



PPAR2021 - Introduction

November 9th – 10th

PPAR Pharmaceutical Process Analytics Roundtable
www.patroundtable.org



2021



THE 2021 PPAR ROUNDTABLE COMMITTEE



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www.patroundtable.org

Skin cells at 20x magnification



Dear PPAR attendees,

We are very pleased to invite you to join the PPAR 2021 conference which will be held virtually & in-person on November 9th - 10th. Over the course of the 2 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 PPAR2021!

On behalf of the Janssen Organizing team

Zoom Meetings

November 10th

<https://jnymeetings.zoom.us/j/96587971304?pwd=VktzWEJFZXF4bUMxUStUbEdiOE56dz09>

November 10th

<https://jnymeetings.zoom.us/j/95699170058?pwd=WFBkeUxBZSs1ZE1JSEVkcQTZk02dz09>

Time	Tuesday 9 th November 2021	Time	Wednesday 10 th November 2021
8:30 - 9:30 AM EST	Real Time Release (Face to Face) Joep Timmermans	8:30 - 9:30 AM EST	PAT Application for Biopharmaceuticals (Face to Face) Tony Wang, Karin Balss, Diana Ritz
10:00-10:05	Opening Remarks – Zoom Call Opens	10:00-10:05	Opening Remarks – Zoom Call Opens
10:05 – 11:00 AM EST	Survey Christian Airiau	10:05–11:00 AM EST	APC/Ongoing Consortium Benoit Igne
11:00 – 12:30 PM EST	Digital Transformation Victor Saucedo	11:00 –12:00 PM EST	SM MSPC Case Studies Dan Hill
12:30-1:00	Break/Lunch	12:00-12:30	Break/Lunch
1:00 – 1:30 PM EST	PAT Talent Gary McGeorge Busolo Wabuye	12:30 – 1:30 PM EST	LM MSPC Case Studies Tony Wang
1:30 – 2:30 PM EST	Regulatory and Modeling Sarah Nielsen	1:30 - 2:30 PM EST	Technology Session Karin Balss Steve Doherty Zhenqi (Pete) Shi
2:30 – 5:00 PM EST	Site Tour	----	----

November 9th



8:30 – 9:30 AM EST



Joep Timmermans /
Sarah Nielsen

10:00 – 11:00 AM EST



Christian Airiau
/ Dan Hill

**11:00 – 12:30 AM US
ET**



Victor Saucedo

1:00 – 1:30 PM EST



Gary McGeorge
Busolo Wabuye

1:30 – 2:30 PM EST



Sarah Nielsen

2:30 – 5:00 PM EST



Real Time Release

This face-to-face morning session will include an open discussion on real time release testing. Including implementation and lifecycle management of real time release testing strategies.

Survey

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

Digital Transformation

Developing fully digitalized processes to centralize and use information. This session will discuss DT and it's overlap with PAT. It will also explore the benefits and opportunities of DT on PAT as well as the challenges faced during its implementation.

PAT Talent

PAT is used for Quality, but it could also increase efficiency substantially. Topics for discussion may include its use to improve process capability, predictive maintenance (modeling) or as an operational decision tool (assistive technology)

Regulatory and Modeling

Thomas O'Connor, Ph.D., Director, Division of Product Quality Research, CDER, US FDA will join us for an open discussion. The topics will include the recent NIR Guidance and enhancing implementation of advanced manufacturing.

Site Tour

Janssen Cell Therapy Center and Discovery Sciences
Discovery Sciences (Biophysics Characterization and Cell Line Development
Groups)

November
10th



8:30 – 9:30 AM US ET



Tony Wang
Karin Balss
Diana Ritz

PAT Application for Biopharmaceutics

In this face-to-face discussion we will discuss best practices and challenges of implementing PAT. The discussion will range from overcoming technical challenges for implementing PAT in this new digital age to building and realizing business benefits for the PAT technology. Regulatory concerns are also a factor that many of us must consider when implementing PAT and this will be explored as well. We look forward to an engaging discussion so that we may learn from all the PAT practitioners in the industry.

10:00 – 11:00 AM US
ET



Benoit Inge

APC/Ongoing Consortium

This session will include a general conversation of APC/Ongoing Consortium (ASTM, IQ, ISPE). Updates/Feedback and Review APC ASTM white paper will be included in the discussion.

11:00 – 12:00 PM US
ET



Dan Hill

SM MSPC Case Studies

We would like to use this opportunity to share some case studies where multivariate statistics have been used in our industry. Process monitoring is a core application for this technology; however, many have also utilized multivariate statistics in a control setting. Through these case studies, we hope to invoke some insights of people working in this area and discuss best practices.

12:30 – 1:30 PM US ET



Tony Wang

LM MSPC Case Studies

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1:30 – 2:30 PM US ET



Karin Balss
Steve Doherty
Zhenqi (Pete)
Shi

Technology Session

This session will focus on novel technologies or novel applications of existing technologies. Members are invited to submit novel technology that you have encountered, or specific measurement problems that you haven't been able to address. Technologies for any platform are welcome.



