



PPAR-2024

TAKEDA - LEXINGTON

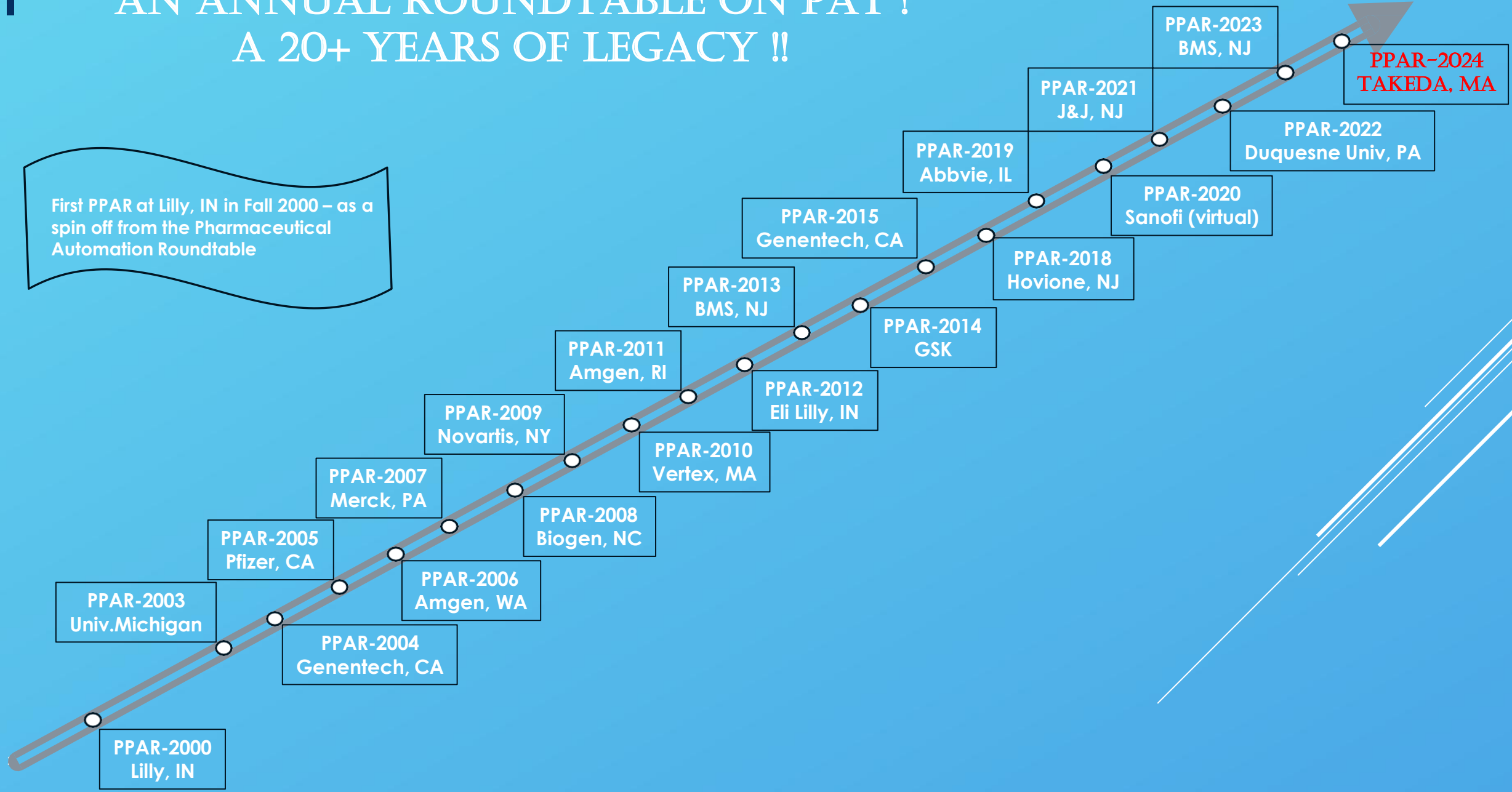
300 Shire Way, Lexington, MA - 02421

Nov 14-15, 2024

WELCOME TO PPAR AN ANNUAL ROUNDTABLE ON PAT ! A 20+ YEARS OF LEGACY !!



First PPAR at Lilly, IN in Fall 2000 – as a spin off from the Pharmaceutical Automation Roundtable



NEWS ARTICLES ON PAST PPAR (2003-2005)



by columnist Terrence K McMahon, in www.controlglobal.com

2003

About 30 process analyzer specialists gathered in Ann Arbor, Mich., in mid-September for the Third Pharmaceuticals Process Analyzer Roundtable (PPAR). Hosted by Pfizer, the meeting drew two dozen analyzer professionals from 10 pharmaceutical manufacturers, a process measurement specialist from the National Institute of Standards and Technology, and the directors of the two leading process analytical academic centers (Center for Process Analytical Chemistry at University of Washington and Measurement and Control Engineering Center at University of Tennessee-Knoxville).

Clearly the process analytical technology (PAT) initiative within FDA [CONTROL--July 02, p74 and Mar. 03, p70] was at the top of everyone's agenda. The formal guidance document was released on September 3 as part of FDA's comprehensive review of the existing regulatory structure for pharmaceuticals manufacturing.

The FDA is attempting to promote a more thorough understanding of pharmaceutical manufacturing processes and, with this understanding, more predictable and efficient manufacturing. Although process analyzers are potentially the vital tool, the PAT initiative has always been about process understanding, predictability, and efficiency, by whatever means can achieve this goal.

<https://www.controlglobal.com/home/article/1138373/8/fdas-analytical-initiative-gathers-steam>

2004

IN OCTOBER 2004, BOTH THE PHARMACEUTICALS PROCESS Analyzer Roundtable (PPAR) and its older brother the Pharmaceuticals Automation Roundtable (PAR) held their respective annual gatherings. These roundtable sessions are designed to facilitate sharing of non-proprietary practices and techniques in these two disciplines within the pharmaceuticals/biotech manufacturing community.

The fourth PPAR meeting was hosted by Genentech in South San Francisco (Oct 12-14). Twelve manufacturers (split 50-50 between traditional pharma and biotech) as well as the two leading research consortia for process analysis were represented among the thirty (30) attendees.

About half of the attendees participated in an extensive tour of a Genentech bioprocess synthesis (fermentation) and separation (process chromatography) facility. Special attention was devoted to the use of on-stream analyzers and analytical data in these operations.

The participants met for two full days of discussion on topics including:

- Formalized Vendor Auditing Procedures
- European and Other Overseas PAT Filing Procedures
- Review of FDA's PAT Guidance Document
- Dealing with Research Data in the Implementation of PAT
- Organizational Structures for PAT

A teleconference was also held with Chris Watts and Ali Afnan of FDA CDER's PATRIOT Team. CDER's progress in training inspectors was reviewed as well as their intention to invite European and Japanese regulators to participate in the next round of PATRIOT training courses.

The results of a benchmarking survey (12 companies participated) were also discussed. The survey covered 13 organizational questions (e.g., size of PAT effort □ number of professionals?), 12 manufacturing questions (e.g., where is PAT currently used?) and 9 research questions (e.g., barriers to the use of PAT in R&D?).

Amgen and Pfizer are potential hosts for the 2005 PPAR session.

<https://www.controlglobal.com/control/distributed-control/article/11383551/roundtable-meetings-on-pharmaceutical-manufacturing-technology>

2005

By Terry K. McMahon, CONTROL Columnist **THE FIFTH** meeting of the Pharmaceuticals Process Analytics Roundtable (PPAR-5) was held in late September at Pfizer's R&D campus in La Jolla, Calif. About 25 individuals attended, representing 13 manufacturers and three supporting organizations. The manufacturers were Amgen, Baxter, Eastman Chemical, Genentech, Invitrogen, Lilly, Merck, NovoNordisk, Pfizer, Talecris (formerly Bayer), 3M Pharma, Vertex and Wyeth. The supporting organizations were the National Institute for Science and Technology (NIST), the University of Washington's Center for Process Analytical Chemistry (CPAC), and the University of Tennessee's Measurement and Control Engineering Center (MCEC). John Loran, science and technology VP at Pfizer's La Jolla-based R&D Center for Pharmaceutical Sciences, opened the meeting, remarking on Pfizer's early use of NIR for process development. With federal regulators demanding sharply increased levels of process understanding and process robustness, now is the time to link key business drivers, such as Pfizer's Right the First Time (RFT), with technological initiatives in pursuit of FDA's Process Analytical Technology (PAT) guidance. Early meetings of this PPAR group, as well as its parent, Pharmaceuticals Automation Roundtable, were initiated by corporate attorneys concerned with potentially collusive, non-competitive discussions. Lately, these introductions have stressed using process technology to promote product safety and uniformity, while improving manufacturing efficiency. Collaboration between FDA's Center for Drug Evaluation and Research (CDER) and pharmaceutical manufacturers to achieve a deeper scientific understanding of drug manufacturing processes is the PAT Initiative's objective. This deeper understanding leads to more robust processes, product reliability, and economic benefits. Several attendees were concerned that FDA's Center for Biologics Evaluation and Research (CBER), a critical group for biotech manufacturers, was not a part of this effort. However, a telephone conference with CDER's Ali Afnan assured them that CBER was represented on the PAT Initiative's steering committee and

"While process understanding (PU) is the real meaning of the Process Analytical Technology (PAT) guidance, □ PU Initiative □ just didn't have the proper ring to it. □

<https://www.controlglobal.com/home/article/11383254/ppar-5-convenes-in-san-diego>

PPAR-2024 AT TAKEDA, MA



Organizing Committee



Muthu Meiyappan
Takeda



Mark Henson
Takeda

Takeda Support Team



Jennifer Tran
Takeda



Gregory Pino
Takeda

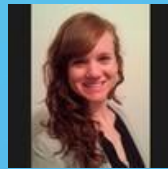
Steering Committee



Alyssa Fidanza
Amgen



Busolo Wabuye
Merck



Caitlin Schram
Vertex



Carrie Sowers
AstraZeneca



Edita Botonjic-Sehic
ReciBio Pharm



Elyse DiMaso
BMS



Erin Masucci
J&J



Joep Timmermans
Pfizer



Marina Hincapie
Sanofi



Nuno Matos
Hovione



Sameer Talwar
GSK



Zheng Li
Genentech

NOV 14TH: DAY-1



Takeda – Lexington, 300 Shire Way, Lexington, MA-02421. Room# 1506

MS Teams video conferencing
Meeting ID: 391 903 242 905
Passcode: RotthC

How to join MS Team with ID/Passcode:

- Select Calendar on the leftmost side of MS Teams
- Select Join with an ID

7:45-8:15 am	Breakfast at Takeda-Lexington	
Session 1 (8:15am-12:30pm)		Moderators
8:15-8:45 am	Takeda Leadership Welcome address & Introductions	Mike Thien (Head of Pharmaceutical Sciences, Takeda) & Muthu Meiyappan
8:45-10:15 am	1.1 New Technology	Marina Hincapie (Sanofi) & Christine Massie (Sanofi)
10:15-10:30 am	Break	
10:30-11:30 am	1.2 Industry Survey	Elyse DiMaso (BMS) & Erin Masucci (J&J)
11:30am-12:30pm	1.3 New Modalities	Edita Botonjic-Sehic (ReciBio Pharm)
12:30-1:30 pm	Lunch	
Session 2 (1:30-5:15 pm)		
1:30-3:00 pm	2.1 PAT Business case	Carrie Sowers (AZ) & Mark Henson (Takeda)
3:30-3:15 pm	Break	
3:15-5:15 pm	2.2 Takeda Lex Lab Tour	Greg Pino & Team
5:15-6:00 pm	Email catch-up & move to restaurant	
6:00-8:30 pm	Dinner at il Casale-Lexington	1727 Mass Ave, Lexington, MA-02420

NOV 15TH: DAY-2



Takeda – Lexington, 300 Shire Way, Lexington, MA-02421. Room# 1506

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7:45-8:15 am	Breakfast at Takeda-Lexington	
Session 3 (8:15am -12:30pm)		
8:15-9:15 am	3.1 Adaptive Sensor Fusion	Caitlin Schram (Vertex) & Nuno Matos (Hovione)
9:15-10:15 am	3.2 AI/ML & Digital Twin	Sameer Talwar (GSK) & Busolo Wabuye (Merck)
10:15-10:30 am	Break	
10:30-11:30 am	3.3 Tech Transfer to Manufacturing	Marina Hincapie (Sanofi) & Zheng Li (Genentech)
11:30am-12:30 pm	3.4 Rethinking Model Validation	Alyssa Fidanza (Amgen) & Ana Costa (Hovione)
12:30-1:30 pm	Lunch	
1:30-2:00 pm	4.1 Misc	30 min - left over discussions
2:00-2:30 pm	4.2 Wrap-up	Mark Henson (Takeda)

Session	Moderators	Session Description
1.1 New Technology	Marina Hincapie & Christine Massie (Sanofi)	Discussion highlighting emerging technologies and critical technology needs essential for advancing the PAT industry
1.2 Industry Survey	Elyse Dimao (BMS) & Erin Masucci (J&J)	Since 2017, PPAR has captured results from a benchmarking survey designed to understand the state of PAT in the pharmaceutical and biotechnology industry. The results from this year will be presented along with past results for a discussion on the adoption of PAT in our industry.
1.3 New Modalities	Edita Botonjic-Sehic (ReciBio Pharm)	Development of new modalities (ex: RNA therapeutics) has seen a huge expansion in recent years. This surge in demand has driven growing need to enhance manufacturing processes, particularly in terms of speed and quality. What role with PAT play in enhancing new modalities production through batch and/or continuous manufacturing?
2.1 PAT Business Case	Carrie Sowers (AZ) & Mark Henson (Takeda)	PAT projects require significant resourcing and leader support to be successful. This discussion will highlight some key elements and lessons learned for building a robust business case and securing approval.
3.1 Adaptive Sensor Fusion	Caitline Schram (Vertex) & Nuno Matos (Hovione)	Using a sensor-fusion example as starting point, presented at an EMA Quality Innovation Group public forum, to discuss pathways being used for non-standard modeling (mechanistic, adaptative, AI/ML, etc.) and if there is a gap to fill in establishing a standard.
3.2 AI/ML & Digital Twin	Sameer Talwar (GSK) & Busolo Wabuye (Merck)	Sharing experience related to developing and deploying L1 (digital model), L2 (digital shadow), L3 (digital twins), and underlying AI/ML models. Lifecycle management of such solutions, utilization of twins to support process understanding, development, and manufacturing operations.
3.3 Tech Transfer to MFG	Marina Hincapie (Sanofi) & Zheng Li (Genentech)	Best practices for scaling PAT from development to manufacturing. Key topics include handling instrument variability across sites, ensuring calibration consistency, meeting regulatory requirements, and managing data integrity, especially when using historical data for model validation.
3.4 Rethinking Model Validation	Alyssa Fidanza (Amgen) & Ana Costa (Hovione)	In this session, we will explore innovative approaches to model validation within biomanufacturing. Current methods often require extensive time, resources, and testing. We will aim to discuss strategies for achieving efficient and agile validation that still meet regulatory requirements. Attendees are encouraged to share their experiences in balancing efficiency with compliance within the evolving landscape of biomanufacturing.

PPAR-2024 PARTICIPANTS LIST



Alyssa Fidanza	Amgen	In person
Ana Costa	Hovione	In person
Andre Cruz	Hovione	Virtual
Andrew Palm	Pfizer, Inc	In person
Ankita Naik	Hovione	Virtual
Caitlin Schram	Vertex	In person
Carl Anderson	Duquesne University	In person
Carrie Sowers	AstraZeneca	In person
Christine Massie	Sanofi	In person
Curt Zanelotti	AstraZeneca	Virtual
Dhanuka Wasalathanthri	Bristol Myers Squibb	In person
Diana Ritz	GSK	In person
Edita Botonjic-Sehic	ReciBioPharm	In person
Elyse DiMaso	Bristol Myers Squibb	Virtual
Erin Masucci	J&J	In person
Fernando Nunes de Barros	Hovione	In person
George Zhou	Merck	Virtual

Greg Doddridge	AbbVie	In person
John P. Marino	NIST	Virtual
John-David McElderry	Biogen	In person
Larry McDermott	Vertex	In person
Marina Hincapie	Sanofi	In person
Mark Henson	Takeda	In person
Mark Jandreski	ReciBioPharm	In person
Martin Warman	Warman Consultancy	Virtual
Michael Tarlov	NIST	In person
Muthu Meiyappan	Takeda	In person
Nuno Matos	Hovione	Virtual
Sameer Talwar	GSK	Virtual
Sankaran Anantharaman	Abbvie	In person
Sneha Suman	Amgen	In person
Yuxiang Zhao	Bristol Myers Squibb	In person
Yi Zhang	AstraZeneca	Virtual
Zheng Li	Genentech	In person

EVENT LOGISTICS



Contacts:

Muthu Meiyappan - 781 583 8205, muthu.meiyappan@takeda.com

Mark Henson - 484-354-3515, mark.henson@takeda.com

Nov 13th 6:00-8:00pm – Networking

Kings – Burlington

52 2nd Ave, Burlington, MA 01803

Nov 14-15, Day-1/Day-2 event starts at 7.45am

Takeda Lexington Site

300 Shire Way, Lexington, MA 02421

Room# 1506

(Visitors' parking behind 200 Shire Way)

Nov 14th 6:00-8:30pm – Team Dinner

il Casale - Lexington

1727 Massachusetts Ave, Lexington, MA 02420

(town parking lot behind the restaurant)

Takeda – Lexington site map

