

Clinical trial supply in 2025: opportunities and threats

Outsourcing in Clinical Trials & Clinical Supply East Asia 2024

4th December 2024

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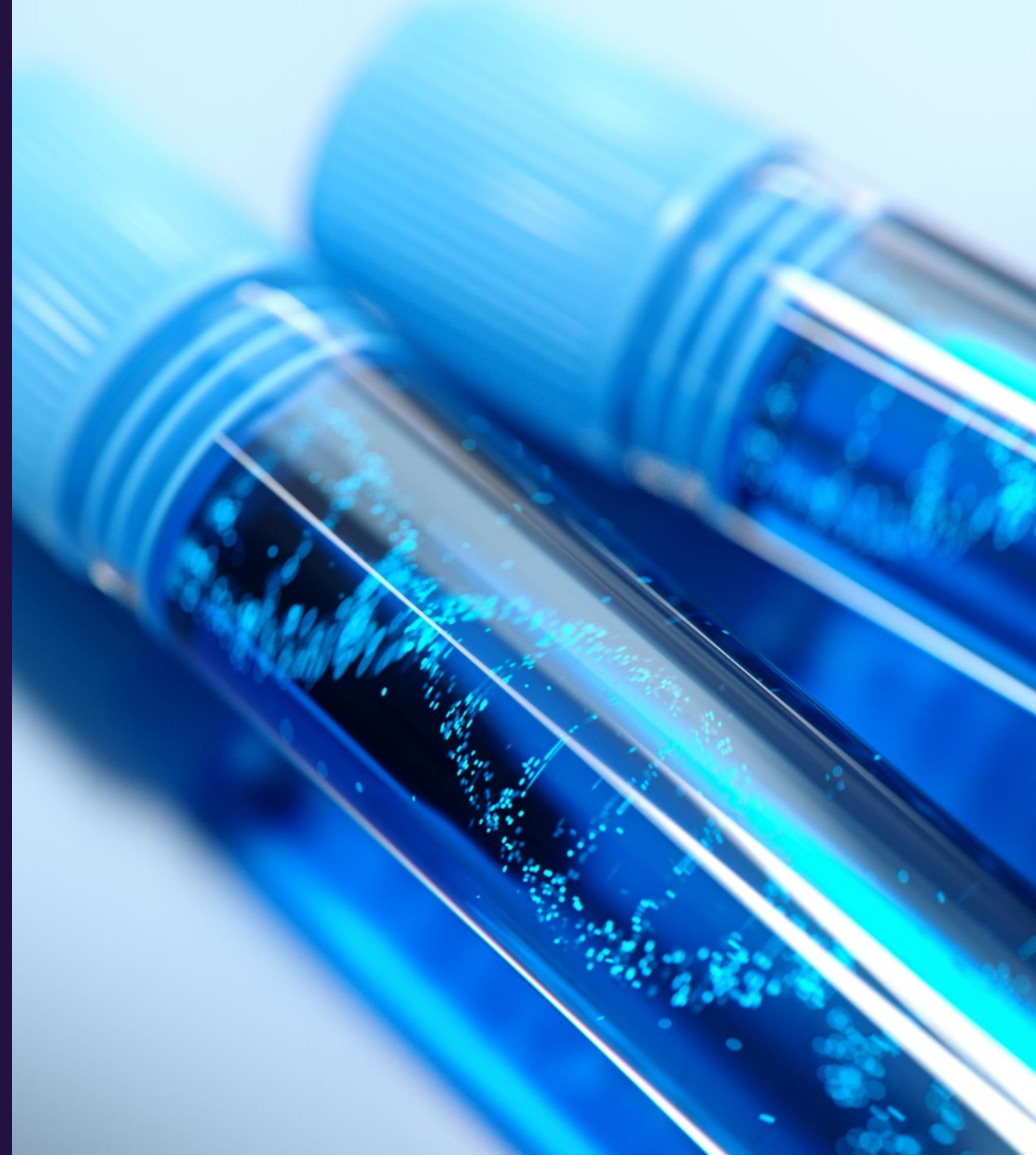


Agenda



- Trends and Opportunities for CDMOs
- Tackling Supply Chain Disruption
- Digitalization of Manufacturing and Supply Chain
- A Look into Sustainability
- Key Takeaways

Trends and Opportunities for CDMOs



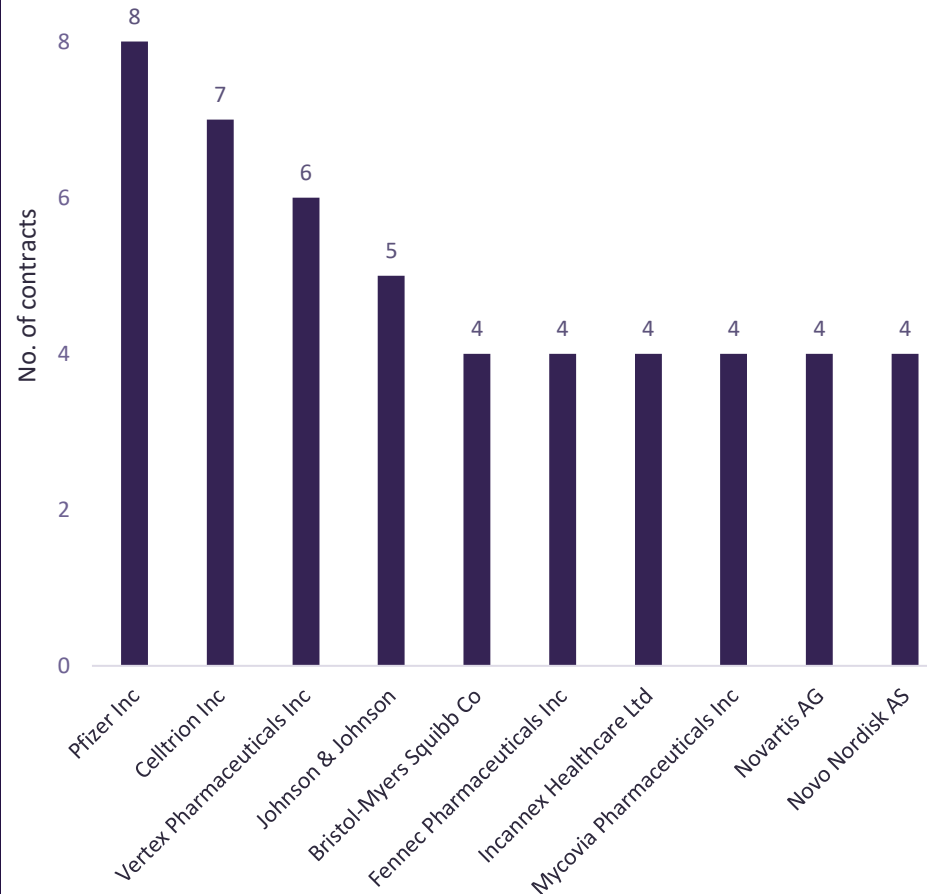
- Pfizer outsourced manufacture of its small molecule and monoclonal antibody drugs.
- Half of Patheon's contracts were for biologics such as peptides, recombinant enzymes, and monoclonal antibodies. A large portion of Patheon's contracts were for small molecules as well.
- Motivations for outsourcing vary. Larger companies choosing to dual-source manufacture (both in-house and outsourced production) can use contractors as an additional site in a multi-site supply strategy that increases supply chain security and offers backup capacity, which is particularly important during times of supply chain disruption caused by trade wars or effects of the global conflict. Outsourcing may also be pursued if it is more favorable in terms of time and/or cost.

Top CMOs and Clients by Contract Manufacturing Agreements 2022-24

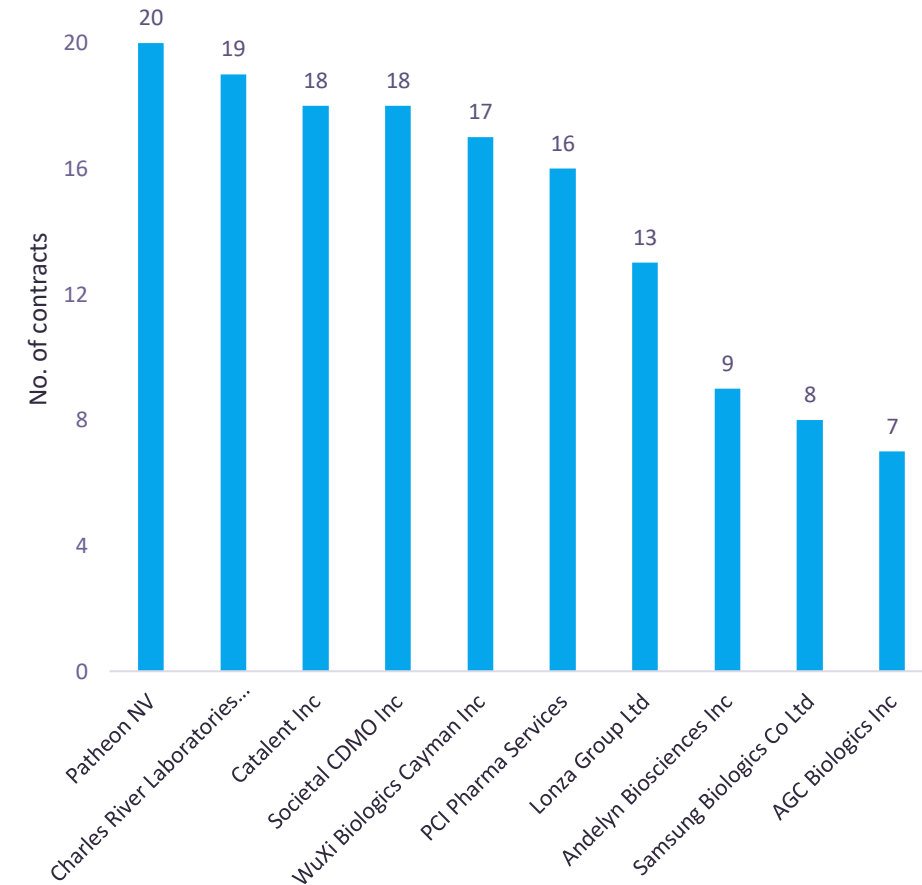


During 2022-24, Pfizer was the client providing the largest number of contracts and Patheon (subsidiary of Thermo Fisher Scientific) was the CMO receiving the largest quantity of contracts

Top Clients by Contract Manufacturing Agreements



Top CMOs by Contract Manufacturing Agreements



Source: Source: GlobalData, Pharma Intelligence Center Deals database (Accessed October 28, 2024)

Latest Contract Manufacturing Agreements



Outsourcing contracts announced in the past month

Contractor	Biopharma Company	Deal	Drug(s)	Number of drugs	Molecule type(s)
AtomVie Global Radiopharma	Radiopharm Theranostics	Radiopharm Theranostics Enters Manufacturing Agreement with AtomVie Global Radiopharma for 177Lu-BetaBart	177Lu-BetaBart	1	ADC
Catalent	IsomAb	IsomAb Enters Manufacturing Agreement with Catalent for ISM-001	ISM-001	1	mAb
Charles River Laboratories International	FibroBiologics	FibroBiologics Enters Manufacturing Agreement with Charles River Laboratories International for CYWC628	CYW-628	1	Cell therapy
FUJIFILM Diosynth Biotechnologies USA	TG Therapeutics	TG Therapeutics Enters API Manufacturing Agreement with FUJIFILM Diosynth Biotechnologies USA for BRIUMVI	BRIUMVI	1	mAb
Lonza Biologics Porriño	Undisclosed	Undisclosed Client Enters API Manufacturing Agreement with Lonza Biologics Porriño for its mAb	Unnamed	1+	mAb
Lonza Group	Pheast Therapeutics	Pheast Therapeutics Enters Manufacturing Agreement with Lonza Group for PHST001	PHST001	1	mAb
Matica Biotechnology	Mongoose Bio	Mongoose Bio Enters API Manufacturing Agreement with Matica Biotechnology for lentivirus	MGB-001	1	Gene-modified cell therapy
NorthX Biologics Matfors	NEOGAP Therapeutics	Neogap Therapeutics Enters API Manufacturing Agreement with NorthX Biologics for Cell therapy products	Personal Tumor Trained Lymphocytes	1	Cell therapy
Nucleus RadioPharma	Clarity Pharmaceuticals	Clarity Pharmaceuticals Enters Manufacturing Agreement with Nucleus RadioPharma for 67Cu-SAR-bisPSMA	67Cu-SAR-bisPSMA	1	Peptide
Octapharma	Zhuhai Beihai Biotech	Zhuhai Beihai Biotech Enters Manufacturing Agreement with Octapharma for Beizray	Beizray	1	Small molecule

Opportunities in Contract Manufacturing



A selection of opportunities for CMOs in the past month

Contractor	Biopharma company	Event	Product*	Relationship
ACS Dobfar	Pfizer	EMA expanded indications	Zavicefta	Parenteral manufacture and packaging
Alchem Laboratories	Atossa Therapeutics	Positive Phase II top-line results	endoxifen	Solid dose manufacture
AstraZeneca	Merck & Co.	EMA expanded indications	Keytruda	Biologic API
Bayer	Sandoz	FDA expanded indications	Zarxio	Parenteral manufacture and packaging
Biogen	Johnson & Johnson	EMA expanded indications	Darzalex	Biologic API
Boehringer Ingelheim Pharma	Merck & Co.	EMA expanded indications	Keytruda	Biologic API
Cambrex	Neuraxpharm UK	UK MHRA approval	Buccolam	Small mol API
Catalent France Limoges	Pfizer	FDA expanded indications	Fragmin	Parenteral manufacture and packaging
Catalent Indiana	Johnson & Johnson	EMA expanded indications	Darzalex	Biologic API
	AstraZeneca	EMA expanded indications	Fasenra	Parenteral manufacture and packaging

Contractor	Biopharma company	Event	Product*	Relationship
Catalent Nottingham	Blueprint Medicines	NICE approval	Ayvakyt	Solid dose manufacture
Charles River Laboratories International	Johnson & Johnson	EMA expanded indications	Darzalex	Biologic API
FUJIFILM Diosynth Biotechnologies USA				Biologic API
IDT Biologika	Sandoz	FDA expanded indications	Zarxio	Parenteral manufacture and packaging
Organon & Co.	Merck & Co.	EMA expanded indications	Keytruda	Parenteral packaging
Patheon	AbbVie	FDA approval	Vyalev	Parenteral manufacture and packaging
	Astellas US	FDA approval	Vyloy	Biologic API
PCI Pharma Services	Blueprint Medicines	NICE approval	Ayvakyt	Solid dose packaging
Piramal Pharma Solutions	Acurx Pharmaceuticals	Trial planned – Phase III	ibezapolstat	Small mol API, Solid dose manufacture
SGS Quay Pharmaceuticals	Shorla Oncology	FDA expanded indications	Jylamvo	Solid dose manufacture and packaging

Source: GlobalData, Pharma Intelligence Center (Accessed November 11, 2024)

*New molecular entities are in bold.

Selected Catalyst Events in Q4 2024: Trial Completions and Results

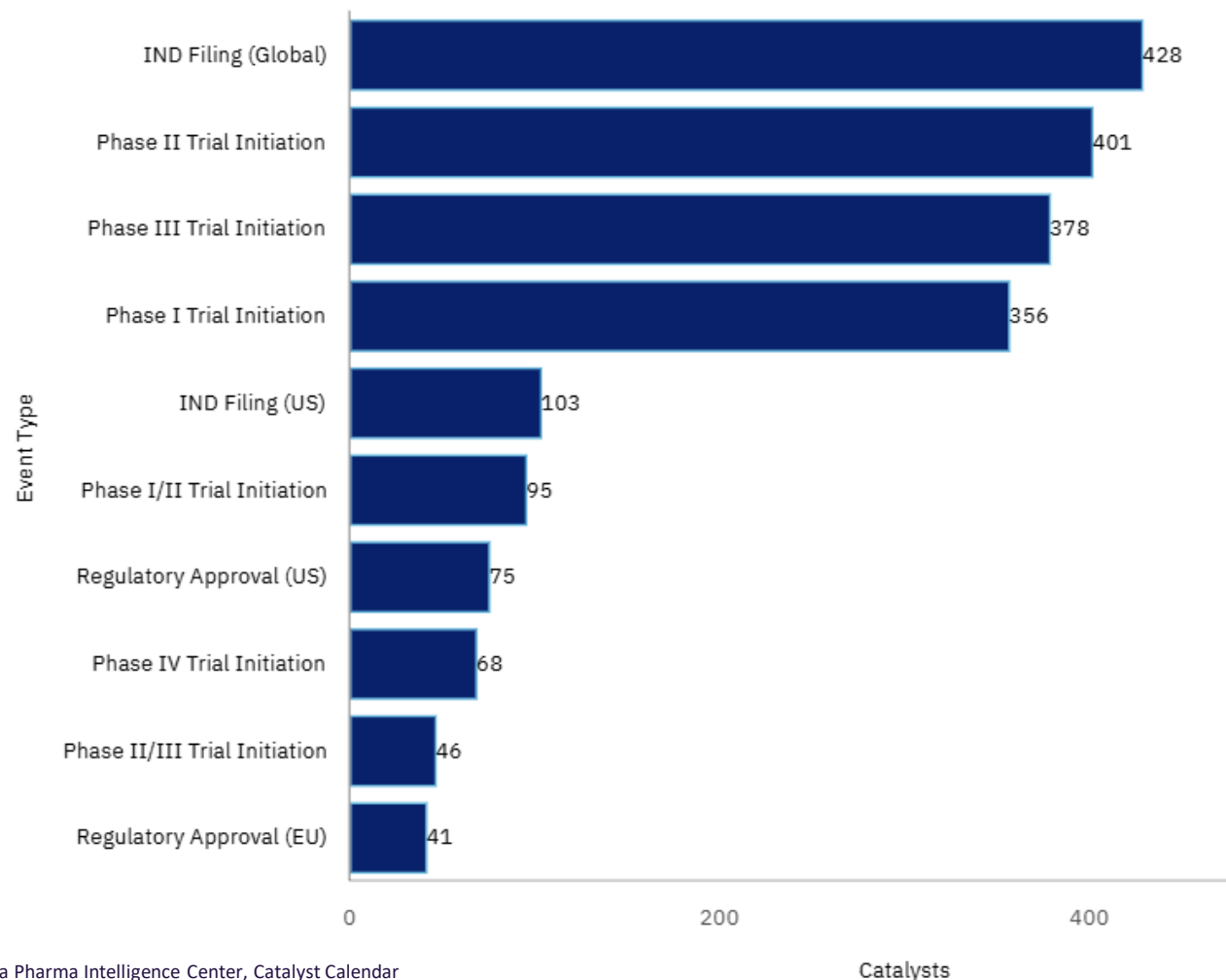
- **CeleCor Therapeutics**
| zalunfiban acetate
| Myocardial infarction | Phase III trial completion | December 1, 2024
- **Capricor Therapeutics**
| deramiocel | Duchenne muscular dystrophy; muscular dystrophy; neuromuscular disorders; unspecified central nervous system disorders; unspecified genetic disorders
| Phase III trial results | Q4 2024
- **Thrombolytic Science International** | TS-01
| Myocardial infarction; percutaneous coronary intervention | Phase II trial completion | November 30, 2024
- **GSK** | mepolizumab | Chronic obstructive pulmonary disease (COPD) | Phase III trial results | H2 2024

Opportunities for CDMOs in 2025



Upcoming Planned Trial Initiations, IND Filings, & Regulatory Approvals in 2025, by Event Type

As of October 25, 2024



Selected Catalyst Events in Q4 2024: Trial Completions and Results

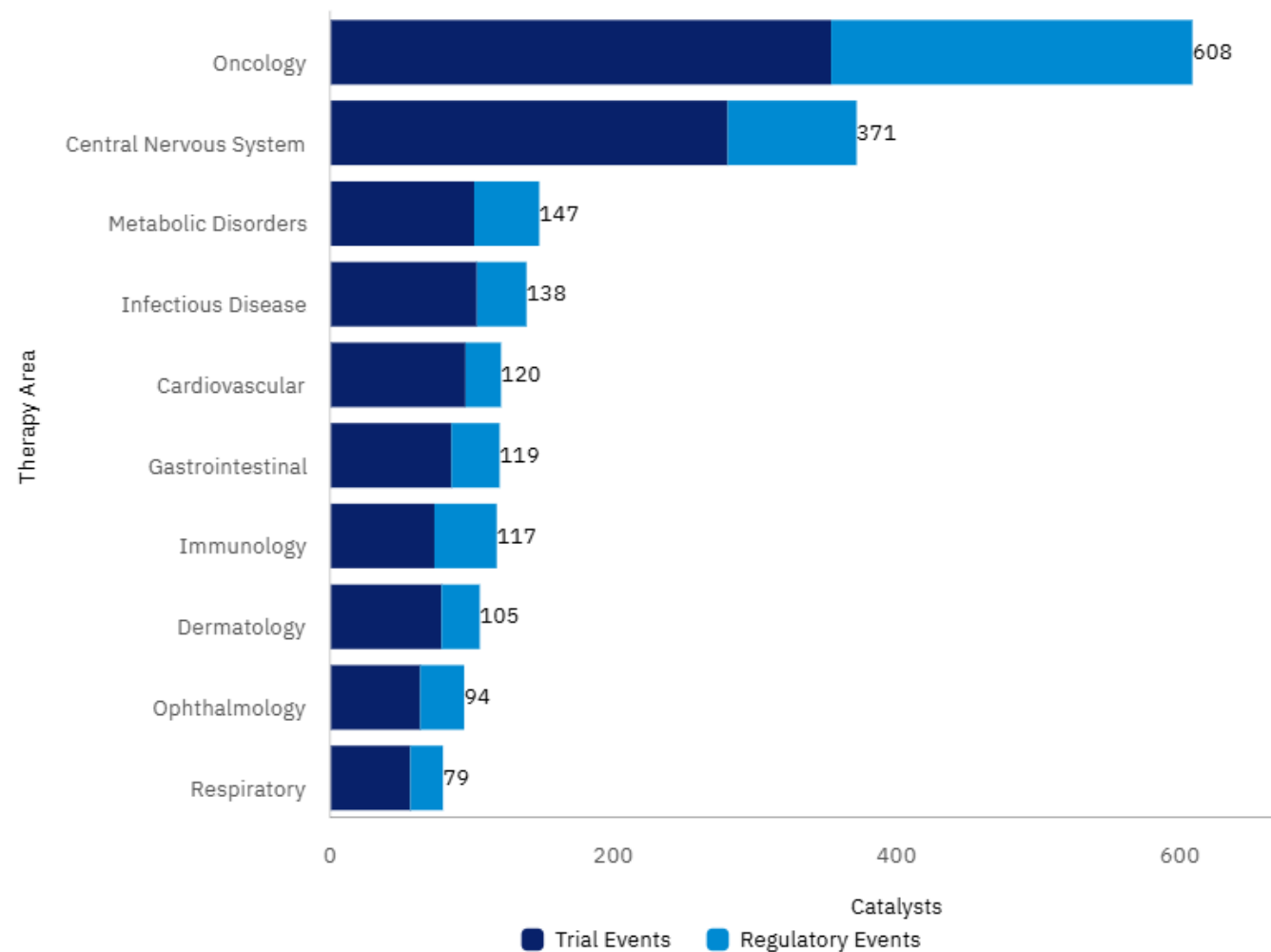
- **NeuroBo Pharmaceuticals** | DA-1241 | Metabolic dysfunction-associated steatohepatitis (MASH); pre-diabetes/impaired glucose tolerance; type 2 diabetes | Phase II trial results | Q4 2024
- **Compass Pathways** | psilocybin | Treatment resistant depression | Phase III trial results | Q4 2024
- **BioCardia** | CardiAMP | Left ventricular dysfunction; myocardial infarction; myocardial ischemia; systolic heart failure | Phase III trial completion | December 1, 2024
- **ALX Oncology** | evorpacept; pembrolizumab | Head and neck cancer; head and neck squamous cell carcinoma (HNSC); recurrent head and neck squamous cell carcinoma | Phase II trial completion | December 31, 2024

Opportunities for CDMOs in 2025



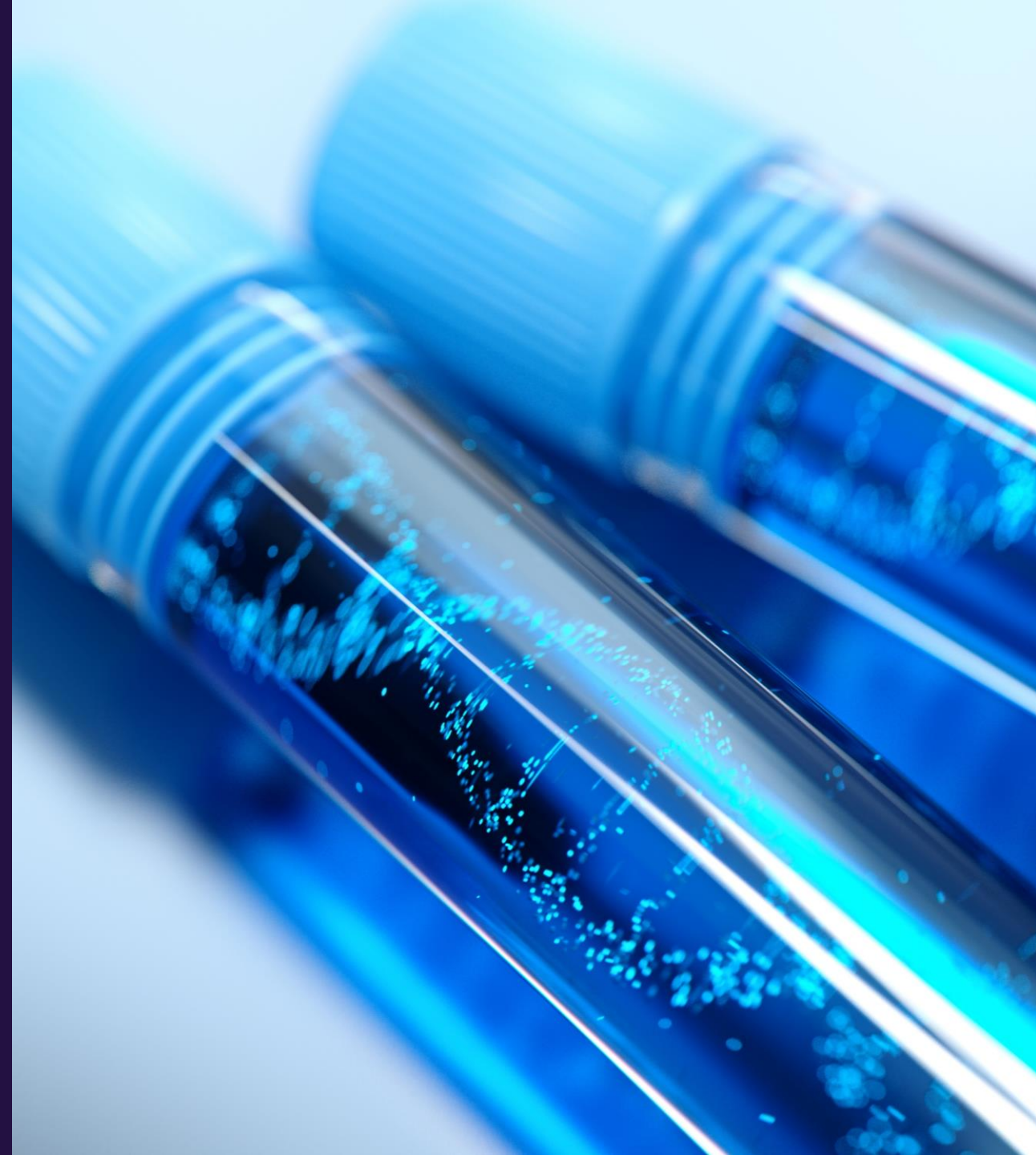
Upcoming Planned Trial Initiations, IND Filings, & Regulatory Approvals in 2025, by Therapy Area

As of October 25, 2024



Source: GlobalData Pharma Intelligence Center, Catalyst Calendar

Tackling Supply Chain Disruption



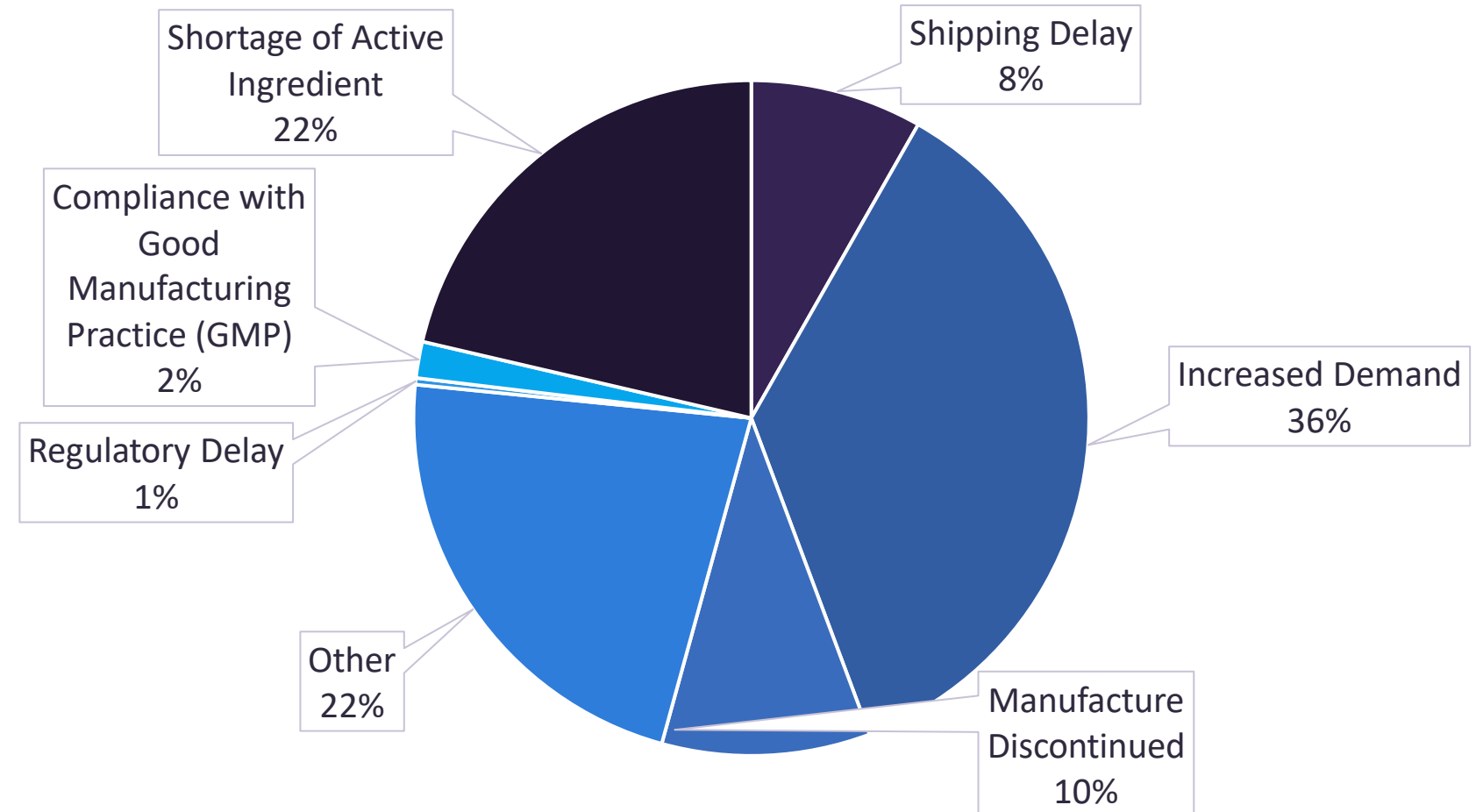
“Supply chain disruption has [an] impact in all the therapeutic areas and all medicines. If the supply chain problems were not solved it could impact medicine availability and the launch of new products. We are seeing several acquisitions of CMO [contract manufacturing organization] and CDMO by VC [venture capital] funds because it will be a profitable business in a near future due to the supply chain situation.”

– Manager, Europe

Supply Chain Challenges

Reasons for current drug shortages in the US

Shortages are impacting both high- and low-value drugs (such as antibiotics). Demand is especially high for anesthetics and oncology drugs. Some pharma manufacturers have suggested that the low prices of generics are a reason for the drug shortages, by forcing generic manufacturers to discontinue production and exit the market.



Source: FDA Drug Shortages database (Accessed October 28, 2024)

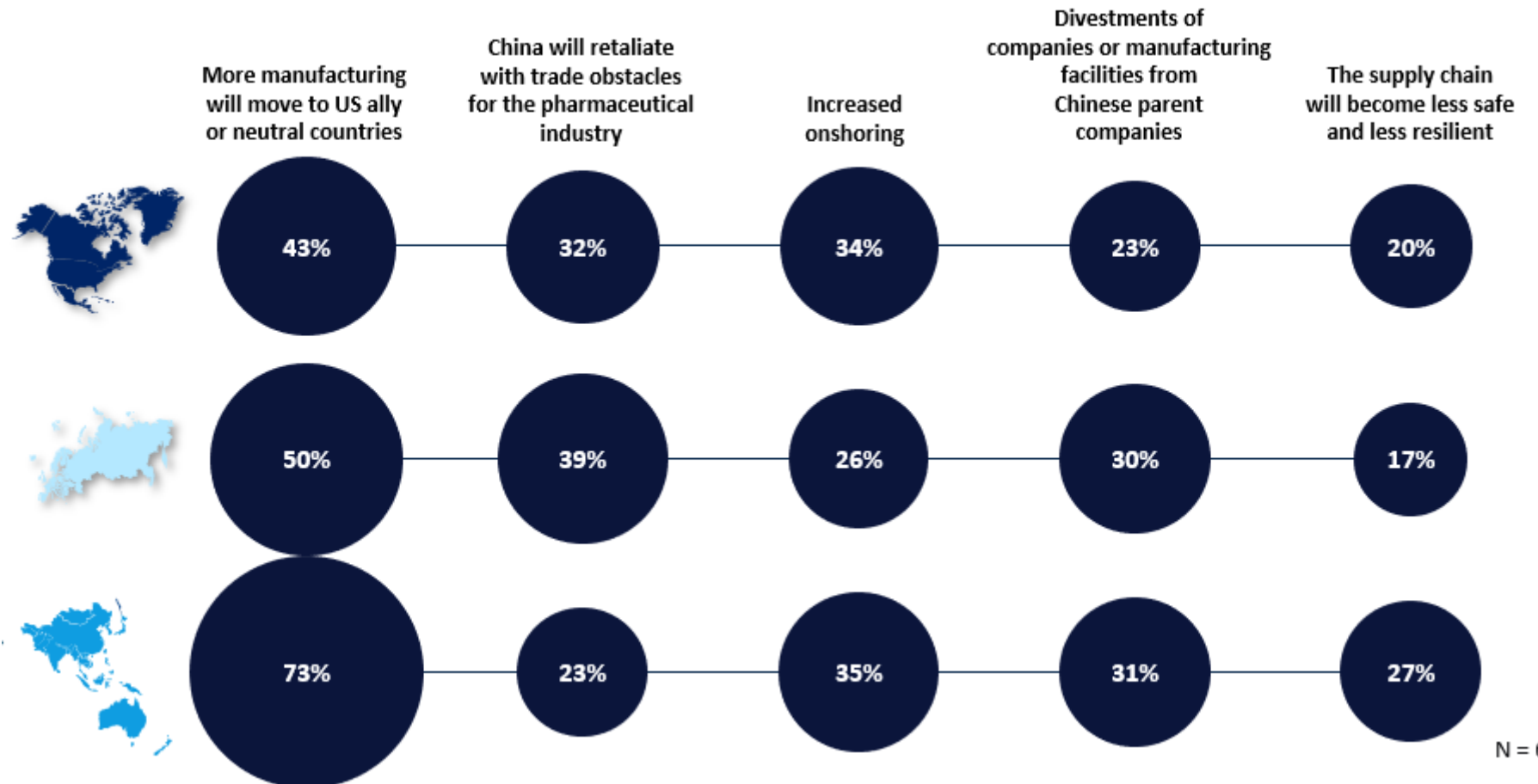


BIOSECURE Act



Top five implications for the pharmaceutical supply chain if the BIOSECURE Act passes, by geography

KOLs expect more manufacturing to move to US ally or neutral countries. This answer was particularly visible with APAC respondents.



Q: If the BIOSECURE bill passes, what would be the wider implications for the pharmaceutical supply chain?
Source: GlobalData, The State of the Biopharmaceutical Industry, 2024 Edition (Mid-Year Update)

“As we decouple from China in the pharma industry, we continue to have a huge demand for base ingredients of the agents that are currently only supplied by China, and we don't have the capacity to bring these back to America in a timely manner. We either find a way to ramp up quickly or we are in trouble with the supply versus demand.”

- Director, North America

Supply Chain Resiliency: Methods of Tackling Supply Chain Disruption



These solutions should be used in conjunction with one another to help mitigate the risks posed by emerging regulatory and macroeconomic trends.



Reshoring, nearshoring, and friendshoring

Relocating to trusted geographies can help reduce costs from trade restrictions and tariffs.



Diversification

Diversification can help reduce disruption when one or more suppliers are compromised.



Digitalization

Digitalization can shorten supply chains, increase supply chain visibility, and help address labor challenges.



Circular economy

Adopting circular economy principles promotes sustainable practices and can help build supply chain resilience.

Automation can relieve pressures from increasing labor costs and skills shortages



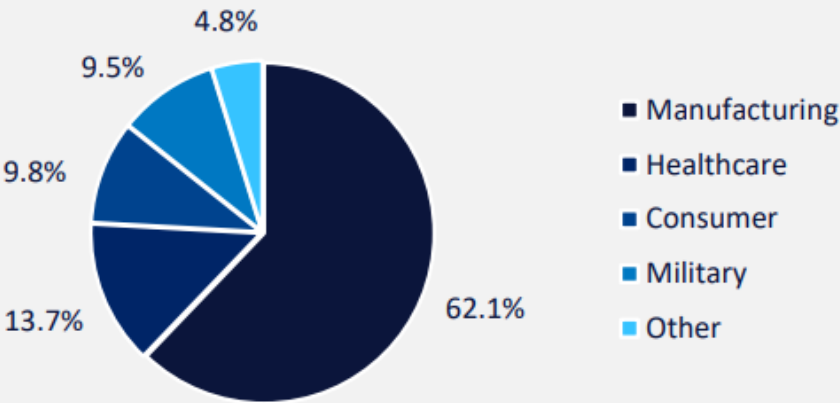
Relocating business operations to high-income countries increases labor costs, making automation even more important.

Types of automation:

1. Basic automation — Automating simple singular tasks.
2. Process automation — Automating more complex and repeatable multi-step processes.
3. Intelligent automation — Automating decision-making across complex processes using AI.

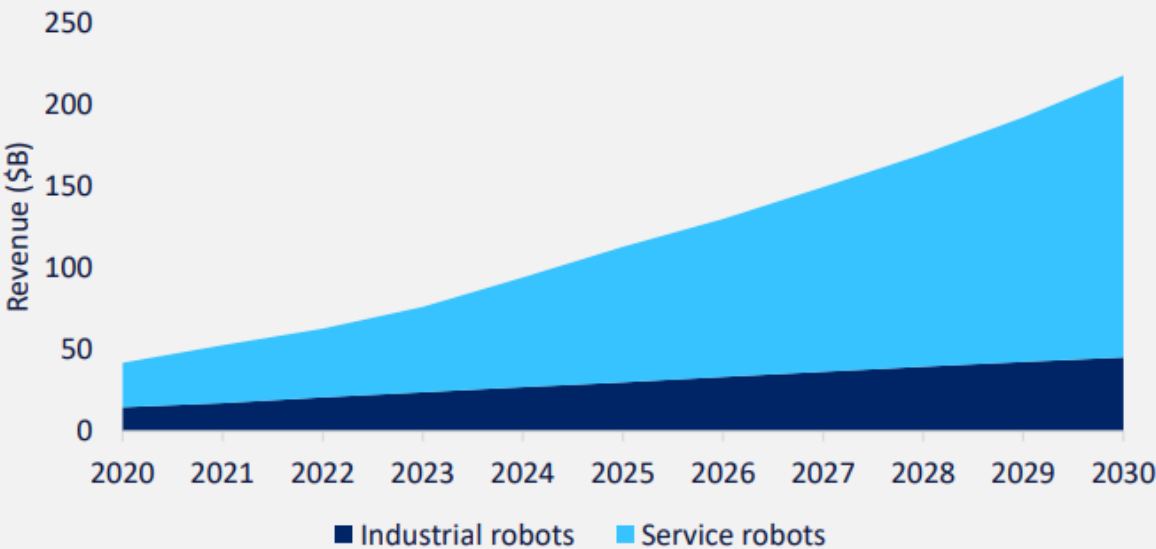
The manufacturing sector will be the most impacted by automation

What are the sectors that will be most impacted by automation?^[1]



The robotics industry will be worth \$217.6 billion by 2030, with a CAGR of 15% between 2023 and 2030.

Service and industrial robots revenue, 2020-2030



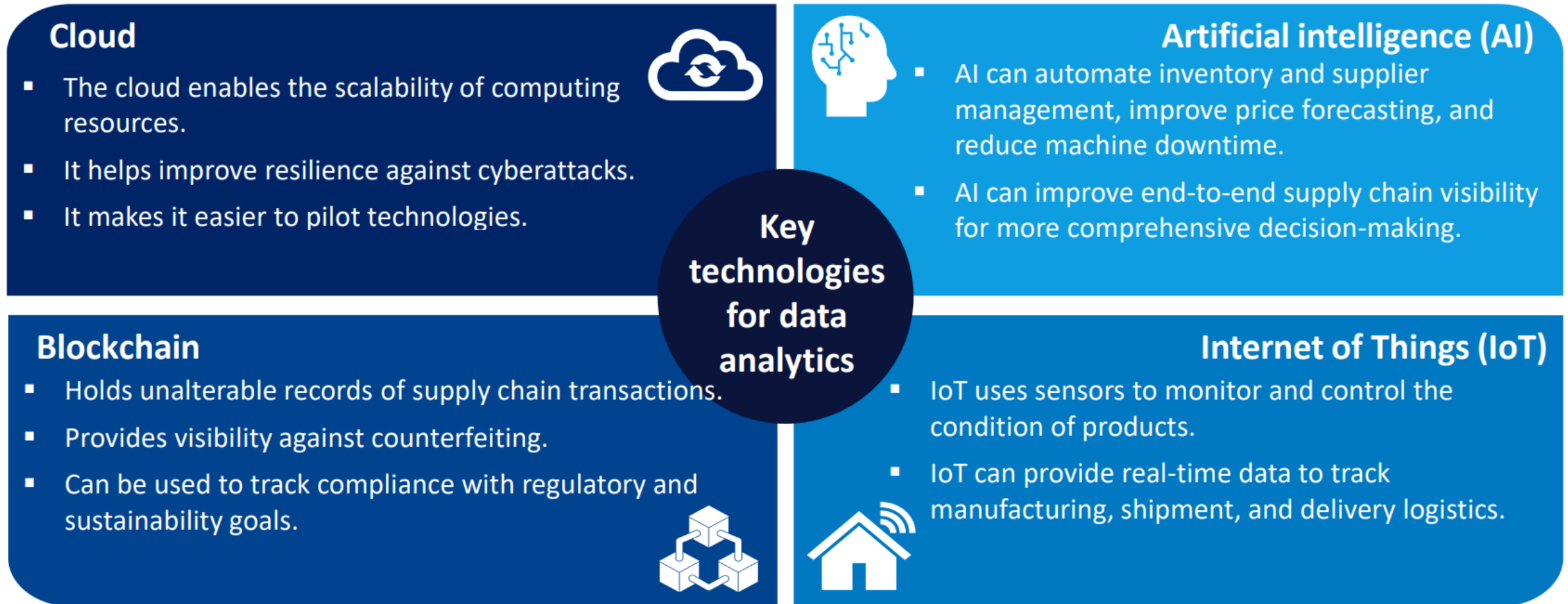
Exoskeletons and logistics robots will be the fastest-growing robotics segments, with exoskeletons expected to grow at a 33% compound annual growth rate (CAGR) between 2023 and 2030.

[1] Verdict Media poll question conducted between Q2 2023 and Q2 2024 with 1,300 respondents
Source: GlobalData, Thematic Intelligence: Supply Chain Disruption

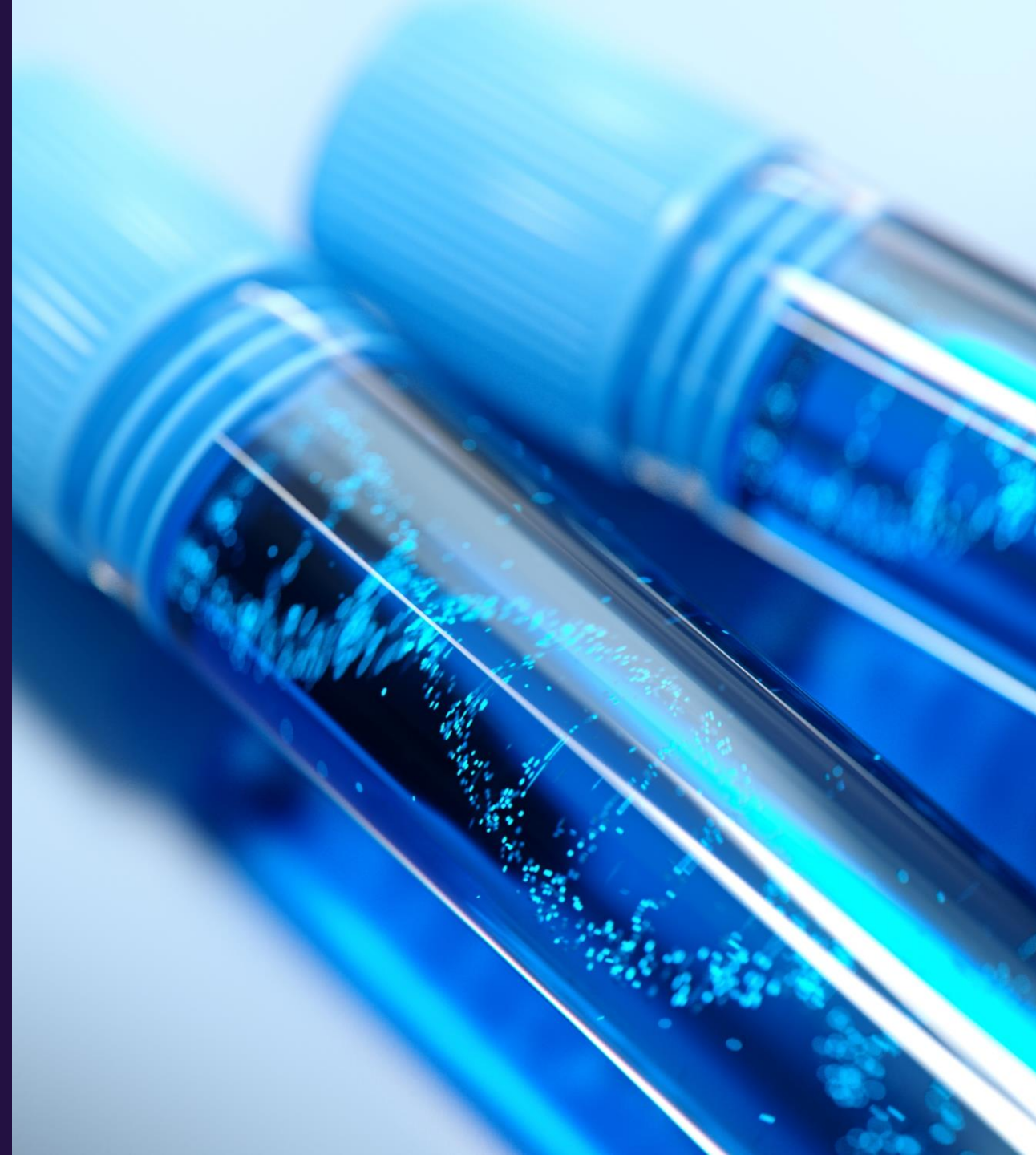
Automation can relieve pressures from increasing labor costs and skills shortages



Below are the key technologies that can help improve supply chain visibility.



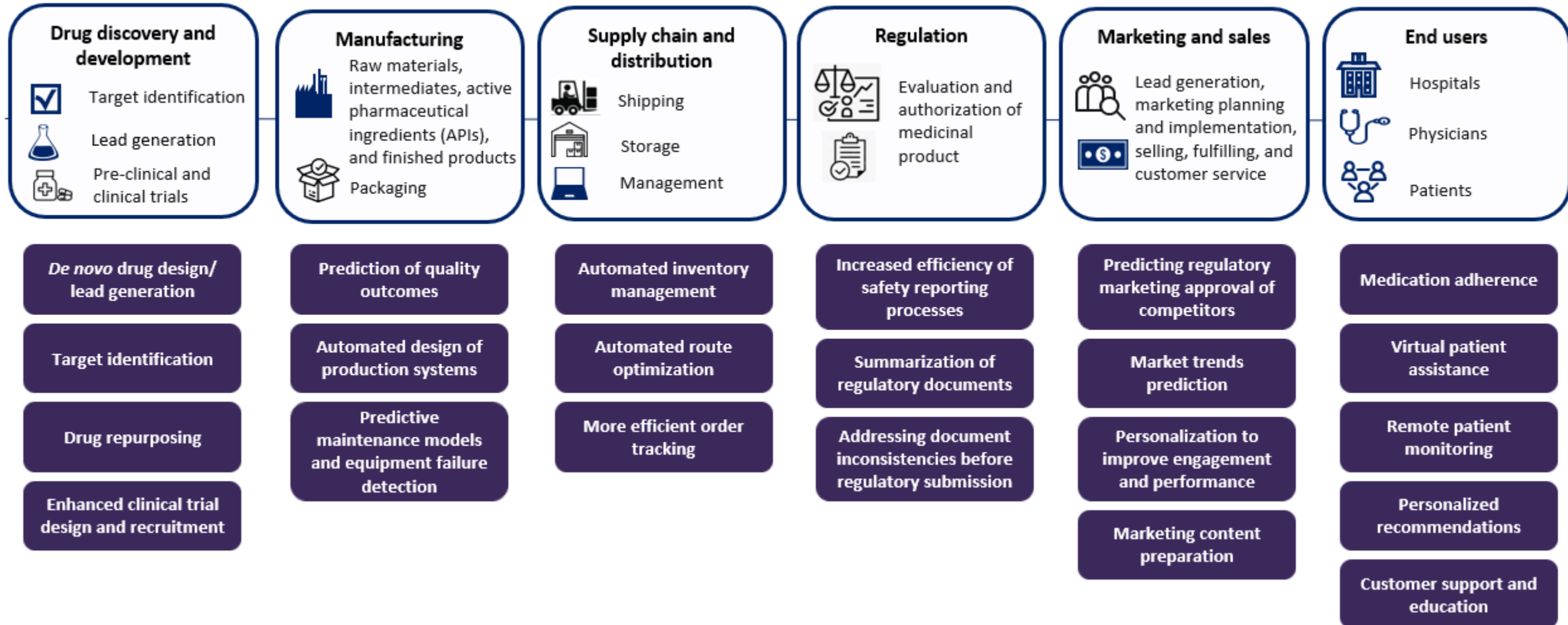
Digitalization of Manufacturing and Supply Chain



AI, Big Data, and IoT Can Be Used Across the Entire Pharma Value Chain



Digitalization and automation can accelerate drug discovery, enhance clinical trials and drug approval processes, optimize manufacturing and supply chains, boost marketing and sales efforts, and improve the patient experience.



AI, Big Data, and IoT Use in Pharmaceutical Manufacturing

KOLs named these tasks as suitable for improvement by AI and big data:

Inventory Management	Authoring manufacturing documents	Generating Process Flow	Biomedical engineering	Input numerous process controls to optimize final product specifications	Document (batch record, sample plan) generation and conversion from format to format
Education and training of employees	FDA audit documentation	Preclinical stage work	Drug delivery innovation (softgel formulations with varying dissolution characteristics)	Process improvement	Operation support
Production planning	QbD [quality by design]	Process steering based on measured parameters	Root cause investigations based on recorded data	Quality control	Research
Safety	Small molecule evaluation	Waste disposal and recycling	Yield control and improvement	CAPA development	Material sourcing
KPI tracking	Performance improvement	Labor cost savings	Report writing	Supply chain management	Processes related to deviations or compliance violation

Q: Are you aware of any parts of the manufacturing process where generative AI is or could be being used in drug manufacturing?
Source: Global AI trends in Pharmaceutical Manufacturing Survey, 2023

AI's ability to analyze and interpret huge amounts of data is one of the most important benefits of applying this technology in the pharmaceutical sector, such as optimizing manufacturing and supply chain processes.

Supply Chain and distribution

Shipping

Storage

Management

Automated inventory management

Automated route optimization

More efficient order tracking

Top Five Emerging Technologies

AI and big data were rated as the most impactful technologies in the pharma industry for five consecutive years. AI will continue to gain more traction and will trend as the most disruptive emerging technology in the pharmaceutical sector in the next 12 months.

Survey fielded April 5, 2024 to May 10, 2024

	Artificial intelligence	Big data	Digital media	Cybersecurity	Internet of things
2024 Mid-Year Update	69%	13%	4%	4%	3%
2024	60%	14%	2%	4%	4%
2023	39%	27%	4%	7%	5%
2022	40%	24%	3%	5%	6%
2021	36%	20%	4%	7%	6%

Q: Of the technologies listed in the previous question, which one do you expect to have the greatest impact on the pharmaceutical industry in 2021/2022/2023/2024/the next 12 months?

Source: GlobalData, The State of the Biopharmaceutical Industry Survey, 2021/2022/2023/2024/2024 (Mid-Year Update) Edition

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Examples:

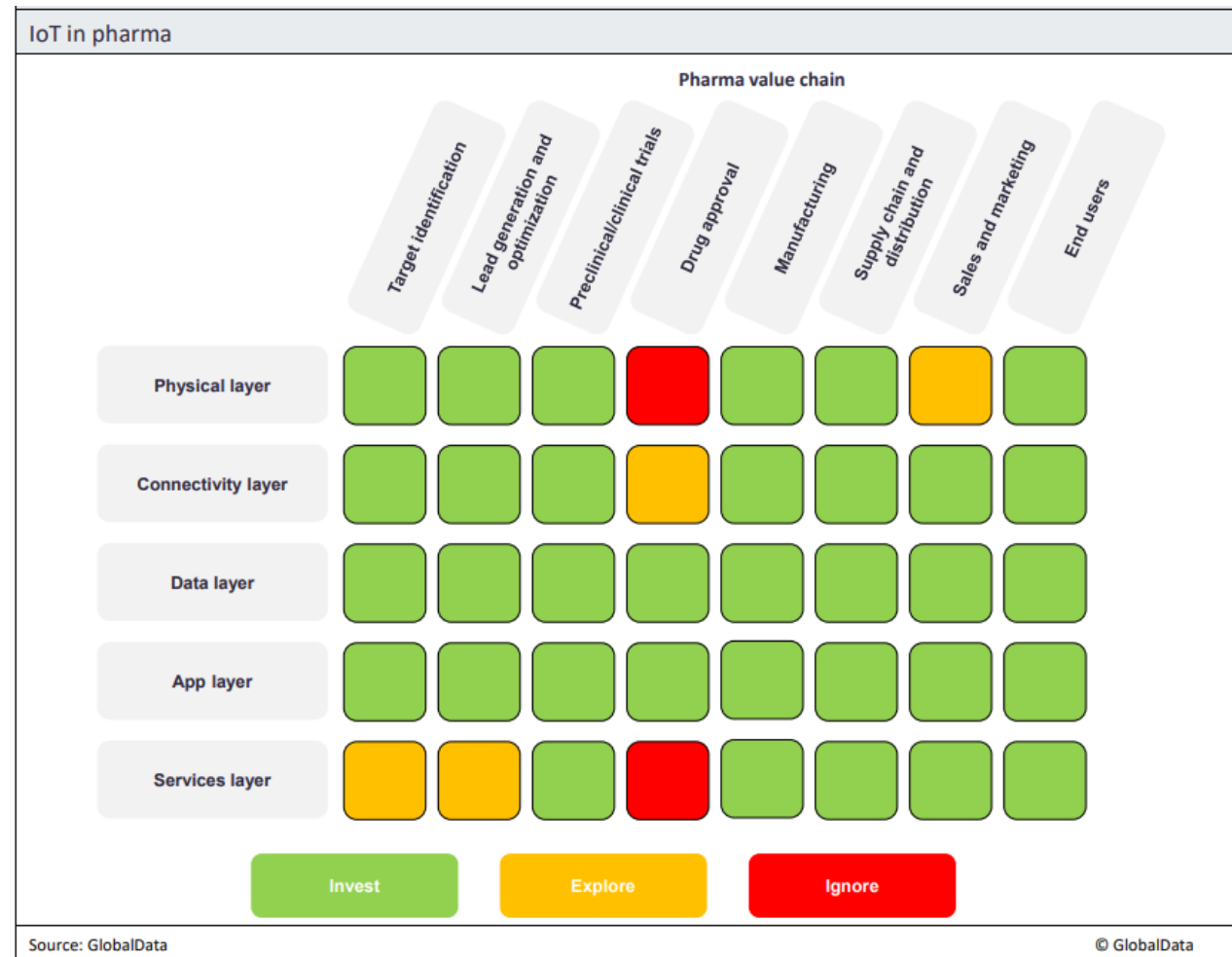
The convergence of 5G, IoT, and sensors could allow manufacturing robots enhanced with AI to be programmed to continually adjust their performance to achieve optimal productivity and efficiency.

Companies use digital twins to recreate a digital form of their supply chain to help address constraints and insufficient processes.

IoT in Manufacturing and Supply Chain



As technologies advance, improvements in automation technology can lead to substantial enhancements beyond productivity increases. Technologies such as robotics, digital twins, sensors, and AI will allow for fully digitized manufacturing processes.



“AI is a technology that has been known by some for many years but only now is becoming more widely known. For it to achieve positive outcomes, all the regulatory, ethical and intellectual, current guidelines, procedures etc... need to be reviewed so that everyone is comfortable as it becomes part of every day business practices within the industry.”

— Manager (all levels),
North America

Areas of Pharma Manufacturing that AI Could Help With



Respondents from contract manufacturing organizations believed that AI is best suited to help with creation of manufacturing optimization plans, real time process monitoring, investigation of faults and small molecule drug manufacturing.

	Pharmaceutical company – develops/markets own drugs and also offers contract services to other companies	Pharmaceutical company – develops/markets own drugs and does not offer contract services to other companies	Contract manufacturing organization	Other
Site design, scale-up, or tech transfer	41%	33%	40%	59%
Creation of manufacturing optimization plans	59%	67%	90%	62%
Real-time process monitoring (preventing faults, improving yield)	65%	57%	90%	72%
Investigating faults or out-of-specification results after they occur	47%	67%	70%	52%
Inventory management	53%	48%	50%	66%
Small molecule drug manufacturing	41%	19%	70%	45%
Biologics manufacturing	53%	29%	50%	41%
Replacing automated tasks	41%	48%	40%	45%
Other	6%	10%	10%	0%

Q: What areas of pharma manufacturing do you believe AI could help with? You may select multiple answers.
Source: Global AI trends in Pharmaceutical Manufacturing Survey, 2023

N = 82

AI and Big Data Implementation Pathway

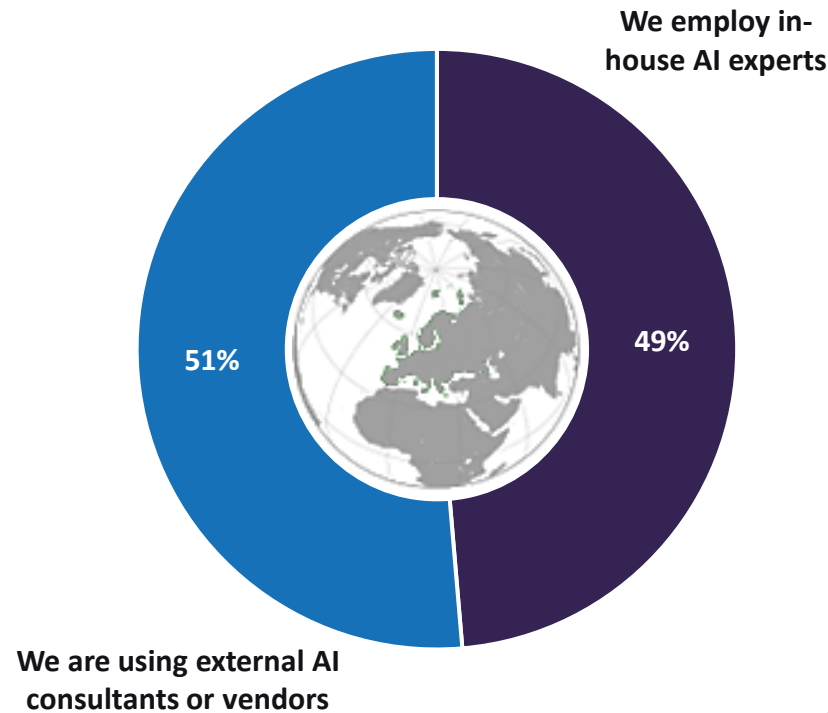


Survey respondents were equally using in-house expert teams and external consultants/vendors to implement AI

"I would love to see greater collaboration between industry and regulators to start implementing AI solutions."

— Europe VP/SVP/EVP,
pharmaceutical company

Company's AI implementation pathway



KOL Insights on AI and Big Data Implementation

"Big data was the "hot topic" of yesterday, now with generative AI, it will help interpret the data and add efficiency."

— North America Director

"AI has the potential to transform the pharmaceutical industry by accelerating [processes], reducing costs, and improving outcomes. However, careful consideration and regulation are needed to ensure that AI is used safely and ethically."

— RoW C-Level Executive

"Big data evaluated by AI or other means will play one of the highest roles in the mid future; already started."

— Europe C-Level Executive

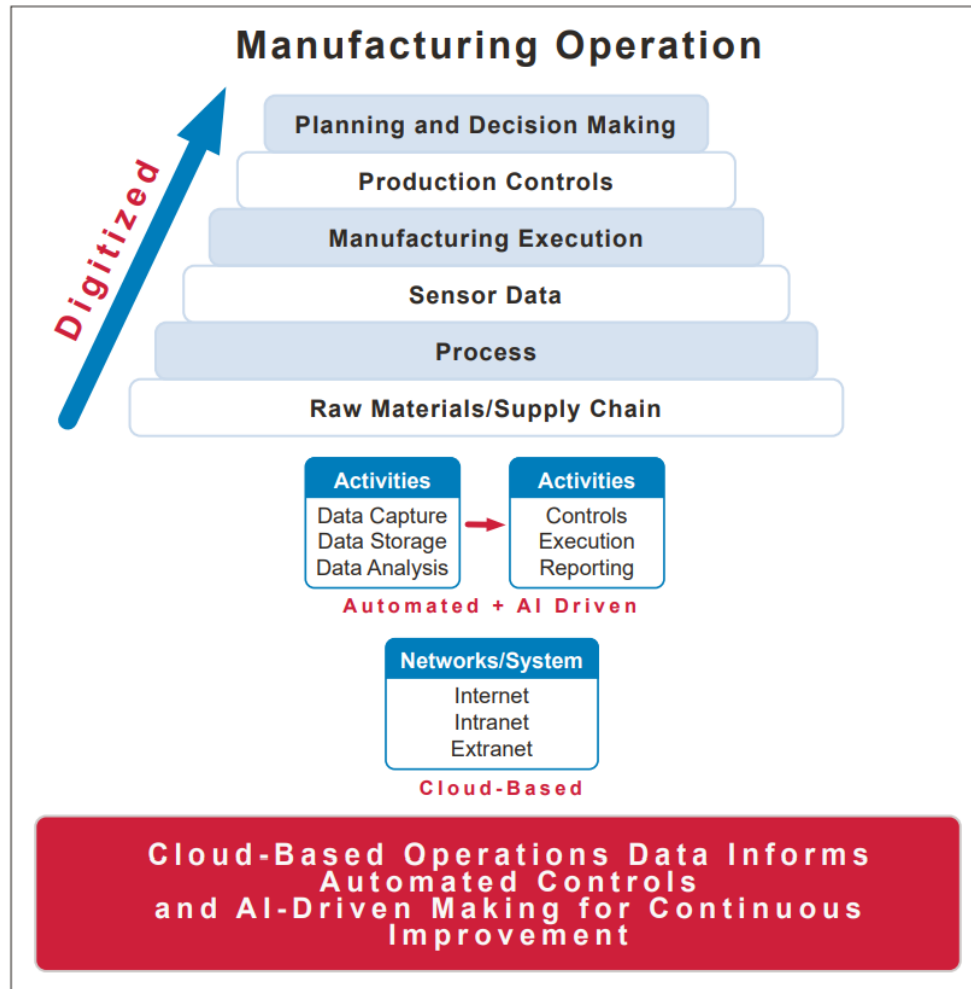
"Joined up data will underpin large language datasets, machine learning and AI."

— North America Director

Q: How is your company implementing AI? You may select multiple answers.
Source: Global AI trends in Pharmaceutical Manufacturing Survey, 2023

The FDA's Stance

The FDA found that AI could be beneficial in process optimization and control, intelligent maintenance, and trend monitoring for continuous process improvement in the new age of "Industry 4.0" — a hyper-connected, digitalized ecosystem and pharmaceutical value chain.



The FDA has stated that these questions remain to be answered:

- Can a new drug application that includes AI in its manufacturing technology can fit within the FDA's current regulatory framework?
- How should existing Current Good Manufacturing Practice (CGMP) regulations apply to AI?
- How should AI be regulated in supply chain management of drugs?
- How should AI be regulated when used in the bioinformatics pipelines as part of the upstream manufacturing process to generate candidates for precision medicine complex biological products, e.g., cancer vaccines, cellular and gene therapies?

FDA's Five Challenges for AI in Manufacturing

Risk management

Cloud applications could affect the oversight of drug manufacturing data and records. The FDA sees potential issues with existing quality agreements between a third party and manufacturer, creating gaps in **risk management**.

Data volume

Digitization of manufacturing (IOT) may increase the **amount of data** generated (frequency and data types) during drug manufacturing, thus affecting existing data management practices and creating a need to maintain data integrity and retention with this increase.

Regulation

Clarity about whether and how certain applications of AI in drug manufacturing is subject to **regulatory oversight** (e.g. CGMP compliance, NDA, BLA)

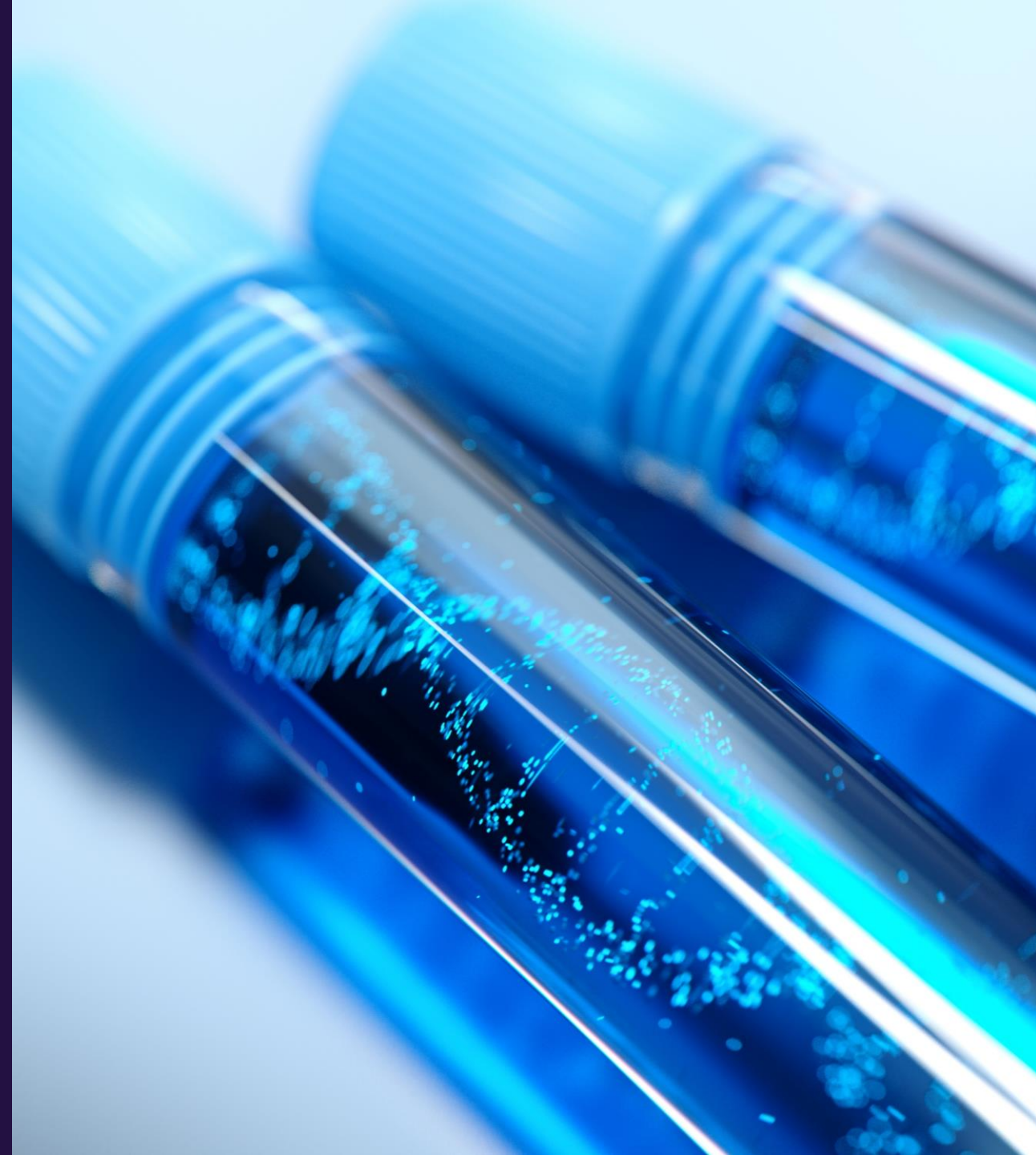
Validation

Standards for the development and **validation** of AI models that impact product quality

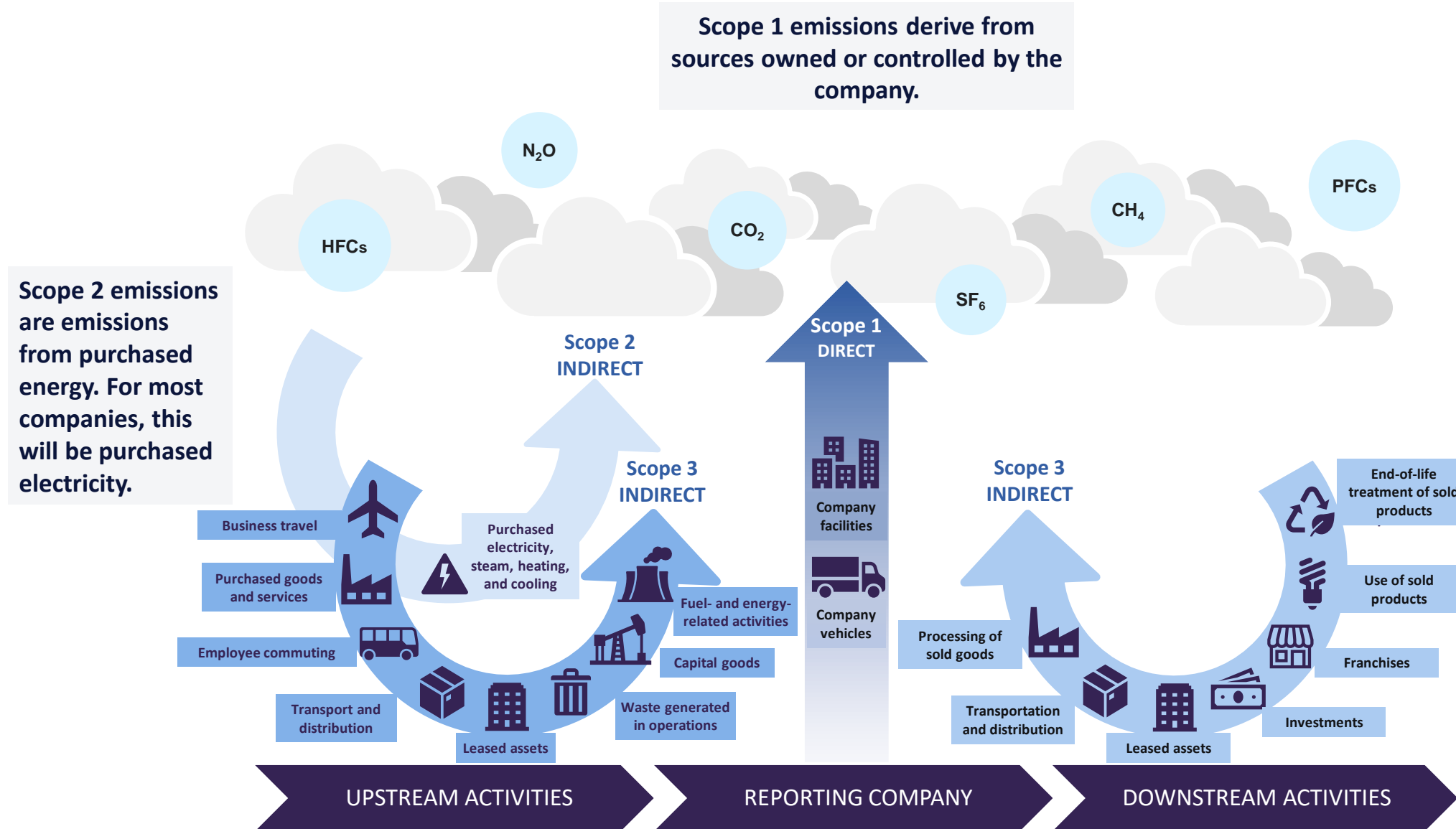
Generative AI

ML-based/generative models that adapt to real-time data may challenge regulatory assessment and oversight, such as when or to what extent a **change notification** to the FDA is required

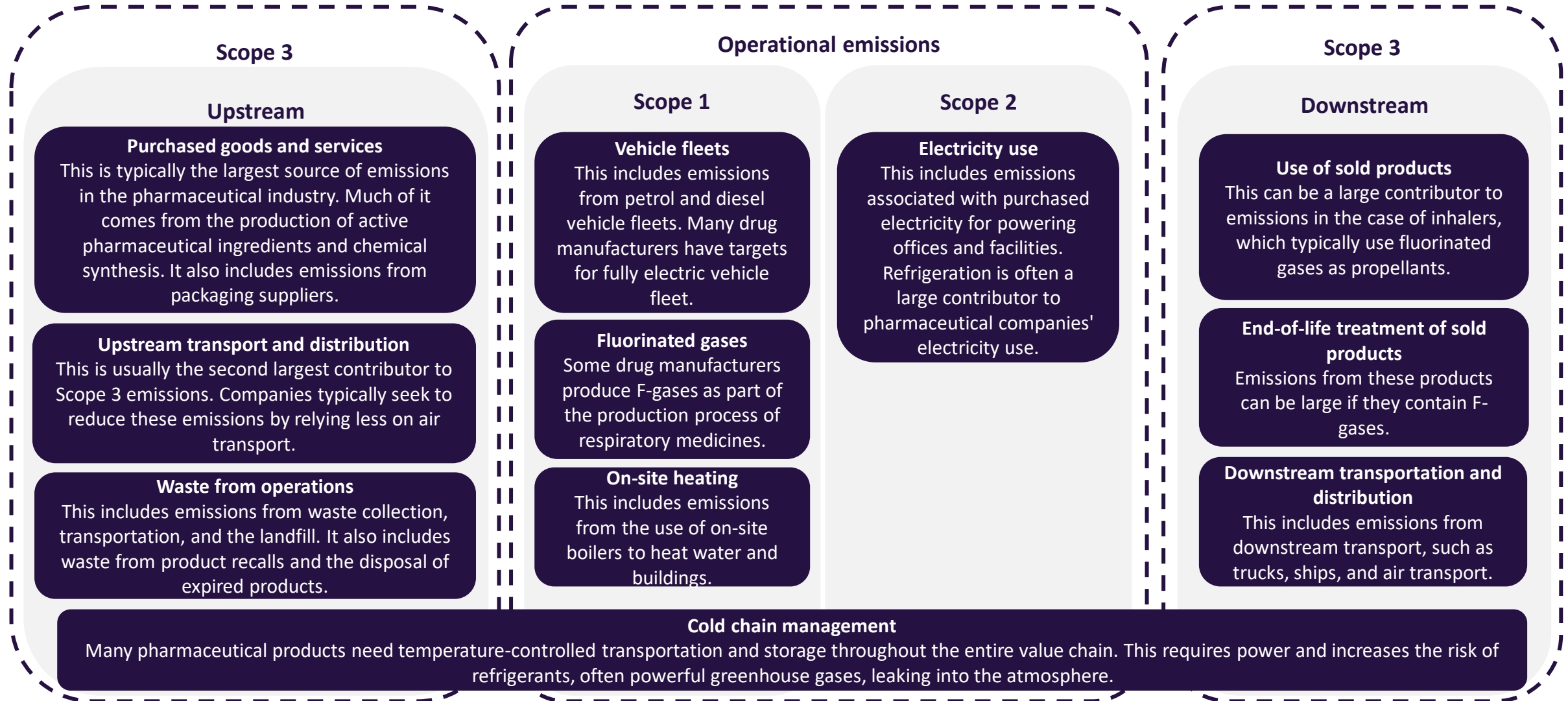
A Look into Sustainability



Where Do Corporate Greenhouse Gas Emissions Come From?



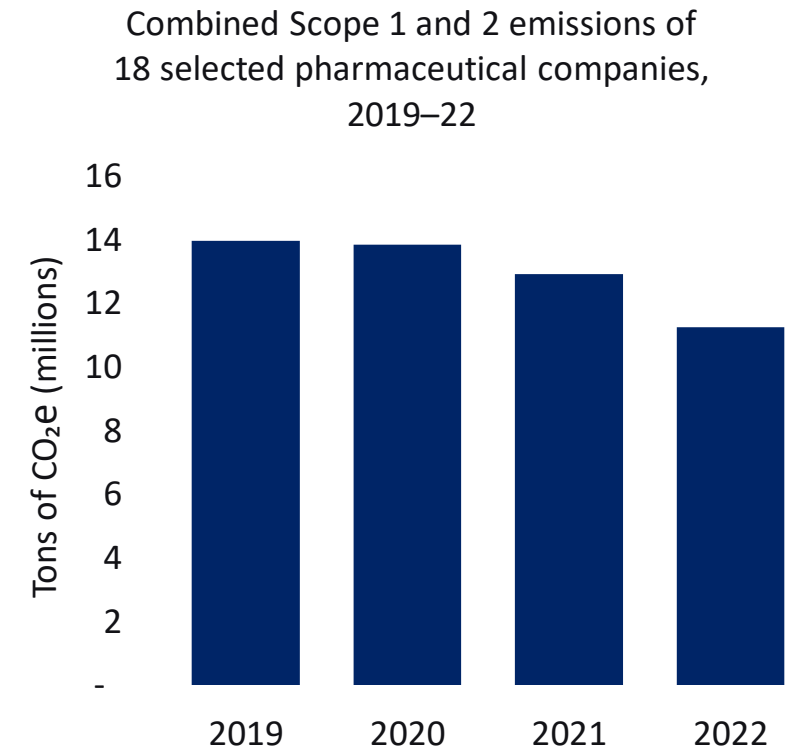
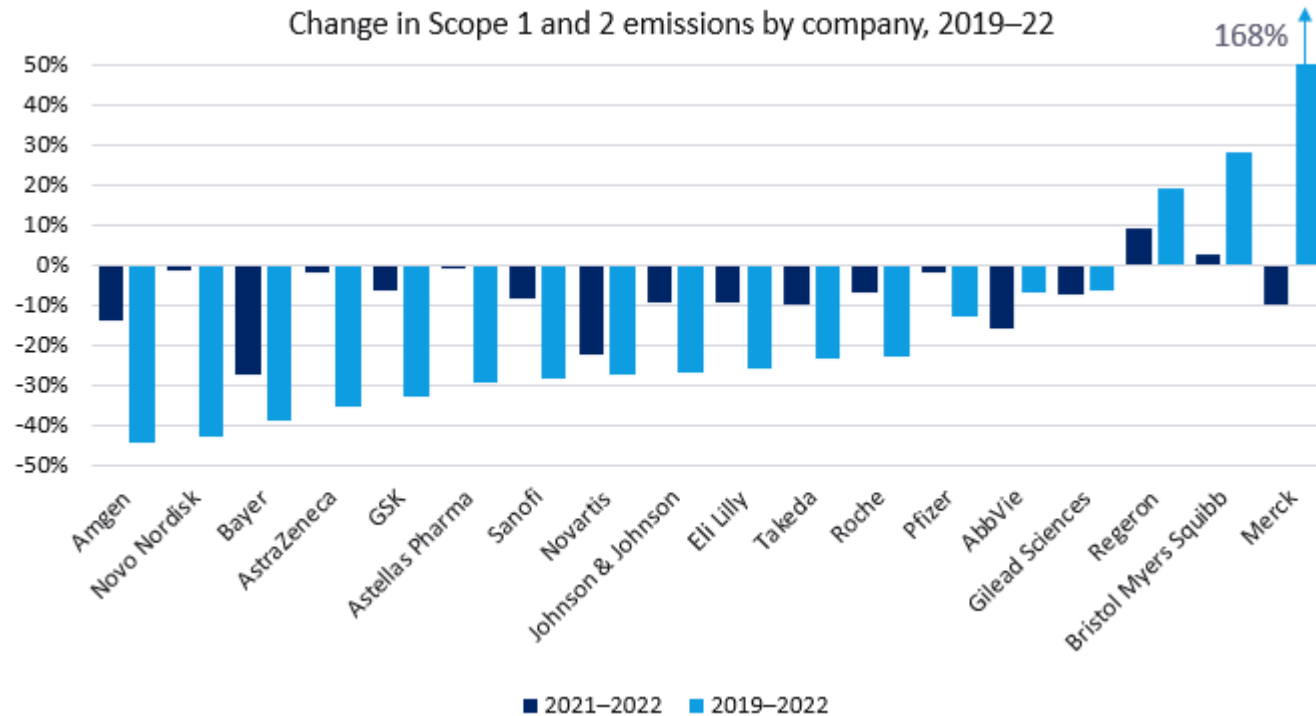
Emissions Across the Pharmaceutical Value Chain



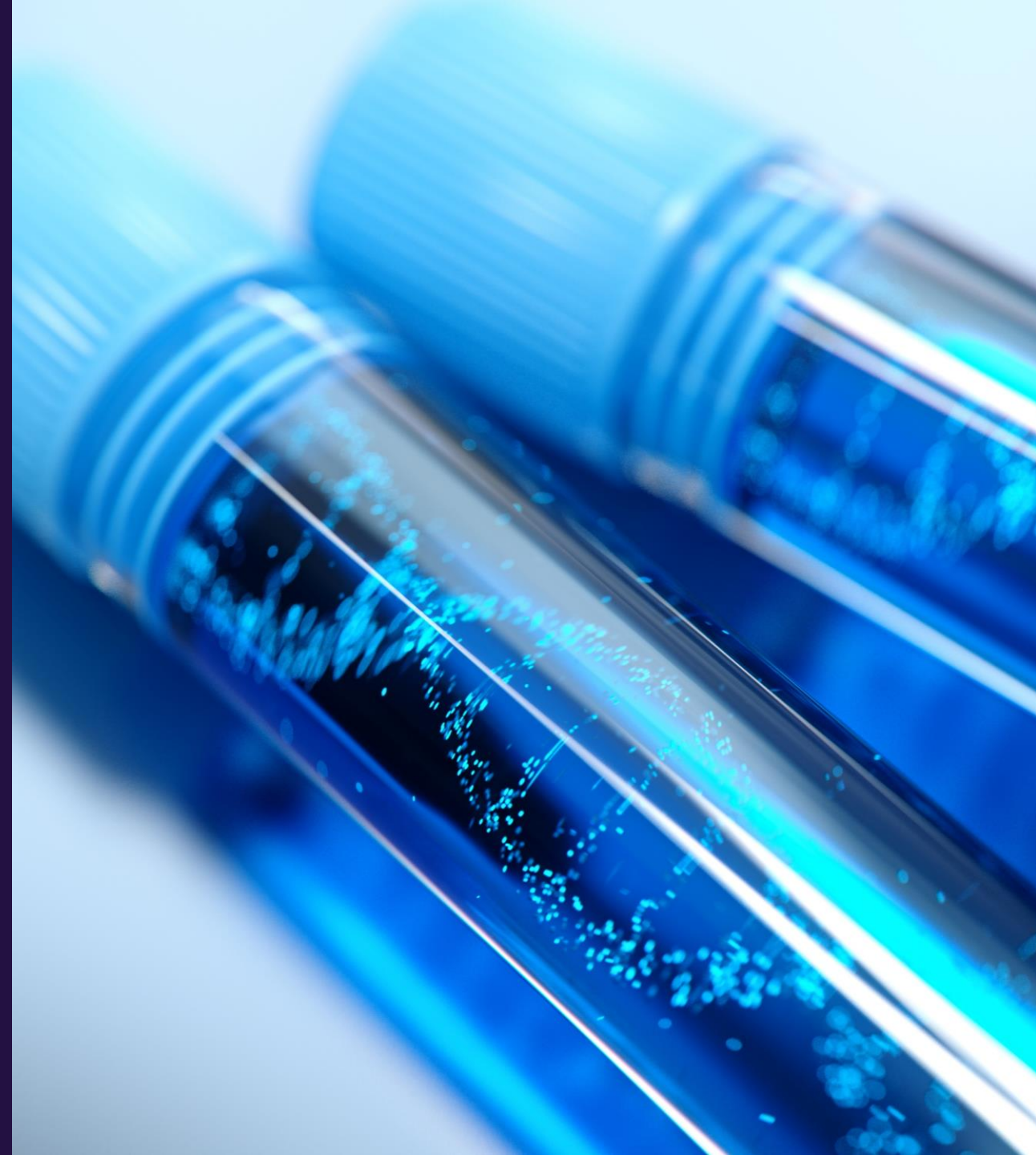
Reduction of Scope 1 and 2 Emissions



- Between 2019 and 2022, 17 out of 18 pharmaceutical companies included in the figure below reduced their Scope 1 and 2 emissions. This was predominantly achieved through greater renewable energy usage.
- Most companies have reduced their emissions over the last three years. Merck's emissions rose sharply from 2019 to 2022 due to its takeover of Versum, a supplier of specialist materials to the semiconductor industry.



Key Takeaways



Key Takeaways



Trends

- Pfizer was the client providing the largest number of contracts.
- Patheon (subsidiary of Thermo Fisher Scientific) was the CMO receiving the largest quantity of contracts.

Supply Chain Disruption

- Top reasons for drug shortages in the US: increased demand and shortage of active ingredients
- With the BIOSECURE Act, KOLs expect more manufacturing to move to US ally or neutral countries.

Sustainability

- Addressing environmental issues used to be an optional exercise for managing a company's public image. Now, it is becoming mandatory and driven by regulation.
- A significant number of pharmaceutical companies have started reducing Scope 1 and 2 emissions.

Opportunities

- The top TAs for trials-related and regulatory events in 2025 are oncology, CNS, and metabolic disorders.
- The largest number of trial initiations in 2025 are for Phase II trials.

Digitalization

- Digitalization could make it possible to improve the efficiency of supply chains, reduce the need for human intervention, improve safety, cut costs, and make predictions about future concerns.
- FDA highlights regulatory concerns and implementation challenges of AI in manufacturing.

Questions?





For any questions or further enquiries, please contact me at:

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