



PPAR 2024 Highlights

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What is PPAR?



- Pharmaceutical Process Analysis Roundtable
- It is a pre-competitive discussion forum of Process Analytical Technology (PAT) practitioners from ~20 Pharma and Biotech companies which has been meeting annually at a rotating host company site since 2000.
 - Abbvie, Amgen, ArrantaBio, AstraZenca, Baxter, Bayer, Biogen, BMS, Duquense University, Expo Process Analytics, Genentech, Gilead, GSK, Hovion, Johnson&Johnson, Eli Lilly, Lyndra, Merck, MIT, Novartis, Novo Nordisk, Pfizer, Procter & Gamble, Roche, Sanofi, Vertex
- The mission of PPAR is to enable networking between PAT practitioners for discussion of experiences, best practices, new technologies, and challenges & needs for PAT spanning the industry.

PPAR Benchmarking Survey



- Since 2017, a survey is sent out to all the companies collect information around their PAT.
 - [Survey Response 2024.docx](#)
 - It is designed to understand the state of PAT in the Pharma/Biotech industry
 - Survey questions range from modalities, skills, size of PAT to what technologies we are utilizing, investment and acknowledgement of use

New Technology Session



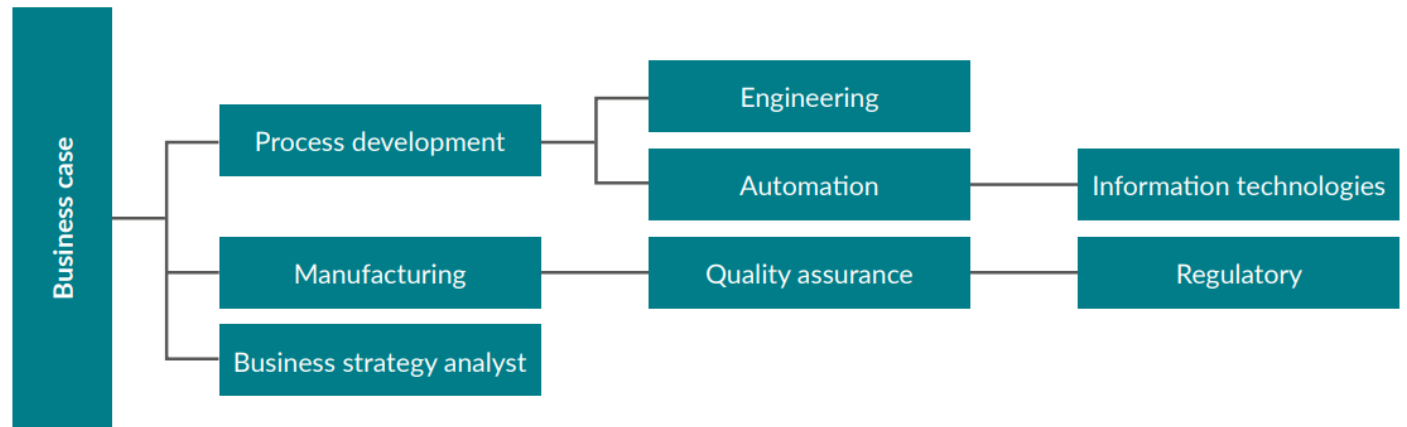
- Discussion amongst the companies highlighting emerging technologies and critical technology needs essential for advancing the PAT industry
 - 2024PPAR_New Technology [DISTRIBUTE].pptx
- After PPAR, another survey was shared amongst the attendees..
 - 2024PPAR_Technology Survey Response.pptx

Session	Moderators	Session Description
1.3 New Modalities	Edita Bottonjic-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.

PAT Business Case

- **ECONOMIC COST/BENEFIT**
 - Capital investment, development, training, LCM costs
 - Reduced offline QC testing (in-process, release)
 - Fewer lost batches
- **QUALITY**
 - Reduced variability via control or continuous improvement
 - Improved assurance of Quality via large-N sampling
- **SPEED**
 - Accelerated development – knowledge, decisions, etc.
- **SUSTAINABILITY & EFFICIENCY**
 - Carbon footprint reduction (energy, solvents, consumables)
 - Water reduction (washing of lab glassware, buffer reduction)
 - Efficiency (end-point determination, reduced hold times, no invasive sampling)
- **SAFETY**
 - Elimination of physical sampling

Potential Business Case Contributors:
From **PAT Monitoring & Control Roadmap**
(BioPhorum, Sept 2024)



- What elements have either **WORKED** or **FAILED** in your pitches to senior stakeholders?
- What best practices have you identified for building (or pitching) a business case?
- For successful PAT implementations, what were the big benefits captured?
 - **ANY NOVEL (AND/OR INTANGIBLE) BENEFITS THAT CAN BE SHARED FOR FUTURE BUSINESS CASES?**