

THE RAPS SWITZERLAND CHAPTER
IS PLEASED TO PRESENT

**REVISION OF EUDRALEX
VOL 4 - ANNEX 1
“MANUFACTURE OF
STERILE MEDICINAL
PRODUCTS”
INDUSTRY BEST
PRACTICES**

Price:

For RAPS
members
(or if your
affiliation
is a RAPS
Enterprise
Member):
CHF 500

Non
member:
550 CHF

THURSDAY, JUNE 15, 2023

9:30 AM - 17:00 PM

FOLLOWED BY NETWORKING APÉRO

**LOCATION: IV-STELLE KANTON BERN,
SCHEIBENSTRASSE 70, 3001 BERN**

**SAVE
THE
DATE**

To register: Ary.saaman@raps-switzerland.ch

Organizing Committee :

Lionnel Lüginbühl (Cytiva)

Valentin Rüttimann (Cytiva)

Gautam Maitra (RAPS Switzerland Chapter)

Ary Saaman (CSL Behring, Bern, Switzerland, and RAPS Switzerland Chapter)

THURSDAY, JUNE 15, 2023 PROGRAM

RAPS member
CHF 500

Non member
550 CHF

09:30 – 09:45 - Welcome

RAPS Chapter

09:45 – 10:30 - Overview of Changes to EU GMPs - Annex 1
Stéphane Gumy, Process Management System Sàrl

10:30 – 11:00- Refreshment break

11:00 – 11:45 - Impact of revised Annex 1 from
a supplier perspective: sterilizing grade filtration, PUPSIT
and single-use systems
Lionnel Lüginbühl, Cytiva

11:45 – 12:30 - Contamination Control Strategy (CCS) for Single-Use
Systems: Integrity and Particles Controls Strategies
Patrick Evrard, Cytiva

-
12:30 – 13:30- Networking lunch

13:30 – 14:15 - Implementation of revised Annex 1
- Industry Perspective (1)
Matthias Schaar, Novartis

14:15 – 15:00 - Implementation of revised Annex - Industry Perspective (2)
Barbara Moser, CSL Behring

Location: IV-Stelle Kanton Bern, Scheibenstrasse 70, 3001 BERN

To register: Ary.saaman@raps-switzerland.ch

REVISION OF EUDRALEX VOL 4 - ANNEX 1 “MANUFACTURE OF STERILE MEDICINAL PRODUCTS” INDUSTRY BEST PRACTICES

RAPS

SWITZERLAND
CHAPTER

THURSDAY, JUNE 15, 2023 PROGRAM

15:00 – 15:30 - Refreshment break

15:30 – 15:45 - RAPS : Regulatory Affairs Professionals Society
Kim Young, RAPS

15:45 – 16:30 - Revision of Annex 1 : An inspection and
enforcement perspective
Rémi Hesters, Fortil

16:30 - 16:55 - Panel discussion
All

16:55 – 17:00 - Closing Remarks and Adjourn
RAPS Chapter

17:00 - Networking apéro

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17:00 NETWORKING APÉRO

Please note:

Max. 100 attendees therefore: first come, first served

Entitlements :

Access to the event

Refreshment breaks, lunch, and networking apéro

Copies of presentation slides (after the event and as made available by the speakers)

Certificate of Attendance

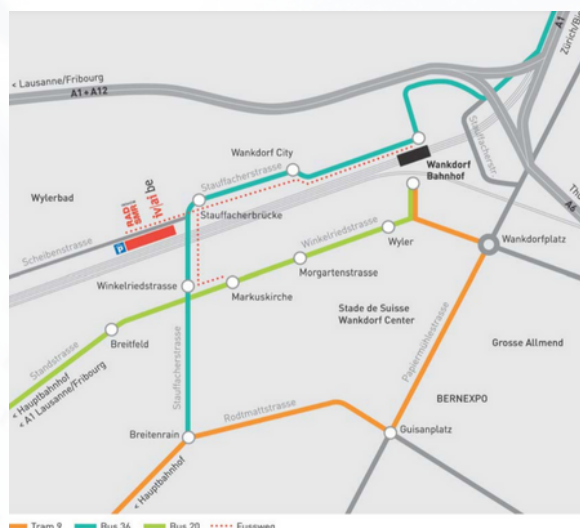
Payments:

Payable via bank transfer prior to the Event or in cash or via Twint at the Event.

We cannot accept Credit Cards.

How to get there:

By Public Transport



Within 20 mins from Bern Bahnhof with public transport. (e.g. Line 20 towards Wankdorf Bahnhof, Stop Breitfeld + 500m walk)

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