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)*

Inflexio Bio Plant	*T2 Bio Pilot Plant*	*Finished Products (BMFP)*
		

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

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Annex 1 Implementation
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Abstracts

Annex 1 implementation strategy, main common impact and key implementation plan
Christophe Haenzler, GSK

Abstract : Provide an overview of Annex 1 implementation strategy, including common impacts and main methodologies to implement the changes. Share some key implementation plan examples for EM, Sterilizationprocesses, facility, gowning and barrier technologies and and lessons learned from multi sites deployment approach

Annex 1 in Force since the 25th of August 2023. New requirements on Barrier and Transfers.
Richard Denk, Skan

Abstract : Since the official publication of new EU GMP Annex 1 on August 2022 the implementation is now since the 25th of August 2023 effective. Beside the EU GMP Annex 1, the PIC/s Annex 1 and WHO Annex 2 which are almost similar for sterile manufacturing became also effective on the same time. The key take away from the Annex 1 is the QRM Quality Risk Management, CCS Contamination Control Strategy, Barriers like Isolators or closed system, Transfers, Automation with Robotics and the prevention of Cross Contamination. All those topics will be covered in this presentation.

Annex 1 implementation, sterilization requirements of direct and indirect product contact parts & biodecontamination of RABS gloves.
Nico Schillebeekx, Benedicte Filez and Liselotte Vandenbussche, J&J



Presentation will cover

- Short intro on implementation approach of Annex 1 (Liselotte)
- Sterilization requirements of direct and indirect product contact parts (Nico)
- Biodecontamination of RABS gloves (Benedicte)

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Abstracts

Environmental Monitoring and Contamination Control Strategy (CCS).
Alain Deloof & Nathan Decoster, Advipro

The new Annex 1 provide general guidance that should be used in the design and control of facilities, systems and procedures used in the manufacturing of sterile products, this to ensure that microbial and particulate contamination is prevented in the final product. In the presentation we will focus on the environment monitoring and best practices and what the importance is of a Contamination Control Strategy (CCS). This Contamination Control Strategy should be implemented across the facility in order to define all critical control points and assess the effectiveness of the controls.

Engineering and Facility Design: Practical Case Studies with Application of Annex 1
Sylvie ALEXANDRE & Paul GILLAIN, Ekium

Abstract : Explore the dynamic world of Engineering Studies and Facility Design in the pharmaceutical and biopharmaceutical industries through the lens of GMP Annex 1. This presentation delves into the latest regulatory concepts, such as Quality Risk Management (QRM) and Contamination Control Strategy (CCS), as introduced in the new Annex 1 of the GMP guidelines. Discover how Ekium, as an engineering office, leverages these principles in recent facility design projects, covering layout optimization, efficient flow management, HVAC systems compliance, and the integration of barrier technologies. In this session, we will glimpse into the multifaceted relationship between evolving regulatory requirements and the complexity of contemporary facility design.

Challenges and opportunities in Annex 1 requirements interpretation when developing a CCS and internal standard.
Olivier Dupont, Global Sterility Assurance Manufacturing Program Lead, UCB

Abstract : Up than 8000 comments in total were raised during the two Annex 1 public consultations in 2017 and 2020 which provide significant evidence than the text was confusing and missing clarifications or non ambiguous interpretations on new or existing requirements. Even after the final publication, industry is sometimes struggling to have a common understanding of some section of the text which would lead to interpretation from regulators or inspectors. Some examples will be covered in the presentation

Annex 1 Implementation
UCB Site Tours

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 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 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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Who should attend?

All stakeholders responsible for:

- Research & Development
- Clinical trials manufacturing and scale up
- Manufacturing & Quality Control
- Technology & Engineering & Automation
- Logistics & Distribution
- Supply Chain
- Regulatory, validation, QA & GMP

and active in:

- Pharmaceuticals
- Biopharmaceuticals
- Biologics
- API
- And related Life Science industries…

Registration

- Open for ISPE Members or Non-ISPE Members
- Registration required (before 10 November) via website : www.ispeconference.org
- Including Lunch and Networking
- Including site visit
- Price :
  - 395 € (for ISPE member)
  - 95 € (for ISPE member – Emerging Leader(*age under 30*))
  - 595 € (for Non ISPE Member, including 1 year membership)
  - 295 € (for Non ISPE member – Emerging Leader (*age under 30)*, including 1 year membership)
- See registration website for payment details.

Contact : info@ispe.be

- ISPE reserves the right to delay the meeting and modify the program and the place, in case of force majeure.
- Any cancellation received later than one week before the event will not be credited.

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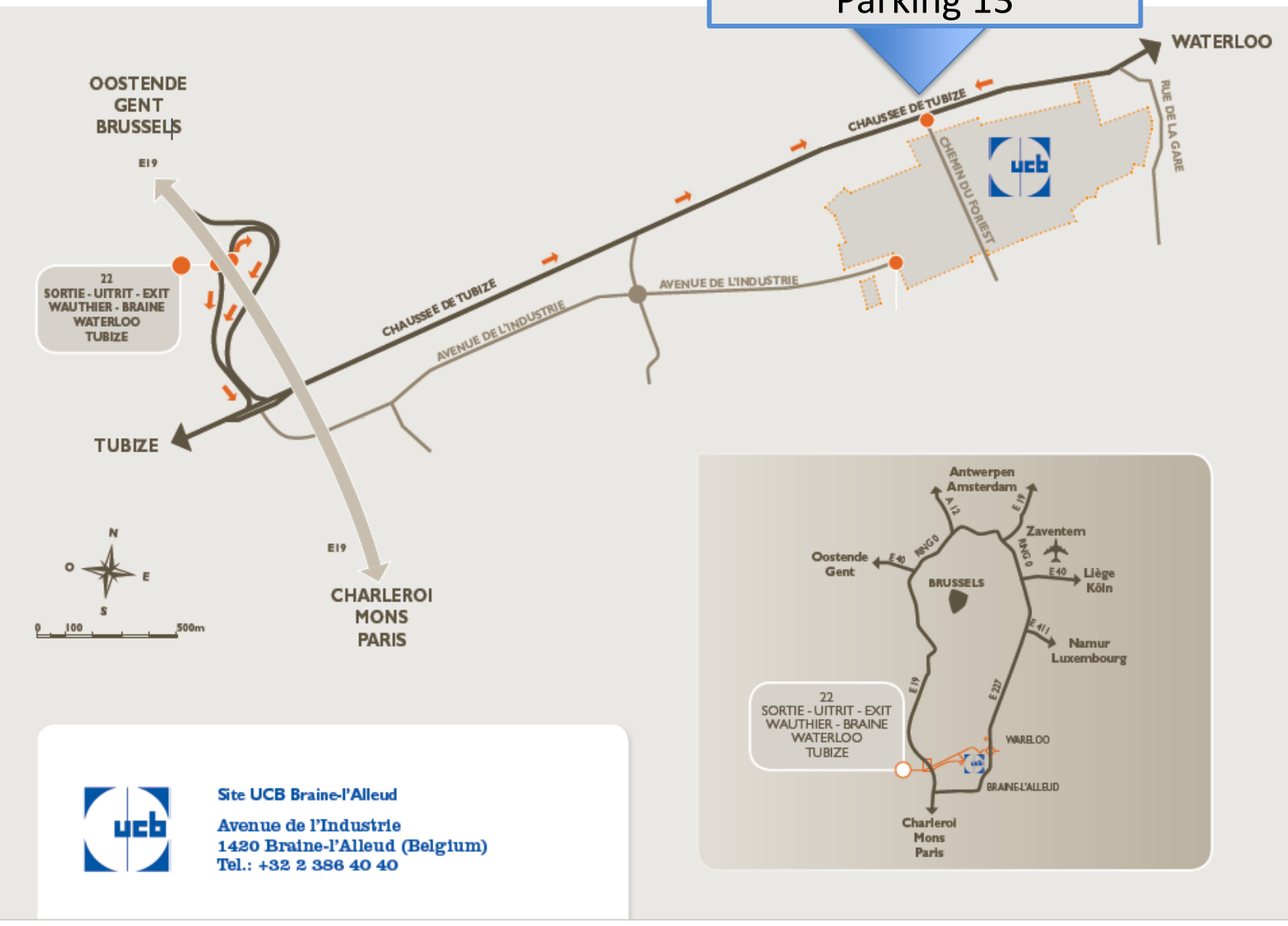
Event location

1, Chemin du Foriest,
1420 Braine l'Alleud
Parking 13



Site UCB Braine-l'Alleud
Avenue de l'Industrie
1420 Braine-l'Alleud (Belgium)
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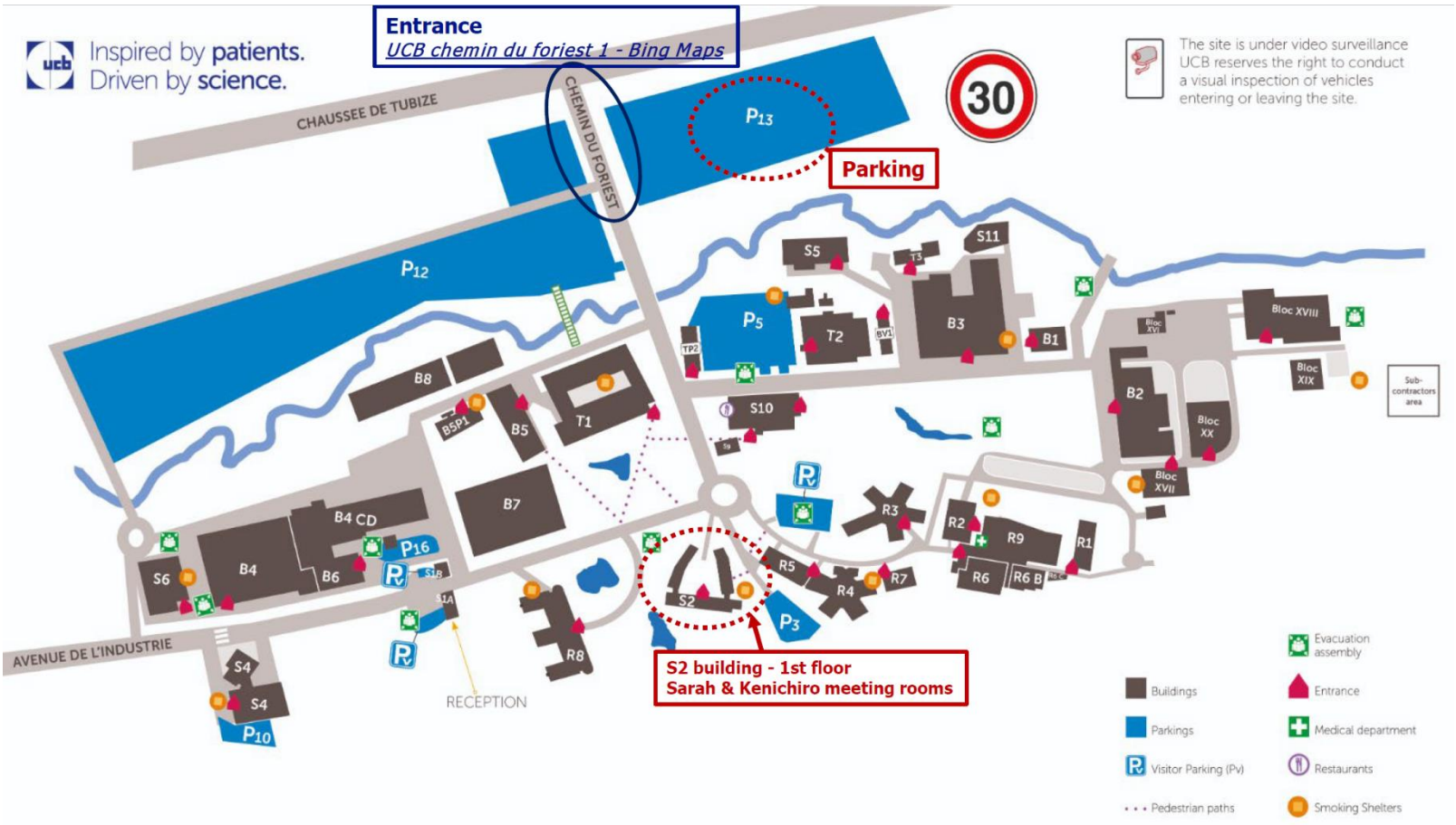
Annex 1 Implementation Challenges & Lessons Learned

Event location



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