Innovations in pharmaceutical manufacturing on the horizon: virtual dissemination workshop

Manufacturing innovation talk #3

Jessica Settimi

Sr. Director Continuous Manufacturing Business

10/28/2021

The world leader in serving science

World leader in serving science

>90,000
employees

5,700
R&D scientists/engineers

$1.4B
invested in R&D

>$35B
in revenue

Industry leading end-to-end pharma services capabilities to simplify the supply chain for customers

- Expertise in drug development, clinical trial logistics and commercial manufacturing
- Flexible business models customized to meet your needs
- A partner from development through commercial supply
- Achieved through a global network of 65+ sites globally

Advances in Manufacturing Innovation: Post-Pandemic

Innovations in pharmaceutical manufacturing

Post-Pandemic: Must enable speed, flexibility and reduce risk

Speed

To clinic, to market, agility

- The definition of speed has changed with pandemic response, and we expect that to be the precedence for the future.
- Technologies will need to enable speed & responsiveness; cycle time reduction, scale up, process simplification, risk-based approach to development.

Flexibility

Scale, geography

- Flexibility to enable changing market demands, supply security and speed including facility builds, automation and knowledge sharing

Reduce Risk

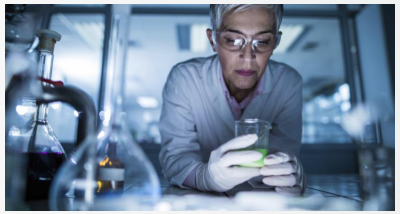
Supply chain, process reliability

- Visibility, control and redundancy will be critical post pandemic for all nodes in a therapeutic or vaccine supply chain.
- Batch-to-batch variability, process reliability, raw material specifications and standards.

Innovations should be measured against these critical attributes

A CDMO perspective: accelerate/decelerate

Based on our experience in API, Biologics, Cell & Gene Therapy, OSD and Steriles….



Speed
To clinic, to market, agility

Flexibility
Scale, geography

Reduce Risk
Supply chain, process reliability

	Drug Substance	Drug Product	C&GT	Drug Substance	Drug Product	C&GT	Drug Substance	Drug Product	C&GT	Accelerate / Decelerate
New routes to drug substances				✓						→
Co-processed APIs	✓									→
Process Intensification	✓	✓	✓	✓	✓	✓	✓	✓	✓	↗
Additive Manufacturing		✓								→
Process Control & Automation	✓	✓	✓	✓	✓	✓	✓	✓	✓	↗
Modular Systems	✓	✓		✓	✓		✓	✓		↗

A CDMO perspective: what's missing?

Based on our experience in API, Biologics, Cell & Gene Therapy, OSD and Sterile Fill Finish

Traceability of Starting Materials	Platform Technologies	Digital: Modeling	Digital: Knowledge Share
• Speed: ✓	• Speed: ✓	• Speed: ✓	• Speed: ✓
• Flexibility: ✓	• Flexibility: ✓	• Flexibility: ✓	• Flexibility: ✓
• Reduce Risk: ✓	• Reduce Risk: ✓	• Reduce Risk: ✓	• Reduce Risk: ✓
• Examples: consumables, raw materials,	• Examples: continuous manufacturing for OSD, resins, media	• Examples: digital twin process modeling to enable tech transfers, machine learning for in silico development	• Examples: Industry/Academia/ Regulator collaborations to drive adoption of new technology
Improve traceability of non-GMP materials	**Standardization of platforms within modalities & within starting materials/components**	**Advanced process, formulation modeling leveraging machine learning**	**Along supply chains/value chains, real time knowledge sharing**

Continuous manufacturing case study

As a CDMO our interactions with the ETT have been driven by customer work.

Situation

- Thermo Fisher Scientific launched a continuous manufacturing capability for oral solid dose production in 2016.
- Product experience has ranged from conversion of a batch to continuous process post launch, transfer and further develop of continuous processes for CTM and numerous proof of concept studies.
- Engagement with the ETT has been specific to products and driven by the customer

Innovative Technologies

- Process Intensification
- Advanced process control and automation
- Modular systems

Opportunities for further adoption

- Technology
  - *Platform Technologies*
  - *Digital: Modeling*
  - *Digital: Knowledge Sharing*
- ETT discussions and collaboration based on manufacturing line outside of product regulatory submission; enable innovation related to process controls, studies to enable TT between platforms, best practice sharing (still a small number of approvals), develop regulatory expertise and experience, address post approval changes

Thank you