Health Advances™

ISPE Conference 2025 Takeaways

November 2025

Takeaways from our trip to the ISPE annual conference reflect broader and ongoing industry trends. Our top observations are:

1. Biopharma manufacturers are beginning to adopt smart factory models with integrated data and automation, laying the groundwork for more agile, AI-driven decision-making

2. Manufacturing for personalized therapies is gradually shifting toward modular, digital twin-enabled facilities that support point-of-care production and faster tech transfer

3. Sustainability has evolved from a philanthropic goal to a core operational metric, with companies deploying strategies to achieve net-zero targets and competitive advantage

Source: Health Advances analysis.

Biopharma manufacturers are beginning to adopt smart factory models with integrated data and automation, laying the groundwork for more agile, AI-driven decision-making.

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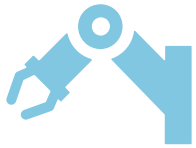


Physical Automation

- Integrated value stream with automated material handling
- Sensors and real-time monitoring
- 100% visibility across manufacturing floor

Integrated Data Platforms

- Vertical and horizontal system integration (e.g., MES, EMS, LIMS, PCS)
- Real-time data lakes and analytics
- Digital twins linking assets to operational data

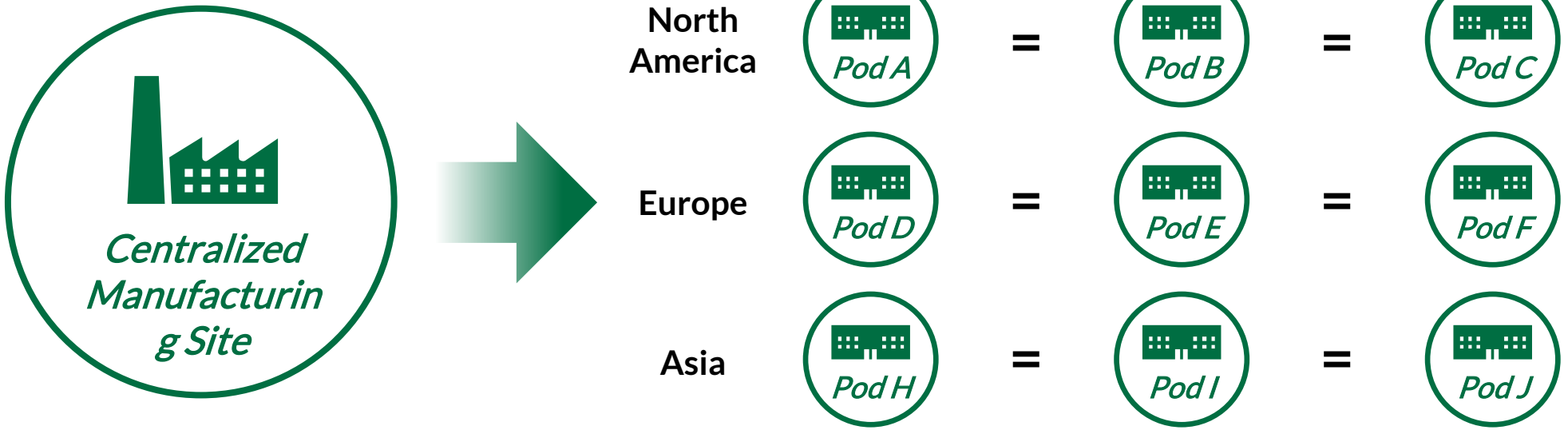
AI-Driven Decision-Making

- Predictive analytics and machine learning for optimization
- Real-time KPIs and control tower management
- Paperless operations with automated decisions

MES = Manufacturing Execution System; EMS = Equipment Management System; LIMS = Laboratory Information Management System; PCS = Process Control System.

Source: Health Advances analysis.

Manufacturing for personalized therapies is gradually shifting toward modular, digital twin-enabled facilities that support point-of-care production and faster tech transfer.

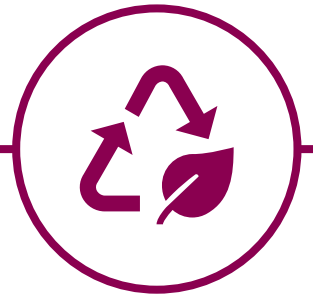


… Requires a Few Key Steps for Success

- Digital twins enabling real-time control across distributed sites by providing process simulation, predictive maintenance capabilities, and virtual training environments that ensure consistent quality and operational performance regardless of geographic location
- Hub-and-spoke governance streamlining multi-site authorization as the centralized Control Site manages quality systems, validation protocols, and training standards
- Automated systems accelerating deployment timelines because integrated material handling, paperless batch execution, and MES-driven operations eliminate manual processes and enable rapid site commissioning without traditional tech transfer cycles

Source: Health Advances analysis.

Sustainability has evolved from a philanthropic goal to a core operational metric, with companies deploying strategies to achieve net-zero targets and competitive advantage.



Pharmaceutical Industry Goals to Achieve Sustainability

- Prioritize resources for sustainability projects
- Consistently collected and effectively leverage data
- Consistent program delivery across sites
- Sustainability mindset integrated network-wide
- Share best practices and reward sustainability leaders

Sanofi presented how the company leverages competition and partnership with McLaren to:

- Increase visibility and excitement
- Promote best practices
- Accelerate standardization and execution
- Celebrate and reward the great work of its sustainability leaders

Drive Sustainability!

Source: Health Advances analysis.

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