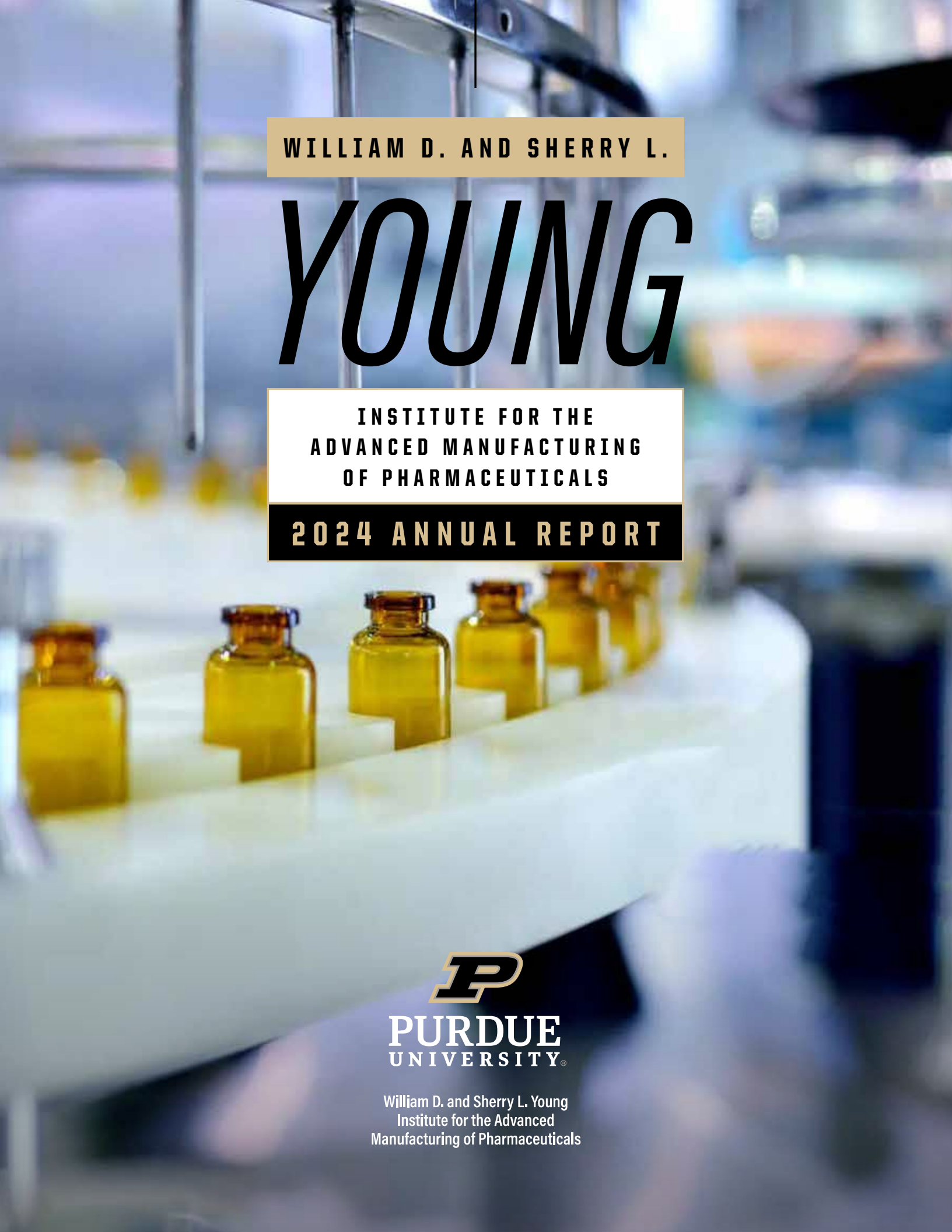


WILLIAM D. AND SHERRY L.

YOUNG

INSTITUTE FOR THE ADVANCED MANUFACTURING OF PHARMACEUTICALS

2024 ANNUAL REPORT

PURDUE UNIVERSITY

William D. and Sherry L. Young
Institute for the Advanced
Manufacturing of Pharmaceuticals

THANK YOU

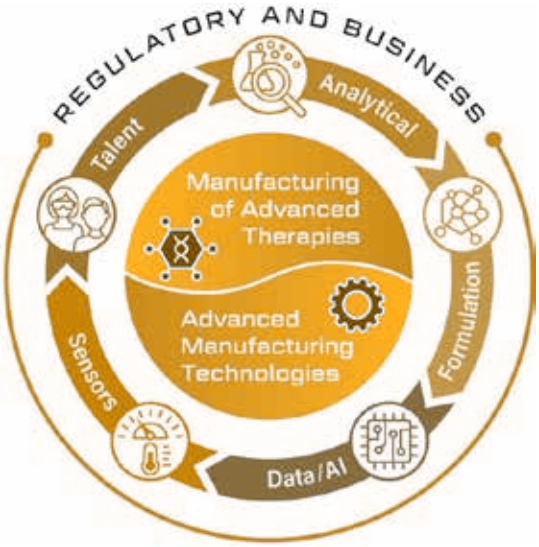
...for your interest in the **William D. and Sherry L. Young Institute for the Advanced Manufacturing of Pharmaceuticals** at Purdue University. William D. (Bill) Young is a Purdue alumnus (B.Ch.E. '66) who developed the manufacturing process for Humulin®, the first drug made by recombinant DNA technology. We're honored to bear his name and honor his legacy of manufacturing innovation. This brief report summarizes the Young Institute's activities in 2024, two years from our founding.

PURDUE UNIVERSITY | William D. and Sherry L. Young Institute for the Advanced Manufacturing of Pharmaceuticals

MISSION AND VISION

The Young Institute's mission is to advance pharmaceutical manufacturing by providing innovative research and industrially relevant education and training. Advancing pharmaceutical manufacturing involves both new manufacturing technologies and new classes of medicines (see figure, right). Related technical areas and the regulatory and business climate inform these activities.

Our vision is that the Young Institute will be internationally recognized for innovative research that transforms the science and technology of pharmaceutical manufacturing, engages effectively with key stakeholders, and provides leading-edge education and training.



Tablets produced in Purdue's Continuous Solids Processing Pilot Plant located in the FLEX high-bay

FACILITIES

To provide a home for its pilot-scale manufacturing activities, the Young Institute is renovating 10,000 sq. ft. of high bay space in the Indiana Manufacturing Institute (IMI) (1105 Endeavor Drive, Suite 600, West Lafayette, IN 47906, see Figure A). Design is complete, construction is underway, and occupancy is expected in the summer of 2025.

The renovation will create four manufacturing bays (Figure B, light blue and gray) supported by an analytical laboratory (green, lower right) and meeting and storage areas (green). One bay designed for fill-finish operations will be ready on occupancy. We are in discussion with other prospective occupants.

Through a generous donation from Eli Lilly, **a self-contained mobile BSL3 cGMP cleanroom facility** for clinical phase manufacturing will be installed adjacent to Suite 600. The facility was built by GermFree (Figures C, D) and was deployed in May 2020 for clinical manufacturing of the first FDA authorized monoclonal treatment for the COVID-19 pandemic.

The IMI facility will provide an identifiable home for the Young Institute and for its training and research activities. The availability of pilot-scale manufacturing space has already been important in several research proposals.

GROUNDBREAKING

INDIANA MANUFACTURING INSTITUTE RENOVATION - OCTOBER 4, 2024

Young Institute members and friends gathered with Purdue administrators on October 4, 2024, to break ground on the IMI renovation and to celebrate the launch of a new lyophilization technology roadmap by our partner organization, LyoHUB.

Pictured clockwise from bottom left: guests heard from Young Institute leaders, reviewed the renovation floor plan and toured the IMI facility during the event.

Purdue leaders celebrated the groundbreaking.

2024 INDIANA LIFE SCIENCES MANUFACTURING SUMMIT

On March 7, 2024, the Young Institute hosted the third annual **Indiana Life Sciences Manufacturing Summit** at 16Tech in Indianapolis. These summits convene industry, academia, representatives of state and local governments, and other relevant organizations to promote life sciences manufacturing research, education, and business development in Indiana.

The theme of the 2024 Summit was ***Regulatory Perspectives on Life Sciences Manufacturing Innovation***. Keynote speakers were Dr. Patrizia Cavazzoni, M.D., Director of the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA) and Dr. Sau Lee, Ph.D., Deputy Director of Science, Office of Pharmaceutical Quality, CDER FDA. Additional speakers included senior executives from Eli Lilly, Merck, Simtra, Genezen, Evonik, Applied Research Institute (ARI), and Nucleus Radiopharma.

More than 100 people attended in person, with additional registrants joining online.

Alina Alexeenko, Young Institute Co-Director, and Jane Dunigan-Smith, Senior Vice President, BioCrossroads

Johna Norton, Executive Vice President, Global Quality, Eli Lilly and Company

Edgardo Hernandez, Executive Vice President and President, Manufacturing Operations, Eli Lilly and Company

Dan Isaacs, Chief Technology Officer and General Manager, Digital Twin Consortium and Chief Strategy Officer, Object Management Group

INDUSTRY CONSORTIUM

In January 2025, the Young Institute launched a **new industry consortium** in pharmaceutical and biopharmaceutical manufacturing, with Eli Lilly and Company and Merck & Co. Inc. as Founding Members. Working together, consortium members will chart the direction for new manufacturing technologies, lower barriers to their adoption, set priorities for training and education activities, and engage with students who will become tomorrow's leaders.

Participation in the consortium will provide industry members with levels of engagement difficult to achieve in one-on-one research partnerships, including:

- access to unique shared-use facilities,
- access to shared and firewalled datasets,
- interaction with regulators and with one another,
- opportunity to shape and participate in education and training activities,
- interaction with graduate and undergraduate student talent pipelines, and
- cost-saving, with 100% of the allocated support used to fund consortium activities

The Consortium has **three membership tiers**:

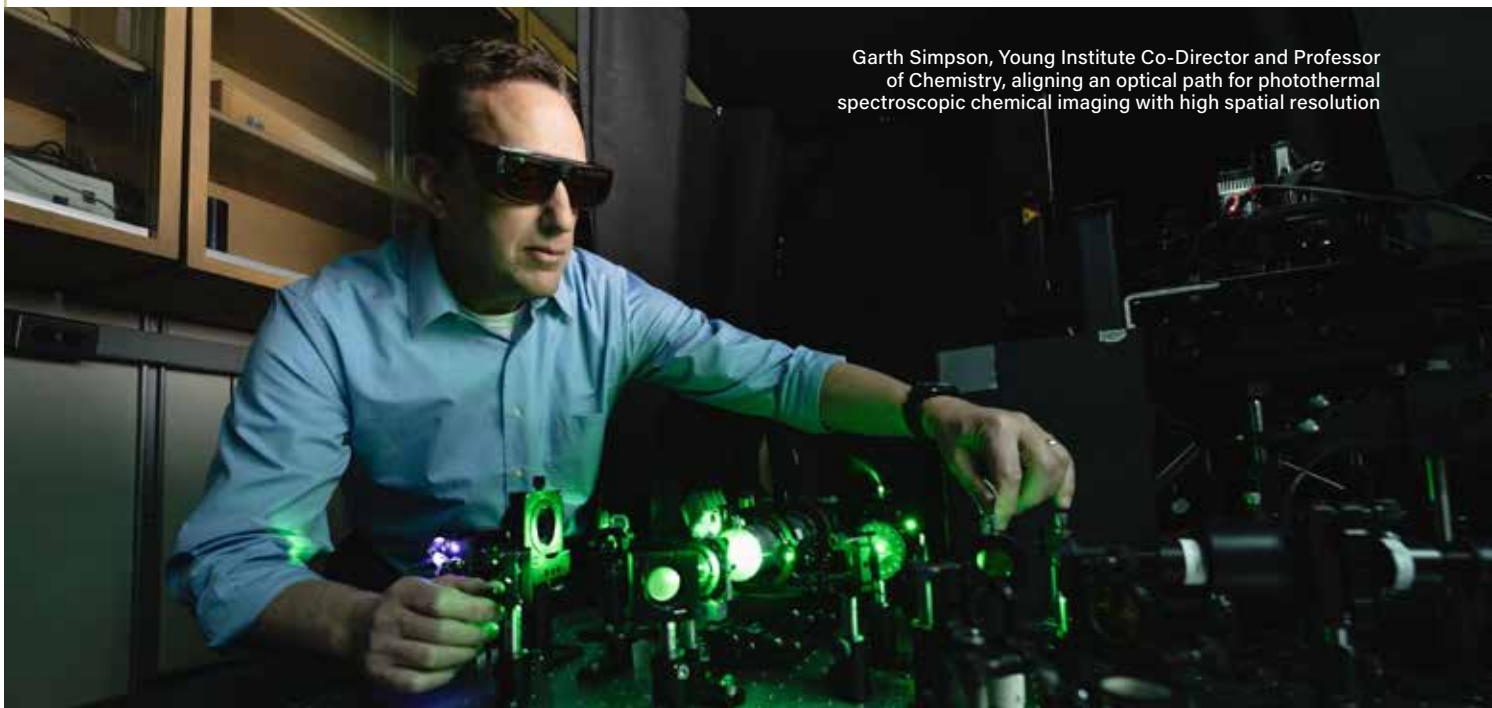
Founding Members help set research priorities, craft calls for proposals and vote to select from proposals submitted. Founding Members will also set priorities for other consortium activities, such as education and workforce training initiatives, symposia, short courses, and white papers.

Tier 1 Members will participate in all consortium activities, will have reduced-cost access to consortium facilities and activities (e.g., short courses), and will contribute to publications and best practices papers.

Tier 2 Members will participate in consortium activities. This Tier is intended to encourage participation by small companies and academic institutions.

INTERESTED?

We'd love to hear from you.
For more information, please email:
younginstitute@purdue.edu



Garth Simpson, Young Institute Co-Director and Professor of Chemistry, aligning an optical path for photothermal spectroscopic chemical imaging with high spatial resolution

RAMP! USA

Resilience with AI for Materials and Medicine Production and Scale Up USA Institute

---

A proposal to NIST (National Institute of Standards and Technology), submitted January 23, 2025

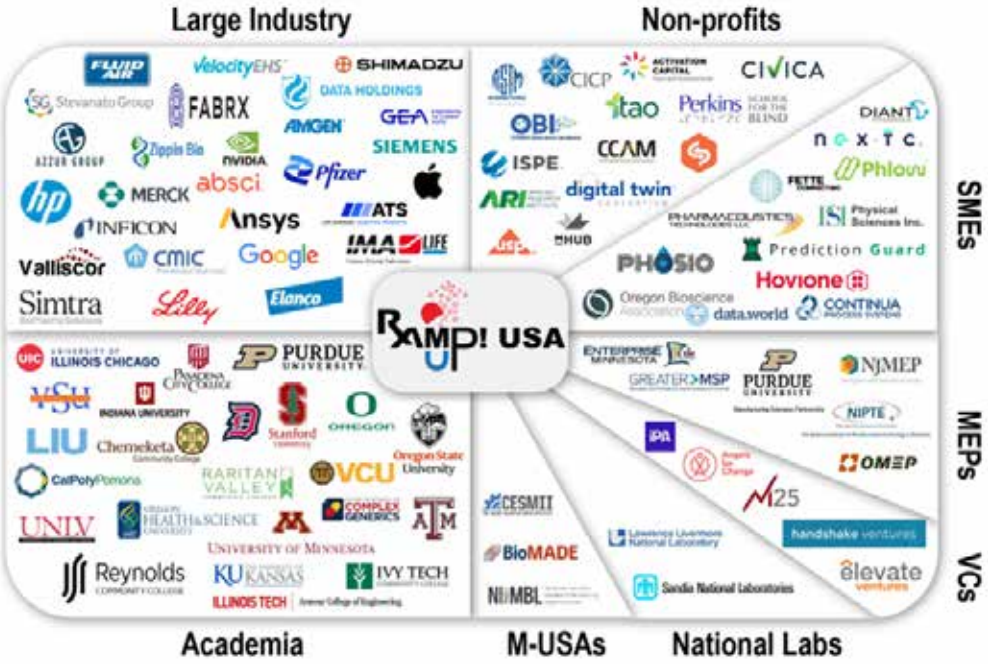
This proposal from the Young Institute seeks to create a public-private partnership that will develop secure trustworthy artificial intelligence (AI) solutions for resilient supply chain of critical pharmaceuticals, vaccines and diagnostics. The project will bring tech industry, pharmaceutical innovator companies, and generic drug product manufacturers together with OEMs and material suppliers to harness the power of AI for making safe, efficacious medicines at a lower cost with better energy, water, and waste management.

MISSION:

Bring together talent, technology, and resources to create tools and standards for AI-enabled resilient manufacturing of critical medicines and materials securing America's health and prosperity.

TARGET IMPACT:

- 40% reduction in drug shortages/duration
- 30% increased adoption of continuous manufacturing
- 25% reduction in water consumption
- 2x reduction in false rejects
- 3-5x increased profitability of generic injectable manufacturing



Purdue University is the lead institution spearheading this public-private partnership federal grant proposal with nearly 100 participant organizations

EDUCATION

AND WORKFORCE TRAINING

The Young Institute is committed to supporting today's workforce and educating the next generation of pharmaceutical manufacturing leaders. In 2024, we received funding for two education-focused projects:

- U.S. Economic Development Administration (EDA), Regional Technology and Innovation Hubs (Tech Hubs), "BioWorks," 5 years, $3.8M subcontract to Purdue. Lead institution: Applied Research Institute (ARI), Purdue PI A. Alexeenko.

  Description: The $51M BioWorks Tech Hub will support early-stage companies and initiatives in workforce development. Purdue will contribute to workforce development initiatives ("BioTrain").

- National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), NIIMBL Experience, "Summer Undergraduate Pharmaceutical Experiential Readiness (SUPER)," (10/1/2024–07/31/2025), $114K, PI A. Alexeenko.

  Description: This project will offer a one-week paid hands-on training program to 10 college students in the summer of 2025, in cooperation with Ivy Tech, BioCrossroads, and Midwest-based biomanufacturing employers.

Professor Rex Reklaitis examining the tablet press in Purdue's Continuous Solids Processing Pilot Plant located in the FLEX high-bay

LEADERSHIP

AT PURDUE AND BEYOND

At Purdue, the Young Institute is led by an interdisciplinary team of faculty with expertise in engineering, chemistry, and the pharmaceutical sciences:

Elizabeth Topp
Director, Professor of Chemical Engineering and of Industrial and Molecular Pharmaceutics.

Alina Alexeenko
Founding Co-Director, Professor of Aeronautics and Astronautics and of Chemical Engineering.

Eric Munson
Founding Co-Director, Department Head and Professor of Industrial and Molecular Pharmaceutics.

Garth Simpson
Founding Co-Director, Professor of Chemistry.

The Young Institute is further supported by a distinguished external Advisory Council:

Robert A. Baffi
President and founder of Baffi Biotech Advisors and former president of global manufacturing and technical operations for BioMarin Pharmaceutical for 23 years.

Mitchell E. Daniels, Jr.
The 12th president of Purdue University and 49th governor of Indiana, who previously held two positions with Eli Lilly and Co.: president of North American operations and senior vice president for corporate strategy and policy.

Michael A. Klobuchar
Chief Operating Officer for Eikon Therapeutics, Inc., a start-up leveraging AI and single molecule technology (SMT) for drug discovery.

Moheb M. Nasr
Principal with Nasr Pharma Regulatory Consulting, who previously served as director of the Office of New Drug Quality Assessment for the Food and Drug Administration's Center for Drug Evaluation and Research.

William D. Young
His significant contribution established the Purdue institute named for him and his wife in June 2022. He is senior advisor for Blackstone Life Sciences and he previously served as chief executive officer for both Monogram Biosciences and Genentech.

HIGHLIGHT

FIRST IN PHARMACEUTICAL EXPORTS

Indiana ranks first among the fifty states in pharmaceutical exports.

Elizabeth Topp, Director

younginstitute@purdue.edu

younginstitute.research.purdue.edu

PURDUE UNIVERSITY | William D. and Sherry L. Young Institute for the Advanced Manufacturing of Pharmaceuticals