The Swiss Tech Convention Center // Lausanne
26th & 27th may 2015

The EPFL campus strengthen an academic output which create a strong bio economy moving forward. Those considerations lead A3P to organize the coming congress at Lausanne (SwissTech convention Center - EPFL) in the heart of the health valley.

The choices of conferences are becoming more and more difficult. But the agenda elaborated by the A3P editorial committee, represent original works of key interest at the cutting edge of development and manufacturing.

The biopharmaceutical industry needs to be able to reduce the cost of some biotech drugs products 10 fold. This major industry challenge has been the driver for the proposed agenda.

Vincent GRIFFOUL
President A3P Suisse

Companies present in 2014

- 3M PURIFICATION
- ACONOV
- ACID
- ADIT
- ADVANCED BIODESIGN
- AFIPRAL
- AGILENT TECHNOLOGIES
- AKKA INGENIERIE PROCESS
- AKTEROM
- ALK ABELO
- ALTRAN TECHNOLOGIES
- AMSONIC HAMO
- ANABIOTEC
- ANSM
- ARECOR LTD
- ASEPTEC PROCESS EQUIPMENT
- ASSOCIATES OF CAPE COD
- ASSYST SYSTEM EOS
- AUCTRIS LIFE SCIENCES
- AXYS NETWORK
- BAXTER BIOSCIENCE
- BCI
- BE VACCINES
- BECTON DICKINSON
- BEKER LABORATOIRES
- BELIMED
- BERGAMOTE
- BIOADVISE
- BIOMERIEUX
- BIOPHARM SERVICES Ltd
- BIOPOL LE CLERMONT LIMAGNE
- BIOPRACTIS TRAINING CENTER
- BOCQUET
- BOCCARD
- BRACO SUISSE SA
- CELL & CO BIOREPOSITORY
- CELLO
- CHARLES RIVER
- CONFARMA
- DEBIOPHARM
- ETABLISSEMENT FRANCAIS DU SANG
- EUROFINS PHARMA QUALITY CONTROL
- EUISA PHARMA
- EVION
- FAB'ENTECH
- FINESSE SOLUTIONS AG
- FLAMEL TECHNOLOGIES
- FONDAATION CAMPUS BIOTECH
- GENETHON
- GENETHION BIOPROD
- GENZYME POLYCLINALS
- GERFLOR
- GLYCOHOPE BIOTECHNOLOGY
- GROUPE NOVASEP
- GSK VACCINES
- GTP TECHNOLOGY
- HLT
- HUDSON GLOBAL RESOURCES
- IDMYK
- INFINITY BIOMARKERS
- INNATE PHARMA
- INSRM
- KIMBERLY CLARK
- LABITECH
- LAPORTE EURO
- LFB BIOMANUFACTURING
- LFB BIOMEDICAMENTS
- LIFE TECHNOLOGIES
- MERCK CHIME
- MERCK MILLIPORE
- MERCK SERONO
- MEDEVAL
- NOVARTIS PHARMA SAS
- OCTAPHARMA
- OXIFARMA
- PALL FRANCE
- PALL LIFE SCIENCES
- PAPASPYROU BIOTECHNOLOGY
- PARKER HANNIFIN FRANCE
- PERNINELMER
- PHARMA BIOTECH
- PHARMA SHIFT CONSULTING
- PHARMADEC
- PHARMTEC
- PIERRE FABRE MEDICAMENT
- PRODUCTION
- PIERRE GUERIN
- PIXON ENGINEERING AG
- PROTEINSIMPLE
- PX THERAPEUTICS
- QUALITY ASSISTANCE
- RD-BIOTECH
- RECIHARM
- RQMP COMPLIANCE
- ROCHE DIAOEGNOSTICS
- ROOT LINES TECHNOLOGY
- SAINT GOBAIN
- SANOFI
- SANOFI AVENTIS
- SANOFI CHIME
- SANOFI PASTEUR
- SANOFI WINTHROP INDUSTRIE
- SARTORIUS STEDM FMT
- SEPPIC
- SGS LIFE SCIENCE SERVICES
- SGS M-SCAN
- SGS VITROLOGY
- SPC MANUFACTURING
- STERIGENE
- SUP BIOTECH
- SYNTHEUS
- SYSTEM C INDUSTRIE
- TECHNIP
- THERMO FISHER SCIENTIFIC
- TOLERYS BIOLABS
- TRANSGENE
- UCB PHARMA
- UNIVERSITE LYON1
**Tuesday, May 26**

8:30 Welcome of the participants

8:45 Opening session
   **Benoit DUBUIS, BioAlps, Eclosion, Inartis**

9:00 Modulation of mAb quality attributes using microliter scale fed-batch cultures
   **Matthieu STETTLER, Merck Serono**

9:30 Characterization of single-use bioreactors: Possibilities, limitations and recommendations from an engineering point of view
   **Sören WERNER, Zurich University of Applied Sciences**

10:00 Approach of PAT: Development of a new tool for Bioprocess
   **Pierre HEIMENDINGER, Transgene**

10:30 Break & visit of the exhibition

11:30 Standardisation of production processes for multi-manufacturing-site companies
   **Volker WEIMAR, Octapharma**

12:00 Continuous Chromatography: towards an Integrated Process Solution
   **Henri KORNAMANN, Merck Serono**

12:30 Lunch & visit of the exhibition

14:00 Workshops Part 1

15:30 Break & visit of the exhibition

16:30 Workshops Part 2

18:00 End of the workshops

20:00 Dinner

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**Wednesday, May 27**

9:00 Welcome of the participants

9:30 ADC Purification: Research vs. Manufacturing Techniques
   **Laurent DUCRY, Lonza**

10:00 Case Study: Design Principles for Single Use Manufacturing Facility
   **Gregor DUDZIAK, io-consultant GmbH & Co.KG**

10:30 Break & visit of the exhibition

11:00 Bulk Cold Chain Transfer Challenges
   **Fabian DE PAOLI, GSK Vaccines**

11:30 Synthetic Virus Like Particles (SVLPs) for the development of prophylactic and therapeutic vaccines
   **Armando ZUNIGA, Virometrix AG**

12:00 Lunch & visit of the exhibition

14:00 Visit: Choice between 2 plant visits
   **Merck Serono // Corsier-sur-Vevey**
   **Merck Serono // Aubonne**

17:00 End of the visits and Bioproduction Congress
   **Transfer to the SwissTech Congress Center**
WORKSHOPS PROGRAM

Tuesday, May 26

A3P workshops gather during half a day a limited number of people around a defined topic co-animated by a tandem of two specialists biotech users & trusted suppliers and an A3P moderator.

PURPOSE: To allow the participants to work together for an initial or a deeper knowledge either upon a defined technical or regulatory matter from a theoretical or a practical point of view. The defined subject is mainly explained and explored through shared case studies. The results/solutions of these case studies lead to written conclusions.

The two moderators are theory and practice experts on the subject of the workshop, their pedagogic approach of the subject must avoid any commercial and/or marketing matter.

SELECT YOUR WORKSHOP AMONG THE 8 TOPICS BELOW

1 - Set-up and optimization of a perfusion cell culture process

Jacky SCHMITT, Glycotope & Manfred PAPASPYROU, Business Consultant

Focus of the workshop:
- Handling large amounts of sterile liquid (cell culture media and harvests)
- Make sure that the process remains sterile over several weeks
- Usage of appropriate cell retention systems
- Single-use versus stainless steel bioreactors
- Commercial considerations

Targeted audience: Upstream technician, Upstream engineers and process scientists, medium production and logistics, process validation engineers.

2 - Passerelle Start Up : First batches make the right choice

Luc-Alain SAVOY, SGS & François CURTIN, GeNeuro

One key to success is constantly finding new ways to “secure our development” by creating value. The workshop will focused on how to prevent quality and variability in raw material supply; risk mitigation strategies; meeting future requirements by defining comparability attributes; ensuring the viral safety of raw materials; and set specification for the first batch as the level of purity and the characterization.

3 - Process validation for biotechnology-derived products

Marie Laure DRANSARD, Sanofi Pasteur & Animator to be confirmed

The 2011, FDA guideline on process validation is based on activities taking place over the lifecycle of the product and process and includes 3 stages:
- Stage 1: Process Design
- Stage 2: Process Qualification
- Stage 3: Continued Process Verification

The EMA draft guideline on process validation is based on 3 steps supported by the process development studies:
- Step 1: Process evaluation
- Step 2: Process verification
- Step 3: Ongoing process verification

The Biopharmaceutical industries often face for defining validation approaches complying with FDA and EMA guidelines.

The objectives of this workshop are:
- First, to compare both guidelines
- Then, to define a common validation approach satisfying both based on a case study2.

4 - Biosimilar Development and Characterisation trends and Challenges

Pierre-Alain GIROD, Selexis & Victor VINCI, Cook Pharmica

Biosimilar development does not enjoy the same luxuries of new drug development due to significantly condensed timelines from early development to First in Human (FIH). The development program needs to quickly accelerate towards preclinical and Phase I studies and typically Phase II studies are not required since dose response and other patient treatment concepts have already been established with the originator medicine.

The key challenge remains with demonstrating comparability and high similarity based on in-depth analytics which can often take multiple iterations in early-stage development. This takes more time that would normally be required of an originator product in early development and is conflicting with the need for rapid development.

The workshop will discuss trends, innovations and challenges in process development and characterization to achieve speed to market.
## WORKSHOPS PROGRAM

**Tuesday, May 26**

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<th>#</th>
<th>Title</th>
<th>Speakers</th>
<th>Description</th>
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<tr>
<td>5</td>
<td>Bioprocess and facility design enabling fast, efficient, scaleable and highly flexible manufacturing in a multi-product CMO environment</td>
<td>Miriam MONGE, Sartorius Stedim Biotech &amp; Simon UPHILL, Fujifilm Diosynth</td>
<td>This workshop will consider the challenges that the biotech industry faces for fast development and process optimization early on, making the right process and technology selection choices to ensure highest productivity and lowest cost of goods as the process is scaled up and prepared for cGMP manufacture. Sartorius Stedim biotech will walk you through their approach to bioprocess project management including the use of process modelling, simulation and facility design tools for optimized facility layout based on single-use or hybrid solutions. The Sartorius risk assessment approach for process validation will be explained by a regulatory expert and the methodology to ensure efficient operator training for hybrid or single-use systems will be addressed. Fujifilm Diosynth will present a case study on the design and implementation of a highly flexible multi-product facility based on single-use process trains Fujifilm Diosynth will present case study on the design and operation of highly flexible multi-product facilities based on the implementation of single-use process technology in their UK and US Sites.</td>
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<td>6</td>
<td>Quality by Design approaches to Viral Safety of Biopharmaceuticals</td>
<td>Caroline GOUSSEN, LFB Biotechnologies &amp; Anissa BOUMILIC, Merck Millipore</td>
<td>Workshop content: Biopharmaceutical processing has evolved recently to apply Quality By Design (QbD) approaches to investigate and establish process design space for one or multiple unit operation. While the primary goal of QbD is to ensure efficient and reproducible production of quality molecules, other aspects are now taken into consideration such as viral safety. Recent downstream development studies alongside with reported contamination cases emphasize the importance to identify critical parameters in order to define a «safe space» where the process step is effective for viral reduction. The implementation of a QbD approach for both, the quality and the safety of the drug substance, will be discussed. What will people learn: learn or discuss QbD vs traditional approaches to evaluate viral clearance for dedicated unit operations, point to consider when evaluating virus clearance technologies, examples of thorough evaluation of virus inactivation or removal process steps and challenges in QbD implementation. Targeted audience: Head of Development, QC Manager, Process Developers, Regulatory Manager, Virus Safety validation specialists.</td>
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<td>7</td>
<td>Case Study: Process analysis technology in Biotech Product Development</td>
<td>Yehoshua ALONI, TEVA Pharmaceutical &amp; Gai ANBAR, Comply</td>
<td>In our highly competitive market, the R&amp;D Units need to work in collaboration and high efficiency to bring to the market new products while meeting increasing budget constraints, shorter time to market and new regulatory requirements. Process Analysis Technology (PAT) is one of the recent regulatory requirements in development and production of biopharmaceutical products which will help to streamline development time. TEVA PHARMACEUTICALS will present their approach to PAT, QbD and the need, constraints and success factors for process and knowledge management in a Biopharma product development company. The workshop will highlight how to select critical parameters, to optimise data capture and analysis for each step of the process. In addition in order to secure data in a GMP environment, participants will have to resolve issues with capturing extensive and complicated data, limited analysis capabilities and limited information sharing. An ROI exercise will be proposed for demonstrating that the implementation of a «robust system» increased compliance, considerably reduce costs and shortened the product development cycle, hence launching the product faster with better quality and better control and better understanding of the production process.</td>
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<td>8</td>
<td>What strategy for biomanufacturing of clinical batches ?</td>
<td>Ludovic NGUYEN, Fab’entech &amp; André DUPONT, Accinov</td>
<td>Current strategies for the production of clinical batches rely on two approaches: outsourcing to CMO and producing internally. Projects, timelines, internal assets and company profile strongly impacts decision-making. To discuss this problematic: the French company Fab’entech will introduce the workshop with a case study highlighting its manufacturing strategy for the production of investigational new drugs. Then, a group discussion will address key decision factors to set-up biomanufacturing, with prepared materials/working sheets to address the subject. The workshop will end on concluding remarks summarizing the brainstorming.</td>
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VISIT OF BIOPRODUCTION PLANTS

Wednesday, May 27

CHOICE BETWEEN MERCK SERONO VEVEY / AUBONNE

The Merck Serono Biotech Center (MSBC) in Corsier-sur-Vevey, Switzerland is one of the largest and most technologically advanced biotech manufacturing plants in the world.

The MSBC complies with the strictest quality and environmental standards for manufacturing facilities. It has successfully passed multiple inspections from regulatory authorities from several countries including the United States, the European Union and Switzerland.

The Merck Serono Aubonne plant has the capability to release all bioproduction drug steps.

Merck Serono // Corsier-sur-Vevey

Process development
- Clone selection and cell bank generation
- Media development
- Cell culture
- Purification
- New technologies

Production
- 4 production suites
- 150,000 liter bioreactor capacity
- Commercial production of Rebif® (interferon beta-1a) for global markets
- Commercial production of Erbitux® (cetuximab) for global markets
- Production of new compounds for clinical trials
- Multiproduct set-up to provide flexible biopharmaceutical production capacity to the Merck group or external partners

Merck Serono // Aubonne

API Production
- Upstream
- Downstream
- Proteins for the treatment of fertility disorders (Gonal-f®, Pergoveris®, Luveris®, et Pergoveris®, Ovitrelle®)

Fill & Finish
- Formulation
- Aseptic Filling
- Freeze drying
- Visual Inspection
- Injection device
- Packaging
Access

SwissTech Convention Center
Quartier Nord de l’EPFL
Route Louis-Favre 2
CH - 1024 Ecublens

http://www.tstcc.ch

The SwissTech Convention Center is located at the north of the EPFL campus. It is easily accessible by car and public transport. From the center of Lausanne, the M1 metro stops right in front of the building and takes only 15 minutes (stop at “EPFL”).

Congress map

The Swiss Tech Convention Center // Lausanne
26th & 27th may 2015
Company/Société: ..............................................................................................................................................
Adress/Adresse: ..............................................................................................................................................
Zip code/CP: .................................. City/Ville: ........................................ Country/Pays: ......................................
VAT number/N° TVA Intra: ............................................................................................................................
Mr/ M. Mrs/Mme: ..............................................................................................................................................
Job title/Fonction: ..............................................................................................................................................
Phone/Tél.: .................................................. Mobile/Port.: .................................................................
E-mail/Courriel: ..............................................................................................................................................

Registration compulsory A3P Association / Adhésion du participant à l’association A3P OBLIGATOIRE : 180€ HT

☐ I register to the A3P Bioproduction Congress 2015 ................................................................. 850€* without VAT / HT
Je m’inscris au Congrès A3P Bioproduction 2015

☐ Special «Small companies» Offer (less than 20 employees), I register .................................................. 500€* without VAT / HT
Ma société a moins de 20 employés et je m’inscris au Congrès A3P Bioproduction 2015

☐ Workshop registration / Je m’inscris à l’atelier N° ............................ (Please tick one workshop / Choisir 1 atelier)

☐ Visit registration (Please tick one box / Ne cocher qu’une seule case)

☐ I will attend visiting the site Merck Serono, Vevey (limited to 60 participants) Je souhaite participer à la visite du site de Merck Serono à Vevey (max. 60 participants)

☐ I will attend visiting the site Merck Serono, Aubonne (limited to 60 participants) Je souhaite participer à la visite du site de Merck Serono à Aubonne (max. 60 participants)

☐ I do not wish to participate in a site visit / Je ne souhaite pas participer à une visite de site

Payment to A3P Services / Règlement à l’ordre d’A3P Services


☐ Chèque bancaire/Only for french companies

☐ Credit card n° ................................. Date d’expiration
Carte bancaire n°

Date ........................................
Signature

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