunities in Annex 1 requirements interpretation when developing a CCS and internal standard  
*(Olivier Dupont, UCB)*
- 14:40 - 15:00 UCB Visit introduction *(Geoffrey Folie, UCB)*
- 15:00 - 17:30 UCB Visit *(Choice between 3 options to be selected during registration)*



- 17:30 – 18:30 Closing of the day with networking reception







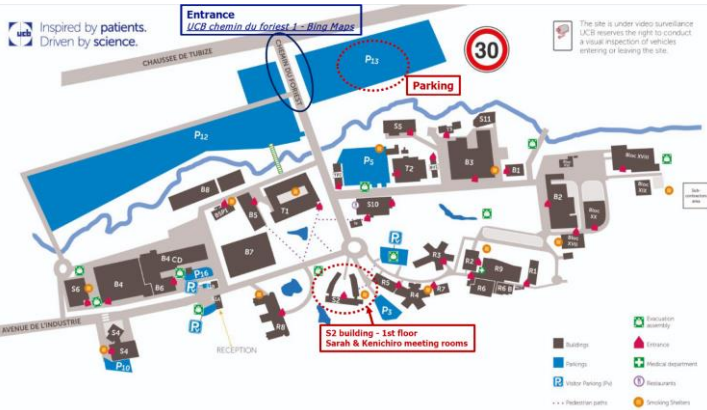




# THANKS TO OUR HOST



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Driven by science.



## Site tour Option 2 - T2

**Brief description on tour:** Bio Pilot Plant is a multiproduct development site dedicated to mAbs expression in mammalian cells (up to 2KL Bioreactor scale; in both SS as well as Single Use) Our mission is to deliver GMP clinical Drug Substance batches incl. IPA/IPC testing to support clinical studies at Phase I, II and III... but not only! Bio Pilot Plant is ~150 people with flexible, agile, and multivalent manufacturing skills across modalities.

**Duration of visit :** 30 min  
**Acceptable number of visitors :** 10 max.  
**Person of contact :** Younes Aarifi  
**Recent picture of the building:**



## Site tour Option 1 - Inflexio

- **Brief description on tour:** The Biomanufacturing plant is a state-of-the-art and sustainable facility which will allow UCB to produce mammalian monoclonal antibody drug substances batches with high efficiency and agility.
- **Built in 2 phases (Bioreactors :** ph1 : 3x10KL, >2026: ph 2 : 6x10KL)
- The building is shared with the Quality Control team and the Manufacturing Sciences & Technology team.
- **Duration of visit :** +/- 45 mn/1hour (depending on number of people)
- **Acceptable number of visitors :** 2x 15 visitors (2 groups simultaneously)
- **Person of contact :** Virginie Lavirotte/ Jean-Luc Roulin
- **Recent picture of the building:**



## Site tour Option 3 - Braine Manufacturing Finished products

- **Brief description on tour:**  
Braine Manufacturing Finished Products (BMFP) is located on the ground floor of B4 building  
The role of the BMFP is to prepare, assemble, package, and label pharmaceutical products securely and in compliance with regulations, making them ready for distribution to patients or healthcare professionals.  
Main activities of BMFP are :  
packaging of blisters and containers  
assembly and secondary packaging of syringes, auto-injectors, safety syringes...  
packaging of IV and oral solutions (vials and glass bottles)  
serialization and aggregation.
- **Duration of visit :** 45 to 60 min
- **Acceptable number of visitors :** Maximum of 7 people per group
- **Recent picture of the building:**





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