

# Young Institute & Pharmaceutical Manufacturing at Purdue

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REX REKLAITIS

DAVIDSON SCHOOL OF CHEMICAL ENGINEERING

# Pharma manufacturing has deep roots in Indiana



Extraction of porcine insulin from pig pancreas at Eli Lilly in the 1920's:

- Examining pig pancreas (*left*)
- Grinding (*right*)

In the 1950s and 1960s, Lilly was a key manufacturer of antibiotics. Manufacturing sites included Tippecanoe Laboratories in Lafayette, IN.

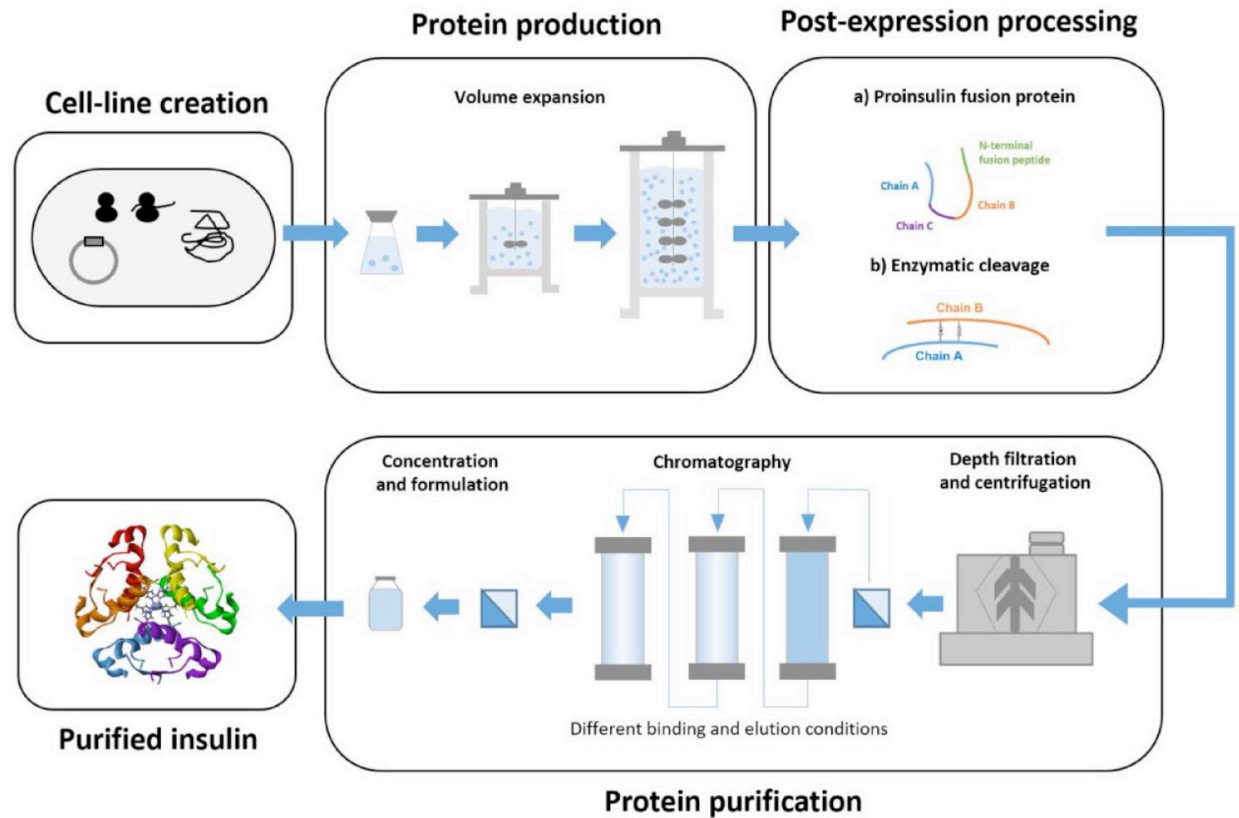
# Synthetic Human Insulin



**William D. Young**

B.Ch.E., Purdue, 1966

Senior Advisor, Blackstone Lifesciences  
COO Genentech (1980-1999)



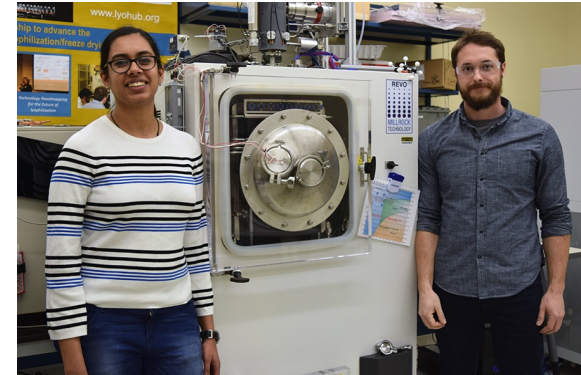
Continuous tablet manufacturing  
*Reklaitis, Nagy, Gonzalez, Mort*



## On-going manufacturing research

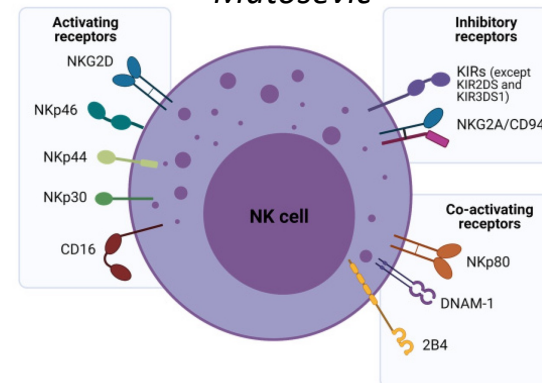


Continuous drug substance  
manufacturing  
*Nagy, Thompson, Cooks*



RF assisted lyophilization  
*Peroulis, Alexeenko*

NK cell cryopreservation  
*Matosevic*



# LyoHUB at a Glance



1  
ASTM  
Standards




2  
New LyoHUB  
Mobile Apps

\$5M  
Government /  
Non-profit Funding

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\$5.5M  
Industry Funding



11  
Patents

825  
LEARNERS  
Lyo101 Online Short Course  
Since 2020



480  
Hands-on  
Lyo Trainees



25  
Professional  
Masters Capstone  
Projects



22  
Undergrad  
Researchers



\$1M+  
In-kind  
Equipment



Best Practice  
Papers



54,000+ Downloads  
6 Papers

1,786 Lyo  
Runs



87,000+ Hours of Lyo  
Run Time



35  
LyoLaunchPad  
Projects



100+  
Publications  
Referring to Lyohub





# The Young Institute

*Established in 2022 by a bequest from William D. and Sherry L. Young*

**Mission:** To advance pharmaceutical manufacturing by providing innovative research and industrially relevant education and training that reduces costs, improves access to medicines, and supports economic development in state and region.

**Vision:** AMP will be an **internationally recognized** institute that:

- provides leading-edge **education and training** in pharmaceutical manufacturing,
- produces innovative **research** that advances the science and technology of pharmaceutical manufacturing, and
- **engages** effectively with other institutes at Purdue, with HEIs in Indiana, with local and national government organizations, and with the pharmaceutical industry.

# Young Institute Leadership

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## ***Director***



***Elizabeth Topp***  
***ChE, IMPH***

## ***Associate Directors***



***Eric Munson***  
***IMPH***



***Garth***  
***Simpson,***  
***Chem***



***Alina***  
***Alexeenko,***  
***AAE, ChE***

# The Young Institute Advisory Council



**Robert Baffi**  
Former BioMarin  
President of Global  
Manufacturing and  
Technical Operations

**Mitch Daniels**  
Former Purdue  
President, Governor  
of Indiana, and  
President of Eli Lilly

**Michael Klobuchar**  
Executive VP and  
CSO for Merck & Co.

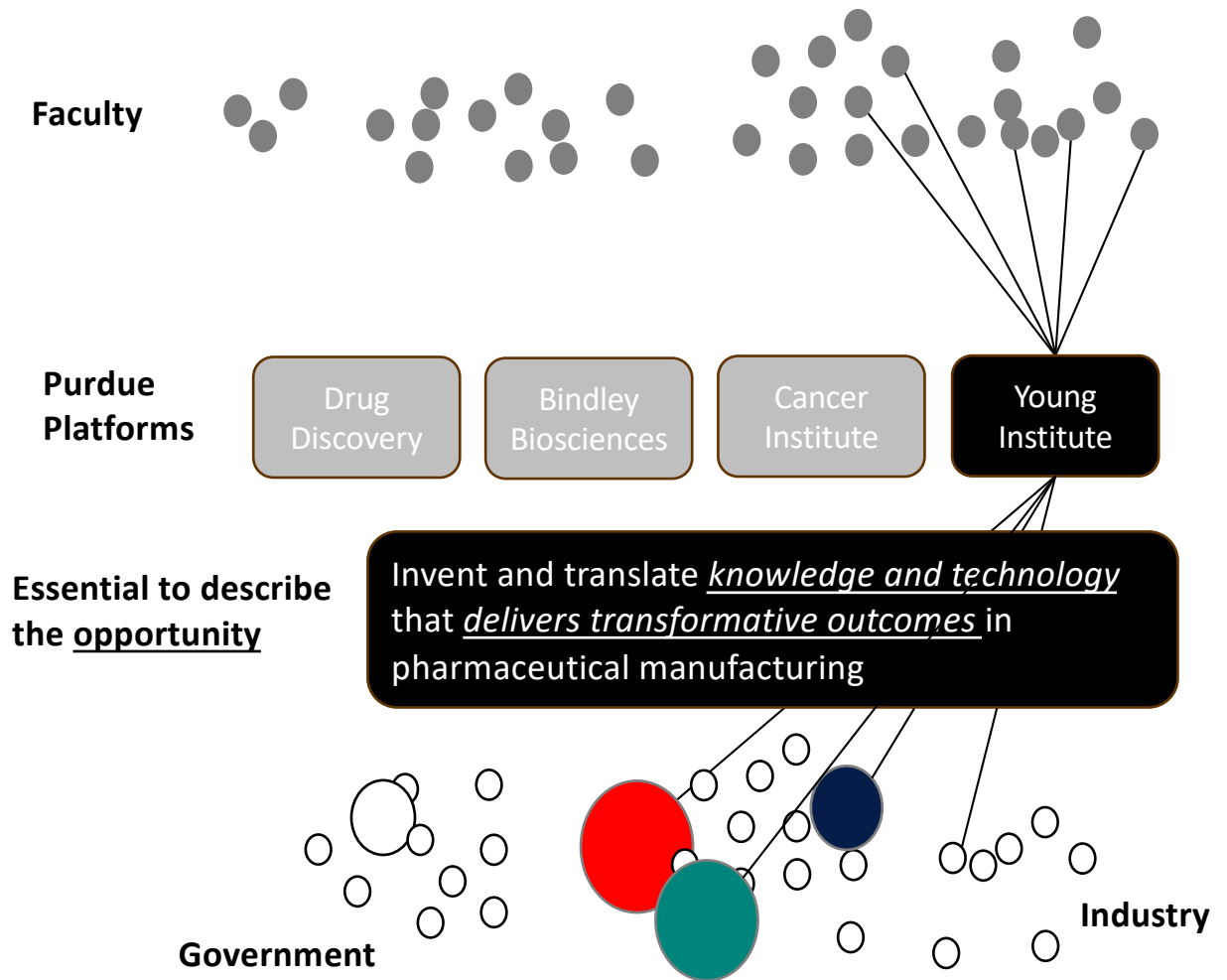
**Moheb Nasr**  
Former VP of  
GlaxoSmithKline, Director of  
FDA Center for Drug  
Evaluation and Research.

**Bill Young**



# What we do

- Drive Purdue's engagement mission supporting the Health Sector
- Partner with Purdue Platforms to deliver value
- This is a complex challenge. We must frame as an opportunity that delivers outcomes that industry cares about.



# Summary of Young Institute Activities

*June 2023 to May 2024*

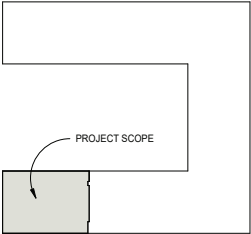
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- Organized and hosted Indiana Life Sciences Manufacturing Summits (2022, 2023, 2024)
- Worked with ArcDesign on renovation plans for Indiana Manufacturing Institute building (IMI)
- With the Office of Industry Partnerships (OIP), convened a lipid nanoparticle (LNP) working group
- With OIP, engaged with prospective industry partners – Voice of the Customer Interviews
- Expansion of educational programs
- Submitted proposals:
  - HEALS (NSF Regional Innovation Engines; lead organization – I-CASE; not funded)
  - BioWorks (EDA Tech Hub; lead organization - Applied Research Institute (ARI), submitted 02-29-2024)
  - FDA Collaborations in Regulatory Science (Purdue lead, submitted 04-02-2024)

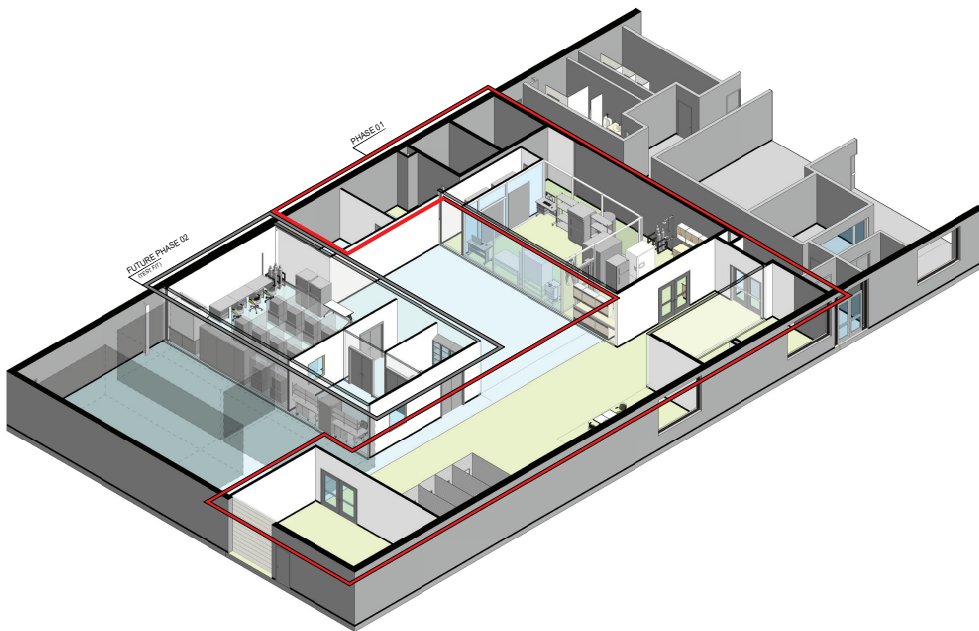
# Indiana Manufacturing Institute



# Existing Conditions



# Axonometric and Schedule



PRELIMINARY SCHEDULE

2024											2025								
MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL			
STUDY																			
			SD																
						DESIGN/BIDDING													
						DD	CD	BID											
											CONSTRUCTION								
																OCC			

# New degrees and courses

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The Young Institute, the College of Engineering, and the College of Pharmacy have developed new courses and programs in pharmaceutical manufacturing:

- **Undergraduate Certificate in Pharmaceutical Manufacturing (16 cr)** - launched Fall 2023, includes experiential learning (co-op/internships/UG research). Core pharmaceutical manufacturing curriculum for Lilly Scholars. **Over 70 students** enrolled.
- **Professional Master's Program (PMP) in Pharmaceutical Engineering** – approved to be launched at Purdue Indy. **Target 25** new M.S. students in the first cohort in Fall 2025
- **Pharmaceutical Biotechnology (3 cr, IPPH 590)** – a graduate level introduction to biologics, including molecular biology foundations, analytical, formulation, and manufacturing. New Fall 2023, **25 students** enrolled.

# EDA Tech Hub Proposal

*U.S. Economic Development Administration (EDA) Regional Technology and Innovation Hubs (Tech Hubs)*

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- Heartland BioWorks, led by Applied Research Institute, received EDA Tech Hub designation in October 2023, one of 31 nationally
- Phase 2 proposal for BioWorks was submitted February 29, 2024. Components:
  - BioLaunch
  - BioTrain
- BioTrain will provide hands-on training for Manufacturing Operators and Lab Technicians at 16Tech in Indianapolis
- Purdue's role:
  - Co-develop curricula (with Ivy Tech)
  - Provide graduate teaching assistants to help staff hands-on courses
  - Enable integration of BioTrain credentials into Purdue degree programs

# FDA Proposal

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Call for Proposals: RFA FD 24-029, (“Collaborations to Enhance Drug Development and Regulatory Science – Clinical Trials Optional”)

## Specific Aims:

- To develop a **consortium**, in collaboration with the FDA and industry, that will promote the *advanced manufacturing of sterile injectable drug products*, and
- To conduct **projects in advanced manufacturing**, with an emphasis on sterile injectable drug products, in collaboration with FDA and industry.

Submitted: April 2, 2024

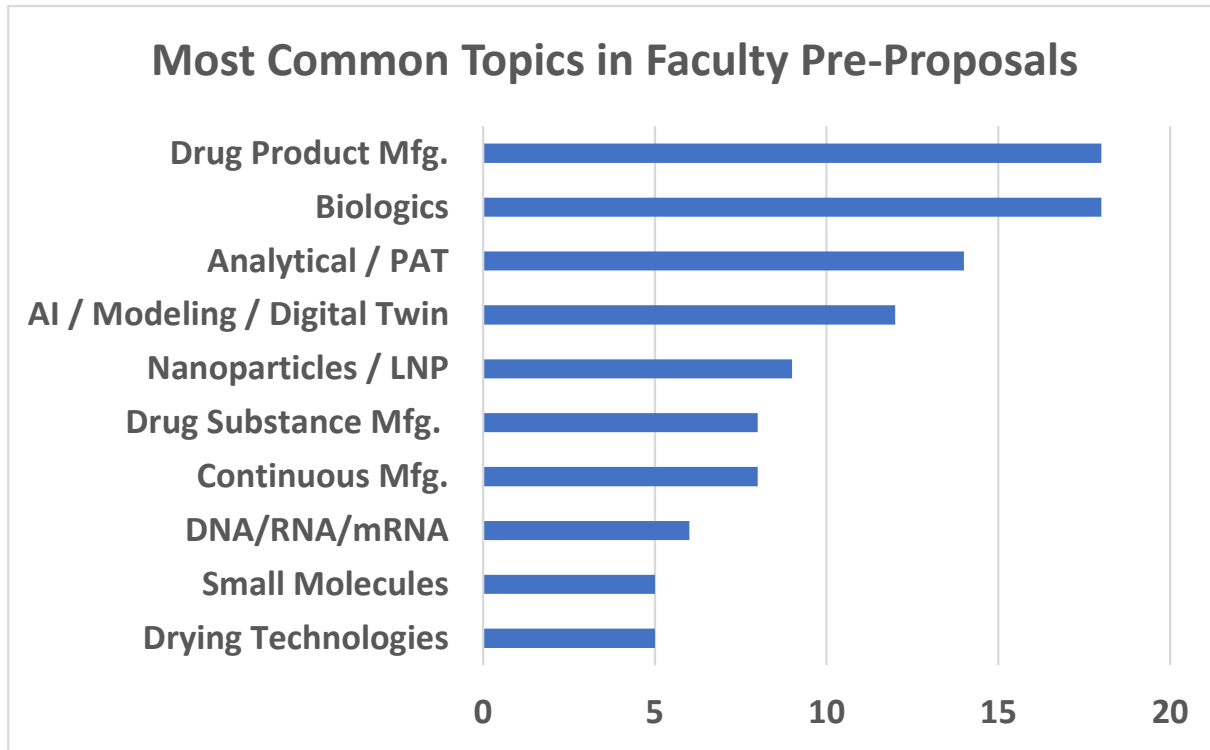
Budget: \$9M

Project Period: 09-01-2024 to 08-31-2029





## Response to Request for Pre-Proposals



Number of pre-proposals addressing each topic, of total of 50 pre-proposals submitted. Categories may overlap

## Other Topics in Pre-Proposals

- Smart Packaging (3)
- Formulation / stability (3)
- Process chromatography (2)
- Cell therapies (2)
- Policy (2)
- Education and training (2)
- Freeze / thaw (1)

*Participating academic units include chemistry, chemical engineering, industrial and molecular pharmaceuticals, agricultural and biological engineering, policy research institute, pharmacy practice, and more*

# Industry Challenge Statements

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<b>Company</b>	<b>Challenge Statement Title</b>
Continuity Pharma	Model Development and Process Control to Guide Release of Drug Substance Produced by Continuous Manufacture
Eli Lilly, Merck	Rapid Testing for Microbial Contamination during the Sterile Filling of Pharmaceuticals
Eli Lilly, Merck	Fault Detection during the Sterile Fill and Finish of Pharmaceuticals
Genezen	Optimizing Lentiviral and Retroviral Vector Purification: Leveraging Continuous Ultracentrifugation for Efficient and Scalable Gene and Cell Therapy Advancements
Genezen	Serotype Agnostic Scalable Platform Approach for AAV Manufacture
IndyGeneUS AI Inc, SanKav Pharmaceuticals LLC	Overcome FDA Drug Shortages

# Some critical next steps

## Building Indiana hard tech corridor

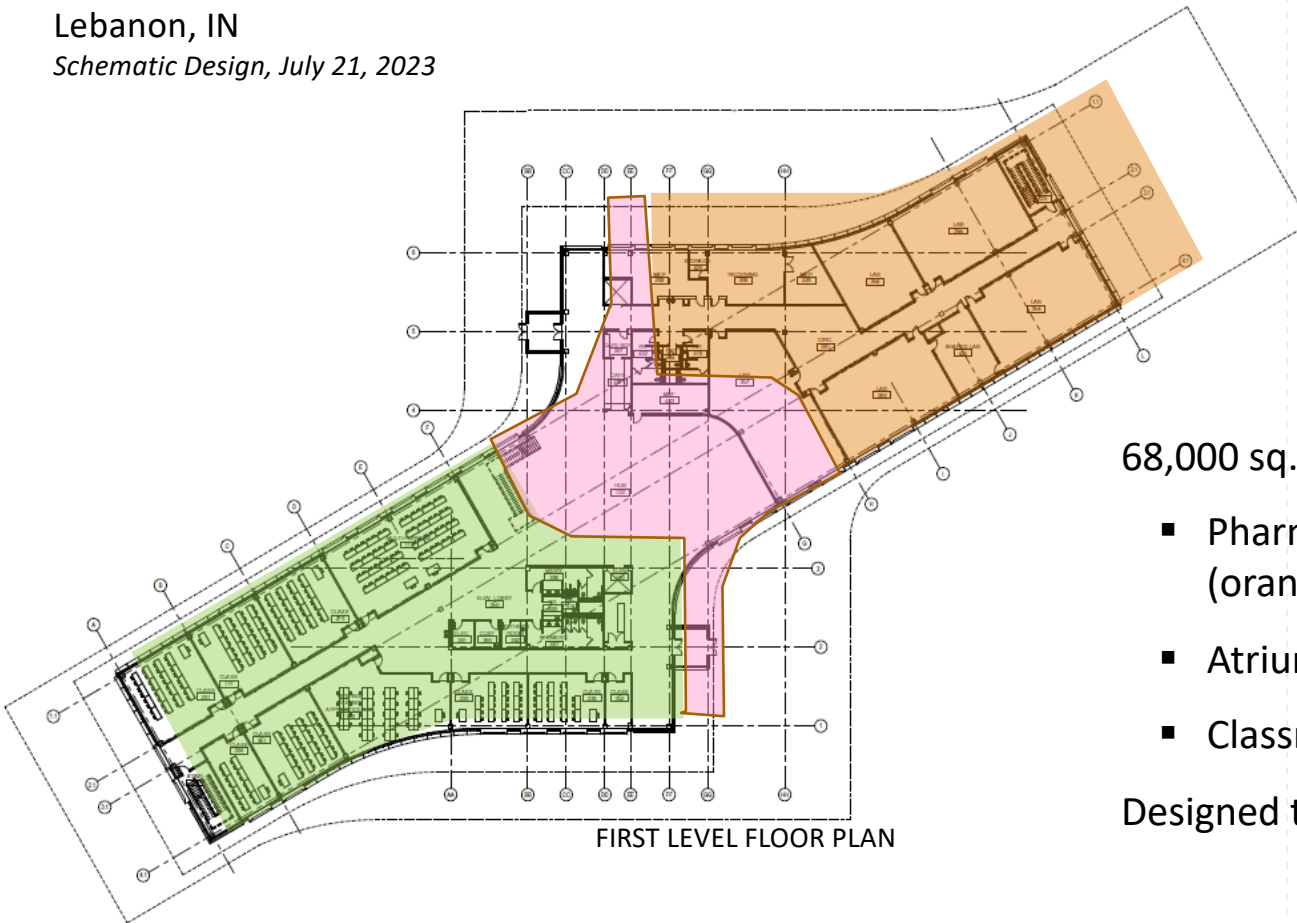
- **Pharmaceutical manufacturing research at IMI, (West Lafayette)** - Complete design and renovation (Young Institute); business model and tenants
- **LEAP Learning Center, (Lebanon)** – Design of two story building for hands on manufacturing training
- **Radiopharmaceutical manufacturing training, (Zionsville)** - Renovation, equipment, staffing
- **Pharmaceutical manufacturing training at EMC2, (Indianapolis)** - Renovation, equipment, partnership (Purdue, Ivy Tech, Biocrossroads), NIBRT training franchise, staffing



# Limitless Exploration / Advanced Pace (LEAP) Learning Center

Lebanon, IN

Schematic Design, July 21, 2023



## Comparators

NIBRT (*Dublin*) = 70,000 sq. ft.

BTEC (*NC State*) = 82,700 sq. ft.

JIB (*Thomas Jeff. Univ.*) = 25,000 sq. ft.

68,000 sq. ft., two-story new build to include:

- Pharmaceutical manufacturing training (orange)
- Atrium and reception (pink)
- Classroom and office (green; )

Designed to allow for future expansion

# LEAP Learning Center

Lebanon, IN



# Young Institute next steps

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- Form a consortium with at least three member companies, in advance of funding decision from FDA
  - Complete IMI design and renovation and identify Phase 2 occupants
  - Continue faculty outreach and team building
  - Continue industry outreach & planning with Advisory Council
  - Prepare for Fall round of FDA BAA's in Pharmaceutical Manufacturing
  - Plan 2025 Indiana Life Sciences Manufacturing Summit
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