**INDIANA Industry RESEARCH AND INNOVATION Needs in LIFE SCIENCES Manufacturing**

Purdue University established the Young Institute for the Advanced Manufacturing of Pharmaceuticals (Young Institute) in 2022 to “advance pharmaceutical manufacturing through discoveries and workforce development for the benefit of Indiana and the nation.”[[1]](#footnote-1)

**Stakeholder Collaboration**

The Young Institute has conducted deep Life Sciences Manufacturing (LSM) stakeholder engagement over the past year. It is from these efforts that we have crafted and fine-tuned our integrated strategy for research, translation, and workforce development. Much of this works was in preparation for a proposal (The Heartland Engine for Advanced Life Science Manufacturing – HEALS) to the NSF Engines program (up to $160M over ten years). Specifically, we conducted:

* The first Indiana LSM Summit on March 11, 2022 in Indianapolis with 80+ representatives from Indiana industry, state and local government and all HEALS core partners.
* Two LSM roadmapping workshops (June 2022 and Oct. 2022) attended by regional academia, government, NGO, and industry representatives
* An Indiana LSM workforce training needs workshop and survey in November 2022 with Advanced Accelerator Applications/Novartis, Baxter, Catalent, Cook, Elanco, Evonik, INCOG, Lilly
* Two industry surveys to identify research, workforce, and translation barriers, gaps, and opportunities
* 100+ interviews by the HEALS team with industry, government, and NGOs to identify specific needs and collaboration opportunities

**Results:**

**Top 5 research themes:**

1. Rapid and predictable scaling of manufacturing
2. Modular manufacturing technologies and approaches
3. Manufacturing challenges for new therapeutics
4. Improved process analytical technologies
5. Advanced control system and use of AI

**Key gaps to innovation success:**

* Lack of testbeds for higher-risk operations and technologies
* Lack of incubator space for startups/small companies
* Regulatory burden slows or halts adoption
* Technology adoption is cost prohibitive for smaller firms
* Lack of sufficient and/or skilled workforce to implement new technologies

**Leading Innovation Opportunities:**

* Subsidize, de-risk technology adoption
* Develop a place to do training and testing: equipment training; fixed bed and suspension bioreactors, TFF/chromatography, isolators, automation/controls
* Leverage manufacturing readiness grants
* Consider existing sites as testbed/training sites in lieu of new investment
* Collaborate on a pre-competitive pilot facility
* Involve governmental officials directly
* Bring together CMO, FDA, Client, Suppliers

**Theme Consensus:**

**After the HEALS stakeholder engagement -** The HEALS research and innovation working group (which also included industry) identified 6 overarching R&D themes:

* **Sustainability**: Standardization and is potential for building sustainable manufacturing processes. Lego block model (i.e. do-learn-improve, or innovation loop)
* **Barriers to adoption**: Processes and models used to evaluate new enabling technologies, utilize collective models of action that can share risk and reduce costs
* **Small scale studies to inform manufacturing innovation:** Test beds to facilitate the introduction of new manufacturing modalities, not just microscale, but millimeter and larger length scales (i.e. demonstrate proof of concept to facilitate transformation)
* **Research resource adjacencies, or “connect to existing capabilities”:** leverage existing centers and research institutes at the four main campuses (i.e. leverage proximity of researchers, students, and facilities to engage industry partners and foster collaboration and innovation.)
* **Collective operations:** Map assets in the Indiana life sciences network to visualize capabilities
* **Tier structure:** companies’ participation is variable, with most preferring a lower tier entry point

**Additional feedback from industry partners**

* Provide avenue for small manufacturers to engage and adopt productivity improvements
* Improve productivity through automation, predictive analytics; not enough people;
* Real-time analytics
* Advanced, faster cleaning technologies and workflows. Sterilization issues need to be addressed (i.e. new technologies that increase sterility assurance, alternative methods of sterilization that have less environmental impact)
* Data systems conversion
* Reduce capital expense by transitioning from batch to continuous manufacturing
* High throughput screening and synthesis
* Data classification is the “intelligence” required to do predictive models
* Faster and cheaper components and supplies, include suppliers such as: Pall, Sartorius, Millipore, Univercells, Thermo Fisher
* Packaging technologies and choices by supplier to customer
* Rapid and easy handling of high potent ingredients (i.e. containment technologies)
* Automation of unit operations
* High throughput screening
* Low cost sensors for real time analytics/bio-manufacturing
* Evaluate process analytical techniques (PAT) that ensure product quality at reduced costs

1. <https://www.purdue.edu/newsroom/releases/2022/Q2/gift-to-purdue-university-establishes-institute-for-advanced-manufacturing-of-pharmaceuticals.html> [↑](#footnote-ref-1)