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In Vitro Biotechnology sector in the EU

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Abstract

In recent years, several EU policy initiatives have emphasised the importance of investing in biotechnology to strengthen European autonomy, accelerate commercialisation of research outcomes, and support scaling-up of biotechnologies.

In Vitro Biotechnology (IVB) is a rapidly expanding sector that leverages biological materials, instruments, software, and services to create advanced *in vitro* models for a wide variety of applications, such as biomedical research, food science, and pharmaceutical development. In 2023, Europe was a leader in 3D cell-based IVB and held the second largest share of the global IVB market after the USA. At the international level, Asia is emerging as a strong competitor with the fastest rate of growth in the IVB sector.

Despite its potential, EU IVB faces several challenges, including high implementation costs, limited technology transfer and scalability, and low end-user confidence. Addressing these barriers requires targeted interventions, such as dedicated funding for technology transfer and implementation of standards, enhanced data sharing, and strategic investment in centralised IVB research and technology infrastructures.

Strengthening the IVB industrial ecosystem will not only boost the EU's competitiveness but will also accelerate the transition towards more sustainable and human-relevant research and development, delivering products and services with higher economic and societal impact.

1. Introduction

The Draghi Competitiveness report[1] emphasises the need for the EU to stay at the forefront of technological advancements and work on closing the innovation gap with the US and China. The EU is home to cutting-edge research and development, but the innovation is blocked at the stages of scaling up and commercialisation. Based on the Draghi's report, the European Commission presented the Competitiveness Compass[2] strategy to enhance the EU's economic growth and competitiveness. The Compass sets a plan on specific actions to ensure advanced technologies can thrive and drive innovation, including biotechnology.

As recently highlighted in the "Boosting Biotechnology and Biomanufacturing in the EU" Communication (European Commission, 2024), biotechnology is crucial for the competitiveness and modernisation of European industries, offering significant potential for growth and productivity. Biotechnology plays a key role in addressing various societal and environmental challenges, including climate change mitigation and adaptation, sustainable use of natural resources, restoration of vital ecosystems, food supply and security, and better protection of human health. According to the Organisation for Economic Co-operation and Development (OECD), biotechnology is defined as the application of science and technology to living organisms and their products and models to modify living or non-living materials for the generation of knowledge, products, and services (Friedrichs *et al.*, 2018).

To transform the European biotechnology sector and boost industrial competitiveness across EU, the European Commission has launched a range of strategies and policy initiatives. The Startup and Scaleup strategy (European Commission, 2025a) aims to promote the translation of research into marketable products and scale businesses, making Europe an attractive site for technology-driven innovation. A special focus has been dedicated to the life sciences with the recent publication of the European Life Science Strategy (European Commission, 2025b). European biotechnologies are strong drivers for innovation in the life science sectors, with high productivity and highly skilled workforce (Haaf *et al.*, 2025). The Life Science Strategy aims to further foster a dynamic and competitive life science ecosystem by reinforcing European Research and Innovation (R&I), enabling faster market access, and promoting the use of the outcoming innovations.

This need is also addressed in other policy initiatives including the Pharmaceutical Strategy for Europe[3] and in the European Industrial Strategy[4]. Additionally, the concept of Open Strategic Autonomy (European Commission, 2021), which aims to promote European autonomy and self-sufficiency in critical technologies, also includes biotechnology.

The EU valorisation policy[5] aims to promote the commercialisation of research outcomes by bringing new products and services to market. As a practical initiative, the STEP (Strategic Transformation Enablement Programme) platform[6] already includes funding opportunities to

1 https://commission.europa.eu/topics/eu-competitiveness/draghi-report_en

2 https://commission.europa.eu/topics/eu-competitiveness/competitiveness-compass_en

3 https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en

4 https://single-market-economy.ec.europa.eu/industry/strategy_en

5 https://research-and-innovation.ec.europa.eu/research-area/industrial-research-and-innovation/eu-valorisation-policy_en

6 https://strategic-technologies.europa.eu/index_en

support the scaling up of biotechnology. The EU Chemicals strategy for sustainability (European Commission, 2020), which aims to reduce the environmental and health impacts of chemicals, also has implications for biotechnologies, as these technologies can be used to develop safer and more sustainable chemicals. Moreover, the European Commission's Roadmap for phasing out animal testing identifies biotechnologies as essential to advancing alternatives to animal testing methods (European Commission, 2023a).

Here we focus on *In Vitro* Biotechnology (IVB), a rapidly growing sector within the broader field of biotechnology that is poised to transform various industries. IVB includes a range of advanced technologies using biological materials, devices, instruments, and software to generate novel *in vitro* models and methods that are being broadly adopted in many domains including biomedical research, pharmaceutical development, and food production. We delve into the industrial ecosystem surrounding the IVB sector, including its market analysis, mapping of the stakeholders involved in the IVB value chain, and identification of the sector's specific challenges and opportunities. Overall, the report aims to provide an overview of the sector that can help in shaping effective policies for promoting the EU's IVB industry competitiveness.

2. IVB definition

IVB refers to technologies that use biological materials, as well as devices, consumables, instruments, software, and services offered by specialised companies. A detailed description of the components included in IVB has been reported by Mennecozzi *et al.*, 2025. In this report, the main technological IVB trends were divided in four categories: cell-based models, 3D (three-dimensional) models, High Throughput Screening (HTS), and *in vitro* toxicology (Table 1). Cell-based models employ cultured cells to investigate biochemical and cellular processes, allowing researchers to assess drug efficacy and potency. 3D models involve the cultivation of cells within scaffolds or matrices that more accurately reproduce the structural and functional complexity of living tissues and organs. HTS, extensively used in pharmaceutical and biotechnology research (*e.g.* drug discovery, target validation), use automation to rapidly test biochemical activity of large compound libraries. Lastly, *in vitro* toxicology focuses on investigating the molecular, cellular, and physiological mechanisms of chemically induced toxicity.

Table 1 Summary of the IVB technologies divided by category.

Cell Based Models	*Consumables*	• Reagents • Assay Kits • Cell Lines (incl. immortalised, primary and stem cells) • Microplates • Probes & Labels • Other Consumables
	Instruments and Software	
	Services	
3D Models	*Consumables*	• Scaffold-based 3D Cell Cultures (*e.g.* hydrogels/ECM analogs, solid scaffolds, micropatterned surfaces) • Scaffold-free 3D Cell Cultures (*e.g.* low attachment plates, hanging drop plates, 3D bioreactors, 3D petri dishes) • Microfluidics-based 3D Cell Cultures • Magnetic & Bioprinted 3D Cell Cultures
	Instruments and Software	
	Services	
HTS	*Consumables*	• Reagents and assay kits • Laboratory equipment
	Instruments and Software	• Liquid-handling systems • Detection systems • Other instruments (*e.g.* microplate washers, centrifuges, incubators, safety equipment, electronic balances, pH meters, benchtop equipment)
	Services	
***In vitro* Toxicology**	*Consumables*	• Assay kits o Bacterial toxicity assays o Enzyme toxicity assays o Cell-based ELISA & Western blotting assays o Receptor-binding assays o Tissue culture assays o Other assays
	Instruments and Software	
	Services	

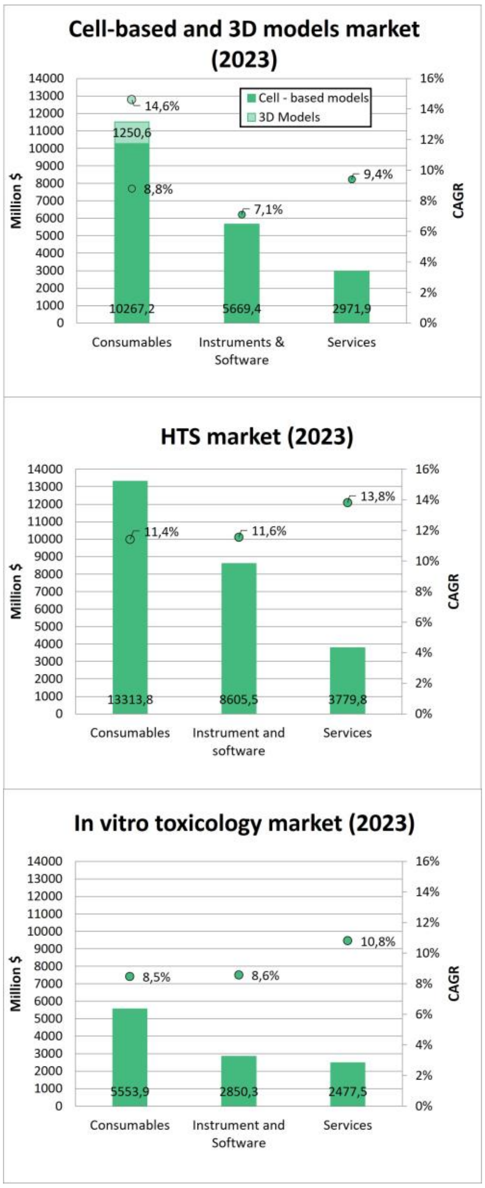
Source: Data analysed internally from Markets and Markets reports (MarketsandMarkets Research Pvt Ltd. 2023a, 2023b, 2023c, 2023d).

IVB is widely applied across biomedical pharmaceutical, food, and other industrial sectors to study biological mechanisms, assess safety, and support product development (Mennecozzi *et al.*, 2025). In biomedical and pharmaceutical research, IVB models, such as iPSC (induced Pluripotent Stem Cell)-derived systems and organ-on-chip (OoC), enable disease modelling, drug discovery, and drug repurposing without animal testing (Witters *et al.*, 2021, Hynes *et al*. 2020, Moutinho, 2023). Similarly, the food and consumer product industries use IVB-based methods, including OECD-validated methods, to evaluate the safety and toxicity of chemicals, additives, and materials (OECD, 2019, OECD, 2023).

3. IVB market analysis

In 2023, the cell-based and 3D model market was worth $ 20159,1M, the HTS market was worth $ 25699,1M, and the *in vitro* toxicology market was worth $ 10881,7M (Figure 1). In all the above markets, consumables dominated the market, followed by instruments and software. The consumables segment emerged as the largest contributor, especially to the cell-based assays market. This dominance can be attributed to the consistent usage and frequent replenishment requirements of consumables, which contrasts with instruments that are typically one-time purchases. However, services are expected to register the highest CAGR (Compound Annual Growth Rate; 9,4% for cell-based models, 13,8% for HTS, and 10,8% for *in vitro* toxicology) in the period 2023-2028, due to the rising outsourcing of Research and Development (R&D) activity by pharma-biotech companies.

Figure 1 IVB Global market in 2023 for cell-based and 3D models (top panel), HTS (centre panel), and *in vitro* toxicology (bottom panel).



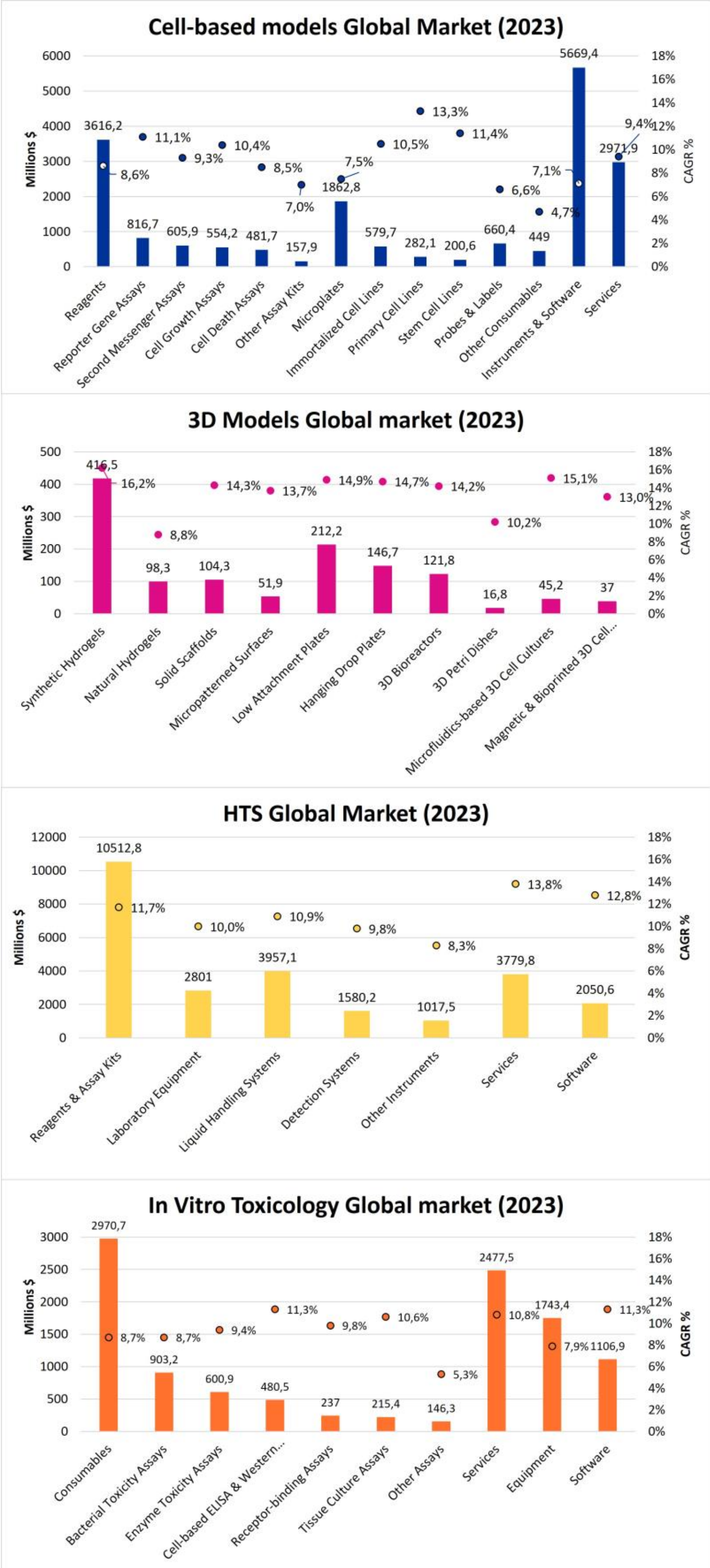
Source: Data analysed internally from Markets and Markets reports (MarketsandMarkets Research Pvt Ltd. 2023a, 2023b, 2023c, 2023d).

In 2023, for cell-based models, reagents and microplates represented the most common consumables, followed by assays and cell lines, which were worth $ 2616,3M and $ 1062,4M respectively (Figure 2). 3D models represented roughly a tenth of the total consumables, but with a CAGR of 14,6% it is a fast-growing category, with potential to progressively replace the traditional two-dimensional (2D) models. Specifically, both scaffold-based and scaffold-free technologies were already dominating the 3D market, with microfluidics devices and 3D bioprinting that were still catching up (Figure 2).

Similar considerations could be done for the HTS market, where single-use assay kit outperformed the market for instruments and software. Services, on the contrary, represented around 25% of the *in vitro* toxicology market, due to the trend of outsourcing testing activities to Contract Research Organisations (CROs) by industry and governments, that increasingly use *in vitro* methods for the safety assessment of various products (*e.g.* medicinal products, industrial chemicals, consumer care).

Looking at the data worldwide, the 2023 IVB market was dominated by North America, followed by Europe and Asia (Table 2). The only exception was the i*n vitro* toxicology market, where Europe had the largest market size ($ 4097M). USA, Germany, and China were consistently the fastest growing countries in the three regions, with China reaching a projected CAGR of 16% and 13% for 3D models and HTS, respectively.

Figure 2 IVB market data divided by technological categories.



Source: Data analysed internally from Markets and Markets reports (MarketsandMarkets Research Pvt Ltd. 2023a, 2023b, 2023c, 2023d).

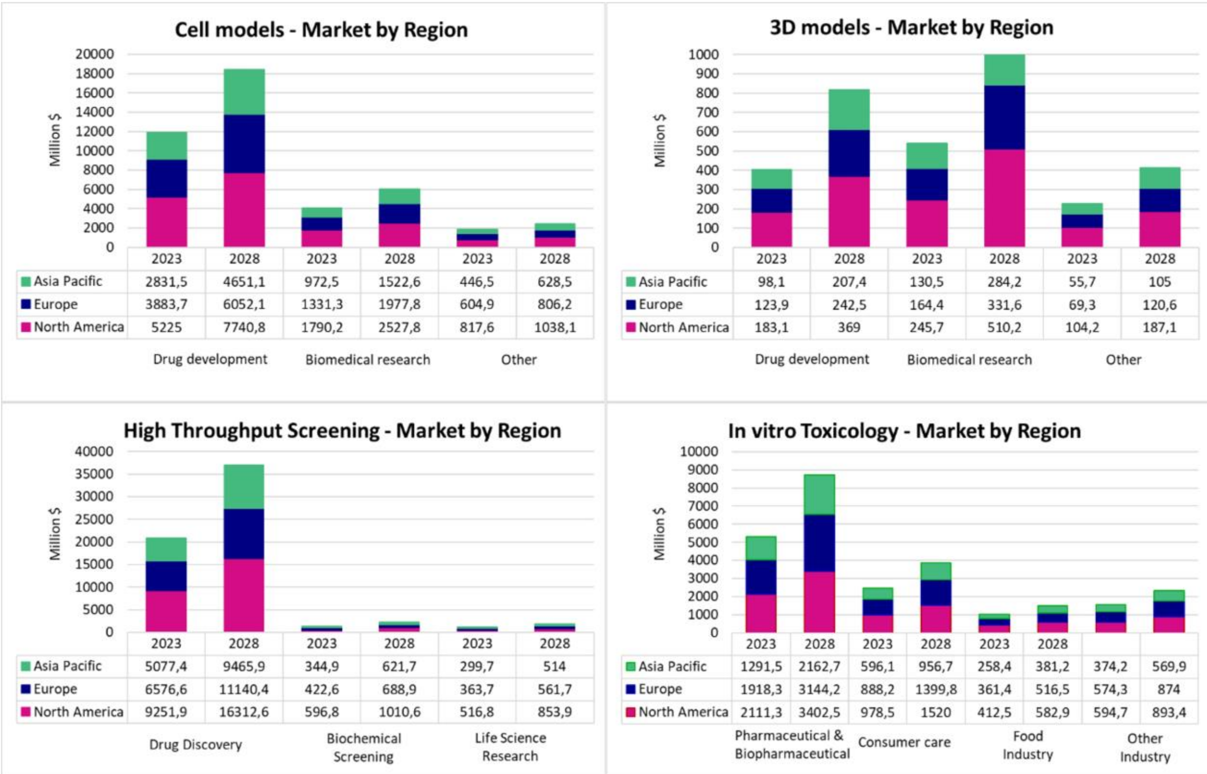
Table 2 Detail market indicators for Europe, North America, and Asia Pacific regions.

Cell-based models	Europe	North America	Asia Pacific	**3D models**	Europe	North America	Asia Pacific
Market size in 2023 (Million $)	5819,9	7832,7	4250,5	Market size in 2023 (Million $)	357,6	533	284,4
Fastest growing country in the region	Germany	USA	China	Fastest growing country in the region	Germany	USA	China
Share in the global market in 2023	30,8%	41,4%	22,5%	Share in the global market in 2023	28,6%	42,6%	22,7%
CAGR (2023-2028)	8,7%	7,6%	9,9%	CAGR (2023-2028)	14,2%	14,9%	16%
High Throughput Screening	Europe	North America	Asia Pacific	**In vitro toxicology**	Europe	North America	Asia Pacific
Market size in 2023 (Million $)	7684	10806,5	5910,8	Market size in 2023 (Million $)	4097	3742,2	2520,2
Fastest growing country in the region	Germany	USA	China	Fastest growing country in the region	Germany	USA	China
Share in the global market in 2023	29,9%	42%	23%	Share in the global market in 2023	37,6%	34,4%	23,2%
CAGR (2023-2028)	10,8%	11,7%	13%	CAGR (2023-2028)	9,3%	9,7%	10,1%

Source: Data analysed internally from Markets and Markets reports (MarketsandMarkets Research Pvt Ltd. 2023a, 2023b, 2023c, 2023d).

As shown in Figure 3, IVB technologies are largely used for pharmaceutical drug discovery and development, especially for HTS that allows to screen many candidates against a specific target. Notably, 3D models (Figure 3) are increasingly being used for biomedical research, mainly due to their capacity of providing human-relevant results and insights in complex biological systems. Due to its use in regulated sectors, *in vitro* toxicology testing (Figure 3) also has applications in consumer care products, food/feed safety, and other sectors, including medical devices and cosmetics.

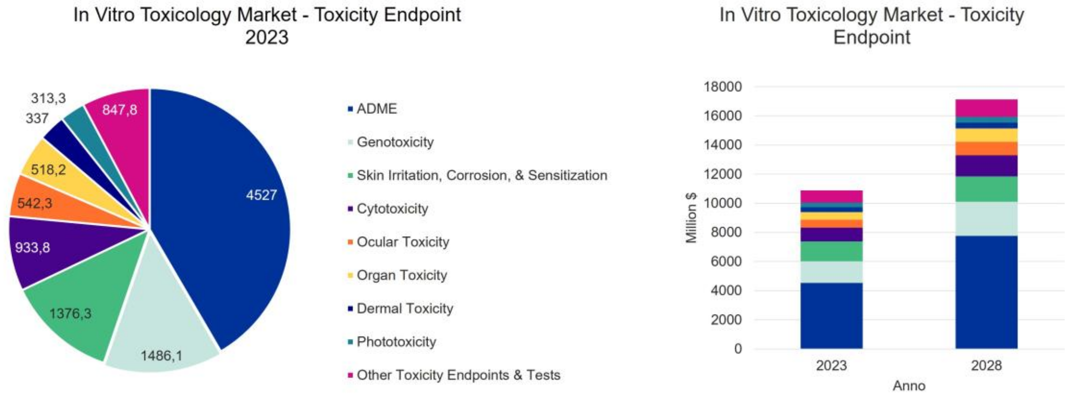
Figure 3 IVB market by applications.



Source: Data analysed internally from Markets and Markets reports (MarketsandMarkets Research Pvt Ltd. 2023a, 2023b, 2023c, 2023d).

Among the most common toxicity endpoints, the market is largely dominated by ADME (Absorption, Distribution, Metabolism, and Excretion) (41%), genotoxicity (14%), and skin irritation, corrosion, and sensitisation (13%), with other endpoints following with percentages lower than 10% (Figure 4). The organ toxicity segment is expected to grow at the highest CAGR of 12,0% during the period 2023-2028, followed by the ADME and ocular toxicity testing, at 11,4% and 11,1% respectively. Slower growth is expected for dermal toxicity, skin irritation/corrosion/sensitisation and phototoxicity, probably because many skin models are already accepted at OECD level and the innovation in this area is foreseen to be lower.

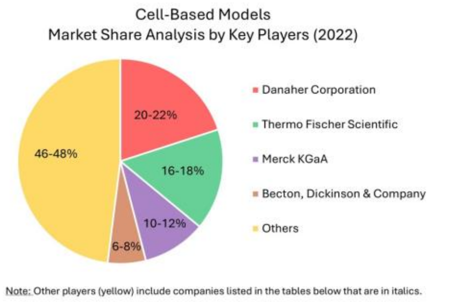
Figure 4 *In vitro* toxicology market by toxicity endpoints.

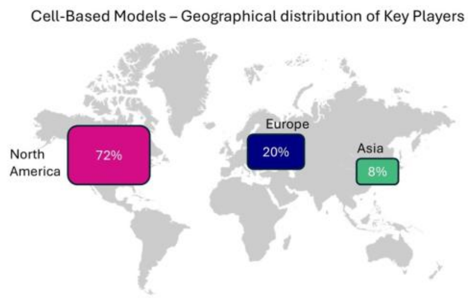


Source: Data analysed internally from Markets and Markets reports (MarketsandMarkets Research Pvt Ltd. 2023a, 2023b, 2023c, 2023d).

Leading companies in the IVB market are mainly based in North America, while Europe hosts many companies developing 3D models, which usually develop products with a high innovation component (Figure 5 and Figure 6). Focusing on the 3D cell culture companies, more than 50% of them are European companies, often spun out from universities or originating from research projects, as is the case for TissUse GmbH, InSphero, and Mimetas. Overall, the IVB market is dominated by international corporations like Thermo Fischer Scientific Inc., Merck KGaA, Danaher Corporation, Lonza Group, and Agilent Technologies Inc.

Figure 5 Market share analysis per key players (leading companies) and geographical distribution based on headquarters – Cell based and 3D models.



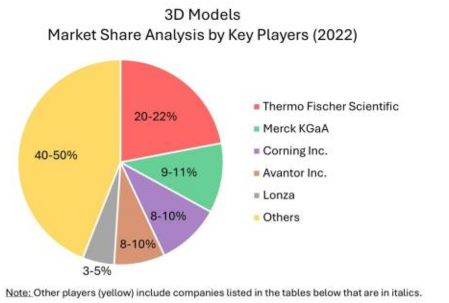


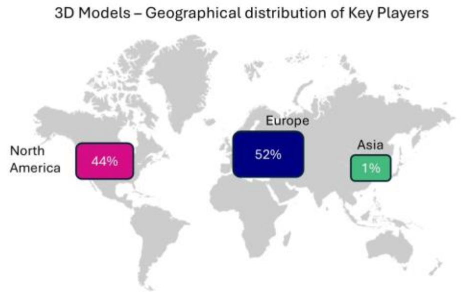
Cell-Based Models – Key Players and Headquarter Location

Company	HQ Location
Danaher Corporation	US
Thermo Fisher Scientific, Inc.	US
Merck	Germany
Becton, Dickinson and Company	US
Lonza	*Switzerland*
Perkin Elmer Inc.	*US*
Charles River Laboratories	*US*
Eurofins Scientific	*Luxembourg*
Enzo Biochem	*US*

Company	HQ Location
Carna Biosciences	*Japan*
BPS Bioscience, Inc.	*US*
BMG Labtech	*Germany*
Cell Biolabs	*US*
Promega Corporation	*US*
Cell Signaling Technology, Inc.	*US*
Bioagilytix	*US*
Reaction Biology Corporation	*US*

Company	HQ Location
AAT Bioquest	*US*
Pestka Biomedical Laboratories, Inc.	*US*
Invivogen	*US*
CA3 Biosciences, Inc.	*US*
Bellbrook Labs, Inc.	*US*
Profacgen	*US*
Hanugen Therapeutics	*India*
JRS Pharma	*Germany*





3D Models – Key Players and Headquarter Location

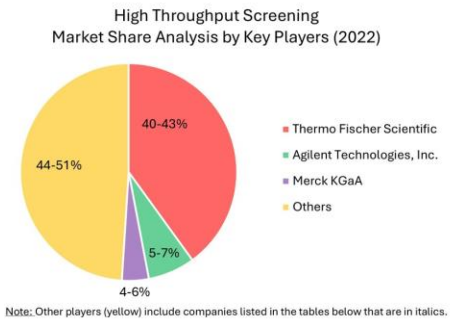
Company	HQ Location
Thermo Fisher Scientific, Inc.	US
Merck KGaA	Germany
Corning Inc.	US
Avantor Inc.	US
Lonza	Switzerland
Tecan Trading AG	*Switzerland*
Reprocell Inc.	*Japan*
3D Biotek LLC	*US*
Synthecon	*US*

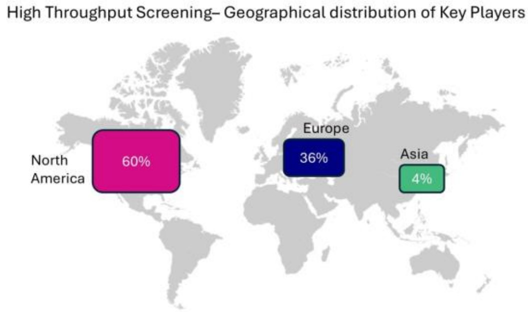
Company	HQ Location
Insphero AG	*Switzerland*
S-Bio, Vaupell Holdings Inc.	*US*
Advanced Biomatrix Inc.	*US*
UPM Biomedicals	*Helsinki*
CN Bio Innovations LTD.	*UK*
Emulate	*US*
TissUse Gmbh	*Germany*
Lena Biosciences	*US*

Company	HQ Location
Cellenders Gmbh	*Germany*
Greiner Bio-One International Gmbh	*Austria*
Promocell Gmbh	*Germany*
Synvivo Inc.	*US*
Amsbio	*UK*
Mimetas BV	*Netherlands*
Kikstall LTD	*UK*
Nanofiber	*US*

Source: Data analysed internally from Markets and Markets reports (MarketsandMarkets Research Pvt Ltd. 2023a, 2023b, 2023c, 2023d).

Figure 6 Market share analysis per key players (leading companies) and geographical distribution based on headquarters – HTS and *in vitro* toxicology.



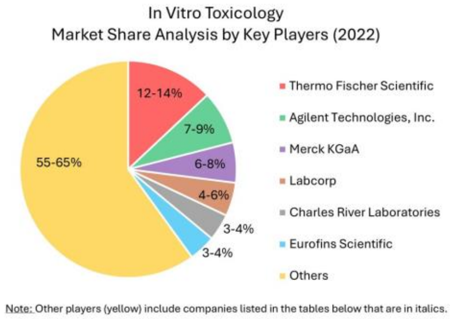


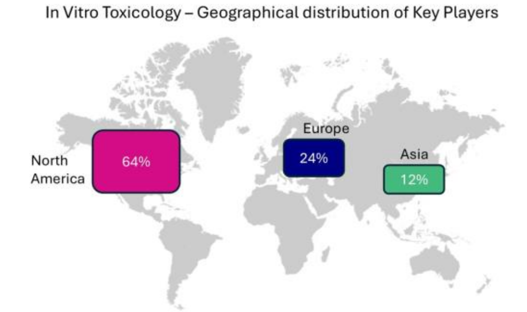
High Throughput Screening – Key Players and Headquarter Location

Company	HQ Location
Thermo Fisher Scientific, Inc.	US
Agilent Technologies, Inc.	US
Merc KGaA	Germany
Danaher Corporation	*US*
Perkin Elmer Inc.	*US*
Bio-Rad Laboratories Inc.	*US*
Eurofins Scientific	*US*
Promega Corporation	*US*
Corning Inc.	*US*

Company	HQ Location
Biomat SRL	*Italy*
Axxam S.P.A.	*Italy*
Tecan Trading AG	*Switzerland*
Charles River Laboratories	*US*
Hamilton Company	*US*
Lonza	*Switzerland*
Crown Biosciences	*US*
Aurora Biomed	*Canada*

Company	HQ Location
BMG Labtech	*Germany*
Reprocell Inc.	*Japan*
Sygnature Discovery	*UK*
Cyclica, Inc.	*Canada*
Nanotemper Technologies Gmbh	*Germany*
HighRes Biosolutions	*US*
Diana Biotechnologies SRO	*Czech Republic*
Creative Biolabs	*US*





In Vitro Toxicology – Key Players and Headquarter Location

Company	HQ Location
Thermo Fisher Scientific	US
Agilent Technologies, Inc.	US
Merc KGaA	Germany
Labcorp	US
Charles River Laboratories	US
Eurofins Scientific	Switzerland
SGS SA	*Switzerland*
Revvity	*US*
Bio-Rad Laboratories Inc.	*US*

Company	HQ Location
Lonza	*Switzerland*
Evotec SE	*Germany*
Catalent Inc.	*US*
Promega Corporation	*US*
Inotiv	*US*
Intertek Group PLC	*UK*
Bioivt	*US*
Creative Biolabs	*US*

Company	HQ Location
Creative Bioarray	*US*
Shanghai Medicilon Inc.	*China*
Aragen Life Sciences LTD	*India*
Enzo Biochem	*US*
Microbac Laboratories Inc.	*US*
Vimta Labs LTD.	*India*
Pacific Biolabs Inc.	*US*
MB Research Laboratories	*US*

Source: Data analysed internally from Markets and Markets reports (MarketsandMarkets Research Pvt Ltd. 2023a, 2023b, 2023c, 2023d).

4. Stakeholders involved in IVB value chain

Diverse stakeholders collaborate to drive innovation and scientific advancement in the IVB ecosystem (Figure 2A from Mennecozzi *et al.*, 2025). During the research and development phase, researchers working on basic or applied science can come up with new ideas to develop novel IVB test methods, materials, devices, or instruments. Working within academic institutions, research centres, and private companies, they apply scientific knowledge to create tools with enhanced precision, efficiency, and wider applicability. The research is driven by collaborative research consortia, often supported through public funding programs, which facilitate knowledge sharing, cooperation, and skill development. Core facilities play a crucial role by providing centralised, shared research resources and standardised protocols to conduct complex experiments and analyses. These facilities offer access to instruments that may not be available in individual laboratories, including high-throughput screening platforms, advanced imaging and microscopy, next-generation sequencing technologies, mass spectrometers, flow cytometers, and 3D bioprinters. They are typically staffed by highly trained specialists who offer technical support, consultation, and training to researchers, ensuring optimal use of advanced methodologies and equipment. Additionally, suppliers offer different types of laboratory instruments and biological components such as cells, reagents, and media.

The technology transfer phase is a critical step in transforming research-driven innovations into market-ready products. At this stage, technology transfer organisations help moving ideas from research to marked-ready products. Technology transfer organisations support intellectual property (IP) protection, negotiate licensing agreements, secure funding, and provide mentorship to ensure the successful transition of innovations into commercialisation. In some cases, these organisations also help developers build a sustainable business plan, develop entrepreneurial and managerial skills, and position their product on the market. Business support organisations connect researchers, Small and Medium-sized Enterprises (SMEs), and industry leaders to strengthen network development and promote collaboration throughout the value chain. These organisations support the economic development of the IVB sector mainly at a regional level in Europe, connecting potential collaborators, facilitating pilot trials, providing capacity building and helping to secure funding.

Scaling up from prototype to market-ready product requires specialised expertise in product development and manufacturing. Contract Development and Manufacturing Organisations (CDMOs) help improve IVB technologies, making them ready for mass production and meeting all regulatory standards. Once development is finalised, technology developers may either commercialise their products independently or rely on established providers and distributors to ensure widespread adoption by end-users.

The final phase of the IVB value chain involves the adoption and use of IVB technologies by the end-user industries, such as pharmaceutical companies or basic and applied researchers. By leveraging IVB technology, companies can streamline research processes and reduce reliance on animal testing. Key stakeholders in this phase are CROs, which provide specialised services, including laboratory testing to assess therapeutic potential, pharmacological properties, toxicological profiles, and ADME studies. CROs also offer regulatory expertise, assisting clients with the preparation of documentation and communication with regulatory agencies to ensure compliance with guidelines and regulatory requirements, and ensure that IVB studies are conducted in accordance with Good Laboratory Practice (GLP). Regulatory agencies play a key role in ensuring that products developed through IVB technologies adhere to high standards of safety, efficacy, and quality.

The IVB ecosystem is supported by a range of public and private funding institutions, which provide direct financial support for IVB research and development, as well as grants and fellowships to foster academic growth and innovation. In addition, consultants help companies to reduce development risks, accelerate regulatory approvals, and enhance market success by providing specialised knowledge and strategic guidance.

5. IVB challenges and opportunities

The EU IVB industry currently has limited market competitiveness, in particular when compared to North American companies. Despite having a strong presence in 3D cell-based models (Figure 6 of Mennecozzi *et al.*, 2025), EU lags behind in terms of IVB market share and number of top companies. Furthermore, Asia is emerging as a strong competitor, with the fastest growth rate expected in the IVB market.

Multiple drivers could stimulate the growth and competitiveness of the EU IVB ecosystem. There is an increasing interest of adopting innovative IVB technologies in drug discovery and safety assessments, opening the potential for reducing drug attrition rates for pharmaceutical companies. Both public resistance to animal testing and coordinated efforts from regulatory bodies to transition away from animal models are increasing the need for human relevant IVB-based models.

However, the EU IVB ecosystem faces important challenges, such as fragmented research and technology transfer to the market, prohibitive implementation costs, and insufficient trust in the technology (Mennecozzi *et al.*, 2025). One significant obstacle is the high implementation costs of IVB technologies. For example, 3D cell-based models or HTS systems require substantial economic investment due to the high prices of materials and instruments, as well as the need for specialised personnel and continuous training. This financial burden can be a significant deterrent for companies, particularly SMEs, to adopt and implement IVB technologies.

Despite extensive funding for developing IVB technologies, technology transfer and scaleup are not keeping up and the commercialisation opportunity for IVB products is often missed by developers and funding agencies. In such an emerging market, there is a high level of uncertainty surrounding the development, commercialisation, and implementation of IVB products. This uncertainty can make it challenging for companies to devise effective business development plans and to choose the specific IVB to adopt, as there is a large variety of products in development with multiple possible applications across different end-user industry sectors.

Limited communication and collaboration within and across stakeholders are also hindering the growth of the EU IVB industry. The majority of IVB data produced by CROs or end-user industries remains unpublished due to IP concerns and business strategy. Additionally, there is limited communication between IVB developers/users and regulatory agencies, which can create uncertainty and hinder the adoption of IVB technologies. Finally, the lack of confidence in using novel IVB technologies is another significant challenge. The limited availability of IVB products with high Technology Readiness Level (TRL), combined with the lack of transparency about when and how IVB technologies are used by different stakeholders, is hampering the trust necessary to support broader development and adoption of IVB across industries.

6. Recommendations

IVB has a substantial potential to contribute to a more competitive, self-sustainable, and resilient EU. While academic innovation in IVB within EU is strong, industrial development and uptake remains insufficient, leading to a competitive disadvantage (Nagar, J. *et al.*, 2024). Strengthening the industrial growth of IVB would boost revenue generation for EU companies, enhance competitiveness, and create new jobs. This would enable a structured access to finance, promote private investments, increase the availability and commercialisation of IVB-derived products, and ultimately ensure that EU citizens are better protected from chemical exposure and have access to better and safer medicines.

- One option to boost innovation and competitiveness of the IVB sector is to establish **dedicated funding programs for technology transfer**. Existing EU funding programmes, such as Horizon Europe and the Innovative Health Initiative (IHI), focus on early-stage research but do not sufficiently support the technology transfer and scaleup of IVB innovations. Dedicated **public-private partnerships** could fund technology transfer initiatives, directing resources to universities and startups. These funding calls could be structured accordingly to the development levels of the innovation (TRL scale). For early stage, low TRL innovations, funding could support patenting, business model development, and professional development training courses for researchers. For later-stage, high TRL innovations, funding could facilitate licencing agreements for technologies with strong business and regulatory potential. Key stakeholders, such as CROs and technology developers, should define priority areas for investments based on their needs and investment strategy, while technology transfer offices mediate between developers and funders.
- Additionally, funding mechanisms should support the **early adoption and implementation of standards in IVB technologies**. Encouraging the integration of existing standards into research and development processes would enhance the translational potential, regulatory acceptance, and industrial scalability of IVB products (Piergiovanni *et al.*, 2021, European Commission, 2023b). Funding calls could explicitly require adherence to relevant standards to ensure interoperability and facilitate earlier market entry. Greater **transparency and data sharing** are also essential steps for increasing the trust in IVB-based methods and models. Currently, identifying IVB-generated data within regulatory dossiers is challenging, as much of this information remains confidential or is difficult to access in European public assessment reports published by European Medicines Agency (EMA). To address this issue, dossier sections containing IVB-generated data (*e.g.* primary and secondary pharmacology, metabolism and ADME, immunotoxicity), details on the study and the outcome, and the agency assessment on the IVB method/data could be disclosed. The rest of the dossier and its final evaluation would instead remain confidential. One interesting approach was recently published on the current use of Physiologically Based Pharmacokinetic (PBPK) models in medicinal products approvals at EMA (Paul, P. *et al.,* 2025). Organising this information in an **open-access database** would provide IVB developers, end-user industries, and regulators with a structured resource to evaluate IVB technologies and promote wider acceptance. Furthermore, incentivising private industries to openly share their experience and successful applications using IVB for pharmaceutical advancement could further strengthen confidence in these methods. Many companies already use IVB-generated data for internal decision-making. Incentives from regulatory bodies, such as faster review of applications, waived

fee, or longer market protection for medications, could encourage companies to openly disclose their IVB methodologies. A similar approach could also apply to data not included in formal submissions, facilitating the adoption of safe harbour agreements to encourage sharing of knowledge while protecting intellectual property.

- Finally, addressing the high costs associated with IVB implementation requires strategic investment to **support open-access centralised IVB research and technology infrastructures** within academic institutions, such as core facilities and specialised centres (European Commission, 2025c). Housing highly skilled talent and costly instruments within state-of-the-art infrastructures would help reduce costs, maintain a critical mass of skilled professionals in IVB, and facilitate the development and adoption of standards. The transnational and multisite collaboration among IVB infrastructures would reinforce the EU IVB ecosystem, ensuring that a larger number of IVB products and services can successfully enter and expand in market.

7. Conclusions

The development and adoption of IVB technologies have the potential to transform several sectors, from pharmaceuticals to food safety, and contribute to a more sustainable and resilient economy. The EU has a strong foundation in IVB research and development but faces significant challenges to bring products and services to the market. Enhancing the competitiveness of the EU IVB industry requires acting at different levels. Dedicated funding programs for technology transfer and private-public partnerships can help bridge the gap between research and industrial development.

Increasing transparency and data sharing can improve the confidence in IVB technologies and promote their adoption. Furthermore, investing in centralised IVB infrastructures can reduce costs and increase efficiency. By tackling these obstacles and capitalising on the opportunities, the EU can drive innovation and growth in the IVB sector, enhance its global competitiveness, guarantee EU citizens access to safe medicines and food, and have better protection from harmful environmental chemicals.

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List of abbreviations and definitions

Abbreviations	Definitions
2D, 3D	Two-, Three-dimensional
ADME	Absorption, Distribution, Metabolism, and Excretion
CAGR	Compound Annual Growth Rate
CDMOs	Contract Development and Manufacturing Organisations
CROs	Contract Research Organisations
EMA	European Medicines Agency
EU	European Union
GLP	Good Laboratory Practice
HTS	High Throughput Screening
IHI	Innovative Health Initiative
IP	Intellectual Property
iPSC	induced Pluripotent Stem Cell
IVB	*In Vitro* Biotechnology
OECD	Organisation for Economic Co-operation and Development
OoC	Organ-on-Chip
PBPK	Physiologically Based Pharmacokinetic
R&D	Research and Development
R&I	Research and Innovation
SMEs	Small and Medium Enterprises
STEP	Strategic Transformation Enablement Programme
TRL	Technology Readiness Level

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