PPAR Pharmaceutical Process Analytics Roundtable
www.patroundtable.org

PHARMACEUTICAL PROCESS ANALYTICS ROUNDTABLE 2020

November 11-13

SANOFI

THE 2020 PPAR ROUNDTABLE COMMITTEE

STEERING COMMITTEE


Doherty Steve
Abbvie


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Biogen


Zhenqi Shi
Lilly

MERCK


Busolo Wabuyele
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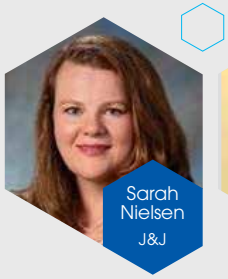
Sarah Nielsen
J&J


Jun Huang
Regeneron

ORGANIZING COMMITTEE


Christian Airiau
Sanofi


Marina Hincapie
Sanofi


Zheng Huang
Sanofi

THE 2020 PPAR ROUNDTABLE COMMITEE

Dear PPAR attendees,

We are very pleased to invite you to join the PPAR2020 conference which will be held virtually on November 11-13 from 9am to 1.30pm US ET.

Over the course of the 3 days we will discuss Industry progress in different areas such as Digital Transformation, Mechanistic modeling, PAT implementation and many more.

You will find in the program all the necessary information regarding Agenda, session chairs and zoom link.

Welcome to PPAR2020!

On behalf of the Sanofi organizing committee,
Christian Airiau, Marina Hincapie, Zheng Huang.

PROCEDURE FOR PARTICIPANTS

Join the conference from either a ZOOM Link or from the ZOOM app by selecting **"Join"** and enter **Meeting ID and Password.**

Day 1: Nov 11th: Meeting ID: 92788324348 and Password: 365898

ZOOM Link: https://sanofi.zoom.com/j/92788324348?pwd=MUVRY1FXRnEzanNZQ093WE54Z3RoUT09

Day 2: Nov 12th: Meeting ID: 96508899818 and Password: 330701

ZOOM Link: https://sanofi.zoom.com/j/96508899818?pwd=dkc4VW9YWnprcC9yeDFMTFk3MWUxdz09

Day 3: Nov 13th: Meeting ID: 96034830371 and Password: 041884

ZOOM Link: https://sanofi.zoom.com/j/96034830371?pwd=VmJHeGt2OW5NOExhNGp0NmdTNDhHZz09

Audio - Support

Make sure to put the sound on your device. You may use headphones for a better experience.

You can also check out for additional information:

Getting started with Zoom

Audio best practices

Back-up TC:

In case you encounter an issue with web conference, dial-in:

France: +33 1 8288 0188
Germany: +49 30 3080 6188 or +49 30 5679 5800
UK: +44 330 088 5830 or +44 131 460 1196
Sweden: +46 850 539 728 or +46 8 4468 2488
Switzerland: +41 43 210 71 08 or +41 22 591 00 05
Portugal: +351 308 810 988 or +351 211 202 618
US: +1 669 900 6833 or +1 646 876 9923

Find additional Zoom International dial-in numbers: **HERE**

Virtual Roundtable Calendar

Wednesday, November 11	EST	Thursday, November 12		EST	Friday, November 13
	8:00			8:00	
	8:30			8:30	
Virtual Breakfast Networking (with registration only)	9:00	**Virtual Breakfast Networking (with registration only)**		9:00	**Virtual Breakfast Networking (with registration only)**
	9:30			9:30	
PPAR2020 Introduction and Process Analytics survey results Christian Airiau Rob Guenard 10:00 a.m. - 11:00 a.m.	10:00	**PAT in Operational Excellence** Pedro Valente 10:00 a.m. - 11:00 a.m.		10:00	**Modeling LifeCycle management - RTRt** Sarah Nielsen Caitlin Schram 10:00 a.m. - 11:00 a.m.
	10:30			10:30	
Digital Transformation Victor Saucedo Guillermo Miro-Quesada Busolo Wabuyele 11:00 a.m. - 12:00 p.m.	11:00	**New Technology and Technology Needs** Steve Doherty Marina Hincapie 11:00 am. - 12:00 p.m.		11:00	**PPAR outreach in model maintenance and beyond** Zhenqi (Pete) Shi Tony Wang 11:00 a.m. - 12:00 p.m.
	11:30			11:30	
Virtual Coffee/Lunch Networking (with registration only)	12:00	**Virtual Coffee/Lunch Networking (with registration only)**		12:00	**Virtual Coffee/Lunch Networking (with registration only)**
Mechanistic/Hybrid Modeling as Part of Control Strategies Mark Henson Jun Huang 12:30 p.m. - 1:30 p.m.	12:30	**Process Analytics for Cell & Gene Therapy** Oliver Steinhof Dan Hill 12:30 p.m. - 1:30 p.m.		12:30	**Wrap-up Session** All 12:30 p.m. - 1:30 p.m.
	13:00			13:00	
	13:30			13:30	

Virtual Roundtable Sessions

11 November

10:00 – 11:00 AM US ET

Session Facilitator

Christian Airiau
Rob Guenard

PPAR 2020 Introduction and Process Analytics survey results

This initial session will provide an overview of the 3-day program and position the main topics we have selected for this 2020 edition of PPAR.

We will share the results of the survey sent to attendees in October, summarizing the key points.

This is the 4th consecutive year that PPAR runs this survey and we look forward to sharing the major trends with you, gathering your insights and comments.

11:00 – 12:00 PM US ET

Session Facilitator

Victor Saucedo
Guillermo Miro-Quesada
Busolo Wabuyele

Digital Transformation

Digital Transformation (DT) – developing fully digitized processes to centralize and use information - is impacting all industries and everyone's lives. This session will start the discussion defining what DT is and how it overlaps with PAT. It will foster the discussion on the benefits and opportunities of Digital Transformation on PAT and the challenges to implement new Digital Transformation technologies. More specifically, the discussion will include the role of Digital Transformation to develop faster processes, the role in GMP manufacturing and the value proposition shift for other groups, such as Quality.

12:30 – 1:30 PM US ET

Session Facilitator

Mark Henson
Jun Huang

Mechanistic/Hybrid Modeling as Part of Control Strategies

Discussion of how mechanistic and hybrid models differ from empirical models in the context of control strategies:

- Opportunities for use – process vs. overall control strategy
- Dependencies (e.g., corroborating sensors/data/models)
- Development/deployment/validation considerations
- Quality/Risk experiences
- Regulatory experiences

Virtual Roundtable Sessions

12 November

10:00 – 11:00 AM US ET

Session Facilitator

Pedro Valente

PAT in Operational Excellence

PAT may be used not only for Quality but also to increase efficiency. PAT in Operation Excellence session aims to capture the current best practices from the Industry, and predict the future trends in using PAT focused on Lean and Agile manufacturing.

Topics for discussion may include the use of PAT to improve process capability, to improve equipment OEE, for predictive maintenance (e.g.: via modeling), or as an operational decision tool (assistive technology). A survey to the participants will performed to screen preferred topics; results will be shared during the session.

11:00 – 12:00 PM US ET

Session Facilitator

Steve Doherty
Marina Hincapie

New Technology and Technology Needs

Take advantage of the collective experience in this community to share technical benchmarking with your peers from across the industry. Many of us encounter common technical issues (e.g. low dose measurement in formulations, robust sterile sampling for off-line analysis), and we all work to identify novel solutions. Sharing our experience in using these technologies can lead to more robust commercial supply and more rapid commercialization for those technologies that meet our needs. Frequently there is existing equipment from other industries that can be leveraged for pharmaceutical purposes, or reconfiguration of small molecule instruments to work in biologic applications.

Gaining a new technical lead or avoiding investment of time in a non-viable approach may be one of clearest benefits to participating in PPAR, so submit your problem statements and share your experience in this interactive session.

12:30 – 1:30 PM US ET

Session Facilitator

Oliver Steinhof
Dan Hill

Process Analytics for Cell & Gene Therapy

This session will offer an opportunity to exchange on our experiences around Cell & Gene Therapy. Who works on these modalities, to what extend and at what stage of development? How are opportunities for the implementation of PAT identified? As many of the GT processes share a lot of similarities with other mammalian cell culture processes, what can be shared with these? What are challenges specific to Cell & Gene Therapy? In USP, current processes coming out of development are based on adherent cell culture, which is not suitable for scale up. The transfection/infection step using plasmids or virus are new operations. In DSP, there are typically less purification steps than in mab processes, but new unit operations such as virus inactivation need to be introduced.

Virtual Roundtable Sessions

13 November

10:00 – 11:00 AM US ET

Sarah Nielsen
Caitlin Schram

Modeling LifeCycle management - RTRt

In this session the benefits and challenges of using real time release testing will be discussed. Case studies and lessons learned will be presented. Some of the benefits are significant reduction in investigations, faster batch release and Green Benefits. Some of the challenges include life cycle management of the chemometric models, site versus R&D responsibilities, and the timeline for development and implementation.

11:00 – 12:00 PM US ET

Zhenqi (Pete) Shi
Tony Wang

PPAR outreach in model maintenance and beyond

The dynamic nature of the field of PAT presents PPAR members a lot of opportunities to contribute to other non-profitable organizations in the format of white paper, oral presentations and webinar etc. with the intention to advance both technical and regulatory agenda on those hot topics with industry consensus. It is important for PPAR to align across the industry on a variety of ongoing efforts in those non-profitable organizations using the "one-voice" approach. The session intends to provide a landscape survey on those ongoing efforts and showcase a case study PPAR participated since 2019 with BioPhorum on PAT model lifecycle management.

12:30 – 1:30 PM US ET

All

Wrap-up Session