December 11-12, 2024 | Philadelphia, PA

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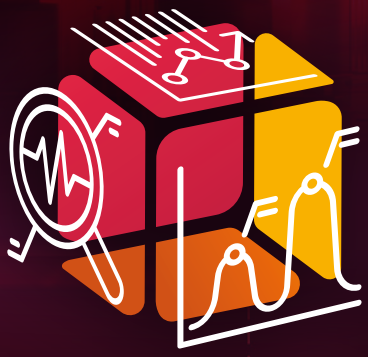

3rd Annual

PAT & Real Time Quality Summit

Control the Future of Smart Drug Manufacturing

Successfully Implement PAT Across the Drug Development Lifecycle to Increase Automation & Drive Cost Efficiency

Expert Speakers Include:

Lorenz Liesum
Head of Advanced Analytical Technologies
Roche

Andreas Kunov Kruse
PAT Specialist
Novo Nordisk

David Zamora
Global Statistical & PAT Lead
Novartis

Emmanuel Appiah
Director, Analytical Enabling Capabilities - Analytical R&D
Merck

Arsh Vyash
Research Data Scientist
Vertex

Maria Silva Elipe
Associate Director, NMR Process Development
Amgen

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Welcome to the 3rd PAT & Real Time Quality Summit

3rd Annual PAT & Real Time Quality Summit
Control the Future of Smart Drug Manufacturing

December 11-12, 2024 | Philadelphia, PA

PAT tools have continued to increase in their maturity over the past year, alongside the required software and chemometrics for control success, creating a perfect storm to finally disrupt classical inefficient quality and analytical approaches, and create the digital manufacturing maturity needed for tomorrow.

Returning for the biopharmaceutical industry for a 3rd year, the **PAT & Real Time Quality Summit** is the only conference dedicated to connecting novel technology to the commercial reality of manufacturing decision making.

From R&D process understanding for new modalities to validating strategies of real time release and lights out manufacturing for established products, the **3rd PAT & Real Time Quality Summit** is the end-to-end playbook for making an impact with PAT in a pharmaceutical environment.

Join **60+ leading PAT scientists, engineers, process development, CMC, MSAT** and **quality** experts through data-led case studies, roundtables fostering collaborative discussions and KOL-led panel debates. Don't get left behind the wave of innovation and meet stakeholders' demands for speed to market, agile and streamlined operations and return on investment through transformative PAT & real time quality control.

What Past Attendees Had to Say:

"A good balance between talks, networking, and roundtables. The roundtable discussions were helpful in learning what others in the field are working on"

Senior Vice President, Scientific & Business Operations, LumaCyte

"Unlike many other professional conferences I have attended, this one had a much more collaborative environment. The information was helpful, but the peer insight was unique at this event"

Senior Principal Development Engineer, Noven Pharmaceuticals

KEY BENEFITS OF ATTENDING

Unlock Cutting-Edge Strategies for PAT Implementation

Gain valuable insights into the successful implementation of PAT across various stages of drug development. Learn from industry leaders at **Roche** and **Takeda Pharmaceutical** about overcoming technical, regulatory and compliance challenges to ensure effective and sustainable PAT integration in commercial manufacturing

Optimize Efficiency & Precision With Advanced Analytical Technologies

Discover the latest advancements in analytical technologies such as liquid chromatography and NMR for real-time process monitoring where **Pfizer**, **Amgen** and **Merck**. Demonstrate how to enhance operational efficiency, reduce solvent usage, and improve process control

Enhance Process Reliability & Quality Through Automation & PAT Tools

Explore how to balance automation with human expertise in continuous processing and flow chemistry by integrating advanced PAT tools for real-time monitoring. Learn how **Vertex** and **GlaxoSmithKline** utilize data analytics and machine learning to interpret complex process data, enabling more informed decision-making and improving overall process reliability and product quality

Strengthen Compliance & Regulatory Adherence in PAT Implementation

Delve into the challenges of meeting regulatory standards in PAT adoption with sessions dedicated to navigating compliance issues. Experts from **Merck** and **Seagen** will share strategies for ensuring secure data capture, real-time compliance testing, and adherence to GMP requirements, ultimately enhancing production efficiency and reducing lead times

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Your Expert Speakers

Aishwarya Ramanan
Downstream Manufacturing, Science, Technologies Labs & Innovation Scientist PAT
Seagen

Andreas Kunov Kruse
PAT Specialist
Novo Nordisk

Arsh Vyash
Research Data Scientist
Vertex

David Zamora
Global Statistical & PAT Lead
Novartis

Elliott Schmitt
Manufacturing Intelligence, PAT
Novo Nordisk Engineering

Emmanuel Appiah
Director, Analytical Enabling Capabilities -Analytical R&D
Merck

Kim Nguyen
Senior Scientist
MilliporeSigma

John-David McElderry
Associate Director - Analytical Systems
Biogen

Lorenz Liesum
Head of Advanced Analytical Technologies
Roche

Manoharan Ramasamy
Director
Merck

Maria Silva Elipe
Scientific Associate Director
Amgen

Nidhi Kotecha
Program Director
Gates Biomanufacturing Facility

Renee Hart
President & CBO
LumaCyte

Jeff Elleraas
Senior Scientist
Pfizer

Rohit Lokhande
Senior Continuous Manufacturing Manager
US Pharmacopeia

Samira Beyramysoltan
Senior Scientist
GlaxoSmithKline

Shashi Prajapati
Associate Director
Vertex

Sankaran Anantharaman
Head of PAT & Innovation Labs - Small Molecule CMC – Biologics
AbbVie

Fabrice Thomas
Senior R&D Manager - PAT Raman Technology
MilliporeSigma

"Well attended with representatives from companies that are highly influential in the PAT space. Small enough of a show to make networking with others comfortable. Plenty of opportunities to share thoughts with others."

2nd PAT & Real Time Quality Attendee, Sales & Business Development Manager, Optimal Industrial Technologies

Conference Day One
Wednesday, December 11

7.45 Check In Morning Coffee & Light Breakfast

8.25 Chair's Opening Remarks

Optimizing Automation & Human Intervention in Continuous Processing

8.30 **Balancing Automation & Human Intervention in Continuous Processing for Optimal Efficiency**

Arsh Vyash
Research Data Scientist
Vertex

- Explore technical integration of advanced automation systems into existing workflows, addressing challenges in compatibility, interoperability, and scalability
- Focus on upskilling personnel to manage and collaborate with automated systems, using real-time data to enhance decision-making and process control
- Implement sophisticated error detection and correction in automated systems to ensure product quality, reduce downtime, and adapt to changing production demands

Maximizing Efficiency & Compliance in PAT Lifecycle Management

9.00 **Quantitative Cellular PAT Analytics Driving Improvements in Advanced Therapy Process and Production Outcomes**

Renee Hart
President & CBO
LumaCyte

- Label-free analysis of intrinsic biochemical and biophysical properties of cells provides real-time insights into cellular changes occurring throughout a manufacturing process. Additionally, ensuring robust cellular fitness of starting material is a crucial component to manufacturing and treatment success
- Learn how Laser Force Cytology™, a label-free, quantitative precision PAT enables real-time monitoring of CQAs and CPPs delivers insights into complex manufacturing processes through its optical force univariate and multivariate machine learning predictive capabilities

9.30 **Panel Discussion: Optimizing PAT Transition from Early Development to Clinical Phases**

- Utilizing PAT tools in the development phase to optimize processes and improve process understanding, paving the way for effective clinical GMP (Good Manufacturing Practice) implementation
- Addressing and mitigating process developers' reluctance to monitor processes during manufacturing, ensuring the timely and efficient deployment of PAT tools
- Implementing strategies to expedite the transition from development to clinical phases, minimizing delays and enhancing overall project timelines

Sankaran Anantharaman
Head of PAT & Innovation Labs - Small Molecule CMC – Biologics
AbbVie

Renee Hart
President & CBO
LumaCyte

10.15 Morning Break & Speed Networking

Streamlining Biologics Manufacturing for Efficiency

11.15 **Crossing the Finishing Line: Implementation of RTRT/PAT for a BioTech Drug Product**

Lorenz Liesum
Head of Advanced Analytical Technologies
Roche

- The elements of an RTRT/PAT-based control strategy for a BioTech Drug Product
- Ensuring effective commercial adoption and overcoming technical, regulatory and compliance-related challenges for an aseptic process
- Harmonizing the goals of development and technical operation to ensure a smooth and sustainable implementation. What are the lessons learned?

11.45 **Navigating Regulatory & Compliance Challenges in PAT Implementation**

Nidhi Kotecha
Program Director
Gates Biomanufacturing Facility

- Establish secure, reliable data practices that comply with regulatory standards for trustworthy, auditable records in PAT
- Develop robust data handling for machine learning inputs, ensuring quality and accuracy to support real-time decision-making
- Employ advanced PAT tools for compliance monitoring and error reduction, ensuring adherence to GMP standards for smoother commercial adoption

Conference Day One
Wednesday, December 11

Shashi Prajapati
Associate Director
Vertex

12.15 **Managing Complexity in Gene Therapy Manufacturing**

- Managing the complexity of gene therapy production by maintaining precise control over multiple variables
- Using sophisticated PAT tools to monitor and control transduction efficiency and vector potency
- Implementing detailed monitoring to ensure the stability and efficacy of the final gene therapy product

12.45 **Lunch & Speed Networking**

Enhancing PAT Implementation in Synthetic Molecule Manufacturing

John-David McElderry
Associate Director - Analytical Systems
Biogen

1.45 **Navigating the Emerging Landscape of Oligonucleotide PAT: Challenges & Strategies**

- Explore the current challenges in developing PAT for oligonucleotides, including the lack of standardized processes and the complexities compared to well-established small molecule oral solid dosage forms
- Discuss potential strategies and approaches to align processing steps and optimizing PAT integration, drawing on early experiences and lessons learned from existing implementations
- Highlight the importance of collaboration and knowledge sharing within the industry to advance oligonucleotide PAT, and propose ways to standardize and innovate in this evolving field

Elliott Schmitt
Manufacturing Intelligence, PAT
Novo Nordisk Engineering

2.15 **Technology Selection and Implementation**

- Selecting and implementing appropriate PAT tools tailored to each unique API process, considering suitable sensors and analyzers
- Carefully considering process requirements to ensure effective implementation of PAT tools
- Choosing between NIR and Raman spectroscopy for monitoring specific chemical reactions to optimize the manufacturing process

Integrating Advanced Analytics in Biologics & Manufacturing: Challenges & Solutions

Aishwarya Ramanan
Downstream Manufacturing, Science, Technologies Labs & Innovation Scientist PAT
Seagen

2.45 **Integrating Advanced Analytical Technologies for Biologics into Downstream Processes**

- Examining how PAT tools are integrated into downstream purification processes for biologics
- Addressing the challenges encountered when integrating advanced analytical technologies into downstream processes
- Discussing strategies implemented to overcome these hurdles, including training staff and modifying process controls

Enhancing PAT Implementation in Synthetic Molecule Manufacturing

Rohit Lokhande
Senior Continuous Manufacturing Manager
US Pharmacopeia

3.15 **Integrating Advanced Technologies in Manufacturing for Supply Chain Excellence**

- Implementing AI and PAT in manufacturing processes to optimize production, reduce waste and ensure product consistency
- Overcoming challenges in global material sourcing by employing innovative logistics solutions and strategic partnerships
- Enhancing supply chain resilience by adopting real-time data analytics and predictive modeling to anticipate and address potential disruptions

Conference Day One
Wednesday, December 11

3.45 **Afternoon Break**

4.15 **Holistic Approach to Optimize PAT Tools Implementation in the Lab & Facility of the Future**

Fabrice Thomas
Senior R&D Manager - PAT Raman Technology
MilliporeSigma

- Streamlining the implementation of Raman technology with ready-to-use capabilities, straylight management and connectivity compliance
- Highlighting capabilities of in-line, on-line and at-line Raman sensors for CQA and CPP monitoring in USP, DSP and new modality areas, from process development to product release in manufacturing
- Proposing various strategies and assessing performances of PAT combination and their coupling with digital tools

Harnessing Advanced Analytical Technologies for Optimized PAT

4.45 **Optimizing Liquid Chromatography for Superior Process Efficiency and Control**

Jeff Elleraas
Senior Scientist
Pfizer

- Implementing liquid chromatography systems to improve precision and reduce solvent usage, enhancing sustainability and operational efficiency
- Facilitating real-time data collection and immediate process adjustments through on-the-spot analysis with portable liquid chromatography systems
- Integrating liquid chromatography with continuous flow systems to ensure seamless monitoring and control throughout the production process

5.15 **Advancing Real-Time Reaction Monitoring With NMR Technology**

Maria Silva Elipe
Associate Director, NMR Process Development
Amgen

- Utilizing bench-top NMR (Nuclear Magnetic Resonance) for real-time chemical reaction monitoring, providing detailed insights into reaction dynamics
- Addressing the resolution limitations of bench-top NMR systems by focusing on reactions with distinctive signals, ensuring accurate and actionable data
- Developing strategies to effectively integrate NMR into continuous flow processes, enabling uninterrupted monitoring and timely interventions

5.45 **Chair's Closing Remarks**

> "Well attended with representatives from companies that are highly influential in the PAT space. Small enough of a show to make networking with others comfortable. Plenty of opportunities to share thoughts with others"
>
> Sales & Business Development Manager, **Optimal Industrial Technologies**

Conference Day Two
Thursday, December 12

8.15 **Check In Morning Coffee & Light Breakfast**

8.55 **Chair's Opening Remarks**

Advancing Production and Quality Control through PAT Innovation and Strategic Partnerships

Andreas Kunov-Kruse
PAT Specialist
Novo Nordisk

9.00 **Optimizing Aseptic Production Efficiency via PAT-Driven Process Validations**

- Explaining PAT as a cornerstone in future Process Validations and a key enabler for OPV/CPV increasing
- Reducing Validation Time to Increase Throughput in Aseptic Production and serve more patients
- A new multimodal spectroscopy approach enables more accurate PAT-based process models

Manoharan Ramasamy
Director
Merck

9.30 **Streamlining QC Testing to Enhance Production Speed & Quality**

- Implementing PAT to perform QC tests more quickly and efficiently, cutting down the overall production lead time
- Incorporating QC tests into the production line using PAT for immediate results, enhancing process streamlining and reducing bottlenecks
- Utilizing PAT to handle various QC tests, including impurity limits and container integrity, ensuring comprehensive quality checks

Kim Nguyen
Senior Scientist
MilliporeSigma

10.00 **Applications of PAT for Bioconjugation Processes**

- PATROL-SEC and/or Flow VPE can facilitate real time protein monitoring in ADC process
- PATROL-UPLC-SEC-DTNB has been applied to monitor bioconjugation process
- ProCellics™ Raman Analyzer with Bio4C® PAT Raman Software can be used to monitor solvent clearance in TFF processes

10.30 **Morning Break & Networking**

11.30 **Strengthening Vendor Partnerships to Optimize PAT Solutions for Improved Production Efficiency and Quality**

- Building robust relationships with vendors to ensure seamless integration of advanced PAT tools, enhancing overall production efficiency and quality
- Collaborating with technology providers to develop customized PAT solutions that meet specific manufacturing needs, driving innovation and process improvements
- Facilitating continuous communication and feedback with vendors, ensuring timely updates and advancements in PAT technologies, maximizing their impact on production processes

Conference Day Two
Thursday, December 12

Enhancing Process Understanding & Control through Specialized Chemometrics Techniques & Quality Optimization

Samira Beyramysoltan
Senior Scientist
GlaxoSmithKline

12.15 Enhancing Industrial Process Monitoring Through Multivariate Statistical Techniques

- Exploring multivariate statistical methods and their applications in process monitoring
- Identifying the main challenges including model development, limited batch data, and model maintenance
- Implementing strategies for overcoming these challenges, such as using simulated batches and adaptive modeling

12.45 Lunch & Networking

David Zamora
Global Statistical & PAT Lead
Novartis

1.45 Unlocking Process Insights With PAT & Advanced Chemometrics

- Utilizing advanced PAT techniques to gain a comprehensive understanding of complex process interactions and variables
- Leveraging chemometric models to support data-driven decision-making, improving process reliability and product quality
- Applying mechanistic modeling to pinpoint critical process drivers, enabling targeted process improvements and optimizations

2.15 Roundtable Discussion: Enhancing Quality Control Through Compliance-Driven PAT Integration

- Exploring the distinctions between online and offline QC testing within PAT systems
- Discovering strategies for ensuring compliance while maintaining flexibility in QC processes
- Examining key regulatory guidelines and frameworks governing PAT integration in QC environments
- Addressing common challenges and pitfalls in achieving regulatory compliance during PAT implementation
- Examining the importance of data integrity in PAT systems and impact on QC

Implementation Driving PAT Success: Enhancing Organizational Efficiency, Financial Performance and Talent Development

Emmanual Appiah-Amponsah
Director, Data Rich Measurements-Analytical Enabling Capabilities
Merck

3.00 Optimizing Organizational Structures for Enhanced PAT Integration and Efficiency

- Integrating PAT teams within process development or analytical teams ensures effective usage, enhancing process understanding, control strategies and release testing
- Facilitating collaboration between development and manufacturing teams prevents delays and promotes seamless PAT integration into commercial manufacturing
- Aligning organizational structures to support analytical validation of RTRT improves accuracy and compliance in real-time data assessment

3.30 Chair's Closing Remarks

> "The workshops were excellent and interactive. The speed networking and networking lunches of the conference were very helpful quickly meeting with many participants and speakers"
>
> Team Leader - Process Intensification, **Government of Canada**

Your 2024 Partners

LumaCyte - Lead Partner

LumaCyte is an advanced bioanalytics company that produces label-free, single cell analysis instrumentation where the use of antibody or genetic labeling is not required. This revolutionary technology utilizes Laser Force Cytology™ (LFC™) to measure the intrinsic biochemical and biophysical properties of each cell. Key applications of the technology include cell bank characterization and management, cell health monitoring, viral infectivity for vaccines and cell and gene therapy, in addition to multiple applications across the biomanufacturing sector for process optimization and quality control.

www.lumacyte.com

MilliporeSigma - Expertise Partner

MilliporeSigma, a life science leader, is a business of Merck KGaA, Darmstadt, Germany. Our comprehensive portfolio supports all stages of the drug manufacturing process and our technical experts help you to address your current and future bioprocessing challenges. Visit our booth to learn more about our Process Analytical Technology (PAT) solutions, including in-line real-time Raman monitoring and Automated Aseptic Sampling platforms.

www.SigmaAldrich.com

InProcess-LSP - Exhibition Partner

InProcess-LSP is a highly innovative organization providing full Process Analytical Technology (PAT) method and instrument development services. It was founded in 2014 and is based at Pivot Park High Tech Pharma campus in The Netherlands.Being experts in nanoparticle size characterization, they are the inventors of the NanoFlowSizer: a unique, non-invasive nanoparticle size instrumentation for real-time measurement. Nanoparticle sizing takes place within seconds, enabling continuous real-time in flow analysis. The NanoFlowSizer is the only instrument capable of measuring particle size and size distribution of turbid nanosuspensions in flow, without the need for sample treatment.

www.inprocess-lsp.com

tec5USA - Exhibition Partner

tec5USA is a manufacturer of tailored OEM & in-line process spectrometers utilizing UV-VIS, NIR, Raman and LIBS methodologies.

We deliver superb Optical and Spectroscopy Solutions for the Analytical markets. In the Process environments, rather than waiting for time-consuming laboratory measurements, we focus on real-time verification by rapidly measuring time-critical chemical and physical parameters to react immediately to deviations in the production line.

We enable consistent quality, waste minimization and rework reduction, yield maximization, end-to-end supply chain optimization and pay per content.

www.tec5usa.com

GET INVOLVED

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Partner With Us

3rd Annual PAT & Real Time Quality Summit
Control the Future of Smart Drug Manufacturing
December 11-12, 2024 | Philadelphia, PA

Your Global Platform for Building New & Existing Relationships in the Rapidly Expanding PAT Field

Senior decision-makers within the top pharma companies have indicated that there is a noticeable gap in the market for vendors specializing in supporting PAT teams. Following extensive consultations, it has become evident that there is a lack of clarity regarding the key companies that offer high-quality services in three specific areas:

PAT Software:
Providing essential software solutions to enhance PAT implementation

Traditional Software Providers:
Bringing expertise from established software companies into the pharma industry

Biologic/ATMP PAT Sensors and Equipment:
Meeting the specific needs of biologic and ATMP processes

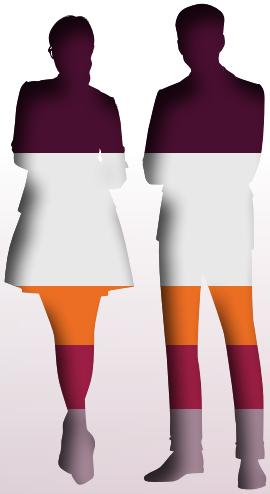
Small Molecule PAT Sensors and Equipment:
Addressing the requirements of small molecule manufacturing

The **3rd PAT & Real Time Quality Summit** offers a unique platform to showcase your solutions to a dedicated audience of purchasing decision makers from leading biopharma companies.

Opportunities include **speaking slots**, **networking sessions** or **exhibition spaces** tailored to your needs. We are committed to collaborating with you to design a customized package aligned with your business objectives.

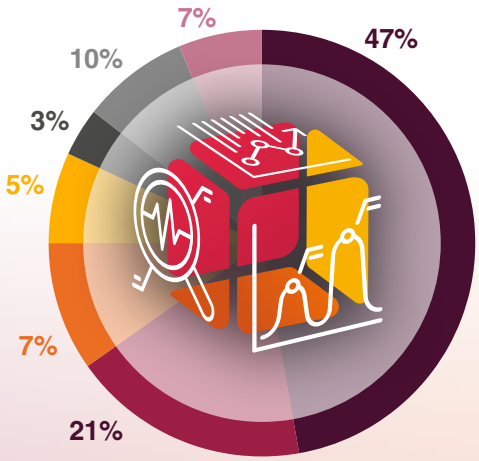
Contact us today to explore how we can create a tailored partnership to support your business development goals.

SENIORITY BREAKDOWN*



- Chief/CXO: 3%
- Director: 26%
- Manager: 10%
- Head: 5%
- Scientist: 31%
- Other: 25%

ATTENDEE BY COMPANY TYPE*



- Drug Developer
- Equipment & Service Provider
- Healthcare Providers
- Industrial Engineering
- Research Institute
- Manufacturing
- Other

*Statistics Taken from 2nd PAT & Real Time Quality Summit

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3 Easy Ways to Book

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DISCOVER the latest advancements and harness the wealth of knowledge available to overcome your PAT challenges

ENGAGE with leading experts from the likes of **Amgen**, **Merck**, **Vertex** and more to forge lasting relationships

SAVE valuable time and resources by gaining immediate actionable insights to improve PAT implementation, advance analytical techniques, automation and PAT modeling

Pharma, Biotech & CDMO Pricing	Standard Rate	On the Door Price
Conference Ticket	$2,899 (save $100)	$2,999
Academic Pricing**	**Standard Rate**	**On the Door Price**
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Conference Ticket	$3,599 (save $100)	$3,699

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- **10% discount – 2 Attendees**
- **15% discount – 3 Attendees**
- **20% discount – 4+ Attendees**

**Please note that discounts are only valid when two or more delegates from one company book and pay at the same time.

Discounts cannot be used in conjunction with any other offer or discount. Only one discount offer may be applied to the current pricing rate.

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Venue

Philadelphia Airport Marriott
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TERMS & CONDITIONS

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