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Introduction

On 15th March 2023, EuropaBio hosted its inaugural Biomanufacturing Policy Summit in Brussels, marking the first major milestone from its newly established Biomanufacturing Platform. The Summit had the mission of setting a vision for Europe's global innovation, competitiveness, and sustainability through biomanufacturing, whilst raising awareness amongst policymakers and other stakeholders.

The Summit established a starting point, a first step for a biomanufacturing policy journey to be travelled by European stakeholders. 80 participants represented translational research, cross-sectoral industry, expert support sectors, investors, policy makers, European advanced technology associations plus national biotech associations.

Starting from a European focal point, the Summit also recognised the global nature of a biomanufacturing transition, with significant global regions already signposting strategy, policy and investment as their industrial focus changes.

The half day meeting had four elements; keynotes set the scene for Europe’s policy, competitiveness and place in the world before ‘I am Biomanufacturing’ told the story of what biomanufacturing looks like for industry, society and Europe’s development. Round table discussions then set ambitions, challenges and priorities before a closing panel looked to the future.

Through presentations, debates, and proposals, participant dialogue built an ambition for Europe reflected in this Summit report.

This report presents a synthesis of contributions and discussions and offers an ambition and pathway for industrial goals making use of the skills, infrastructure and policy and regulatory frameworks through which Europe develops its industrial, environmental and societal future.

It also showcases a ‘Biomanufacturing 101’ definition presented for the first time at the Summit. This definition will underpin the Biomanufacturing Platform, with the intention to develop further over time, supported from case studies and narratives.

Finally, the report closes with ten recommendations to underpin EuropaBio’s work over the coming years with members and stakeholders to support strategy, policy and regulatory frameworks to deliver biomanufacturing in Europe.
About EuropaBio

EuropaBio - The European Association for Bioindustries is Europe’s largest and most influential biotechnology industry group. Founded in 1996 to represent the interests of the biotechnology industry at European level, EuropaBio speaks for innovation from the early days of SME start-ups, through to global multi-nationals. It seeks to create a positive legislative, regulatory, and financial environment for biotechnology, so that impacts are maximised world-wide, and Europe’s world class research translates to economic, employment, sustainability and quality of life advances.

The company landscape
EuropaBio represents companies across sectors. Members range from next generation biotech start-ups, SMEs and growing companies through to globally recognisable companies. These companies are revolutionising our health, living world and economies through biotechnology, catalysing a transformation to biological processes and products in all aspects of our lives.

The national voice
National and regional Association members are the backbone of EuropaBio, representing over 2600 biotech companies, of which the majority are SMEs. These members help to shape the fabric of Europe for biotechnology and ensure that national interests work in alignment as a voice for biotechnology. Over its 26 year history, EuropaBio has grown alongside the scientific, business, and societal framework of biotechnology, working with national, European and global stakeholders to represent a frontier technology in its continuing development.

About the Biomanufacturing Platform

EuropaBio’s Biomanufacturing Platform has the mission to represent biomanufacturing at the highest policy levels in Europe, to ensure that it is visible and recognised within the industrial strategy and Europe’s green and digital transitions. EuropaBio champions biomanufacturing across its Healthcare, Industrial Biotechnology and National Associations Councils and a cross-sectoral Platform brings these voices together to accelerate Europe’s growth.

EuropaBio’s Biomanufacturing Platform addresses the policy and wider frameworks through which biomanufacturing is delivered. Together with members and stakeholders, it addresses how economic growth, employment and resilience are achieved through policy, legal frameworks and regulation at EU and national levels.
Biomanufacturing Definition 101

What is biomanufacturing?
Biomanufacturing is the use of biological mechanisms to i) synthesize products ii) act as tools or iii) undertake processes, at a scale required for commercial use.

Biomanufacturing can use different sources for the desired biological mechanisms:
- Animal and human cells;
- Plants, either individual cells or whole plants;
- Micro-organisms such as yeast, bacteria, fungi, and microalgae;
- Viruses.

Biomanufacturing can either use biological processes to synthesize desired products, or the biological material is the product itself.

What are different types of biomanufacturing?
- Immunotherapy, where human cells are a biomanufactured product, having been modified to target cancer using the patient’s own immune system.
- Food ingredients including alternative proteins and other ingredients such as vitamins can be synthesized by microorganisms through a biomanufacturing process commonly referred as fermentation.
- Viral vectors are a biomanufactured tool where viruses are adapted to deliver genes into cells for use in gene therapies or in vaccine manufacture.

How does biomanufacturing play a role in our lives?
Biomanufacturing is applicable across many sectors, helping to create products and processes that are part of our everyday life, including medical therapies, food and animal feed ingredients, fuels, textiles, plastics, cosmetics, detergents, and intermediates for other manufacturing processes. This all contributes to the bioeconomy, which is recognised as economic activity linked to life sciences.

Why is biomanufacturing important?
Biomanufacturing is increasingly used around the world, as scientists and engineers are able to achieve reliable and consistent manufacture at higher scales and with increasing complexity and efficiency.

The primary drivers behind the growth of biomanufacturing include:
- Creating novel products that were not previously available: Advanced therapies and vaccines are examples, allowing previously untreatable or incurable diseases to be addressed.
- Transforming current manufacturing: Biomanufacturing processes can create products using reduced energy, resources and requirement for fossil fuels, fewer petrochemical products, simplifying processes, plus reducing demands on biodiversity through replacing the need for natural extraction.
Biomanufacturing is a result of biotechnology innovation translated into industrial process and capacity. Europe’s industrial transition is essential for a sustainable and competitive future. The sustainability market is growing at tremendous rate (anticipated at 40% of global GDP over the next 30 years [1]). Sustainability is not only about reaching crucial environmental targets but includes value creation and return on investment for Europe’s society.

Industry is an important stakeholder in ensuring Europe’s values of cohesion and democracy. At a global level, it is increasingly acknowledged and acted upon that economic development through sustainable solutions like biotechnologies support wellbeing, economic growth and geopolitical stability. Countries worldwide have recognised biomanufacturing as key to industrial transition, including the United States, China and other significant economies such as Japan and Brazil.

In the USA, the Bioscience Industry directly employed over 2M people in 2021 and had a total impact of over 10M jobs and 3 trillion dollars of economic output [2]. In September 2022 the White House announced an “Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy” [3] focusing on health, climate and energy, food and agriculture, and supply chain resilience.

Europe still holds a strong research position globally for pharma and biotech and has strong biomanufacturing assets. However, this is counteracted by global trends in investment, patents and public spend in R&D where Europe is increasingly out-performed. This trend is underpinned by features such as slower speed to patients through regulatory and reimbursement pathways. It is a factor influencing Europe’s ability to mature research into therapies, with the knock on impact for scale of investment into biomanufacturing, both within biotech companies and contract manufacturers.

Biomanufacturing is key to Belgium’s industry growth and economic development following several decades of political prioritisation and investment within a national biomanufacturing strategy. Between 2011 and 2021, employment increased by 150% to 37,505 FTE, exports by 240% to €83bn and R&D by 240% to €5.1bn, with a value-added increase of 200% to €11.6bn [1]. Belgium was at the forefront of the response to Covid, with the first large scale manufacture, significant clinical trials and a major export base for the vaccines worldwide. Biomanufacturing investments into Belgium have included Pfizer, Legend Biotech/Janssen Pharmaceutica, Univercells/Exothera, Eurogentec Kaneka, Takeda, GSK, UCB and Sanofi.

Europe’s production capacity for advanced biologicals reflects the advances now possible within healthcare and also demonstrated its critical role within the COVID-19 response.

Increasing biomanufacturing capacity for healthcare is a unanimously recognised need. Pharmaceutical legislation will strongly influence Europe's capacity, both in the strategic decision making within global companies and the ability of smaller companies to secure sufficient investment for maturation of disruptive and high-risk innovation. It is critical that these legislative and regulatory frameworks enable the long-term investment into increased capacity across countries if patients are to benefit.

From an innovation view point the speed of change continues to impress as digitalization and automation make biomanufacturing increasingly cost effective, increasing yield and quality, and enable faster go to market of novel products. This would in principle translate into faster improvements to peoples’ lives and the economy.

Preparedness and readiness for emerging diseases and pandemic outbreaks also become more attainable thanks to increasingly available modular biomanufacturing capabilities. However, barriers to scaling still exist, requiring continued investment in capacity and innovative technological solutions.

Progress in biotechnology, artificial intelligence and digitalization of processes and product development all point towards accessible improvements and cost reduction in biomanufacturing. However, SMEs, CMOs and CDMOs with strong R&D often lack the capital expenditure to scale, whilst larger actors assess stability and predictability of regulatory frameworks and market access for long-term investment decisions across global regions. The regulatory framework for biomanufacturing must become agile in order to match the speed of innovation and tech transfer potential. Currently, innovators face regulatory hurdles to integrate disruptive innovation into the healthcare space.

Consistency and cooperation must be higher within trade dialogues in order to minimise duplication of efforts across territories (particularly between EU and USA). Staying ahead of new technologies will enable regulatory bodies align globally and minimise divergence for innovators.

The ecosystem and supply network are also critical for biomanufacturing and Industry 5.0 vision is central; re-skilling and upskilling of the workforce is necessary to address talent shortage and insure job creation and fulfilment.
Biomanufacturing for resilience, competitiveness, and sustainability

Summit Discussion Session

Europe’s expansion of biomanufacturing, both to achieve sustainability objectives and create high value novel products, is taking place within a rapidly changing global landscape. Biomanufacturing represents a transition to next generation manufacture and is an opportunity to attract, retain and grow businesses within Europe.

Europe is lagging globally in terms of public funding and private investment. Large companies face a lack of policy alignment and poor incentives for significant investments required over decades, whilst SMEs are agile but lack resources. The EU’s competitive position must be achieved through the legislative and regulatory framework being built now and must enable emerging smaller companies and global actors to achieve manufacturing focus and scale. It is a priority to set a long term target and work backwards with tangible milestones for industrial capacity.

Europe is already a preferred IP generator and testing ground, with the logical next step to ensure it is a preferred production territory. R&D alone is not enough to achieve this, the regulatory system must be agile and able to absorb and process innovation advances through to market, including alignment across regulatory boundaries.

Reducing complexity across legislations, removing unintentional barriers and creating a genuinely single market will enable impactful growth, including national variations in critical factors such as permitting processes. Finally, a green paradigm for regulation is needed, as the language of current regulations is based on a fossil-derived past and initial legislative responses to early biotechnologies.

A reliable value chain and ecosystem is core. A skilled workforce transitioning from carbon focused jobs is crucial and scaling bioreactor capacity to a cost-effective point is essential for EU companies. Public strategy and investment infrastructure plus development of know-how goes hand in hand with a skilled workforce. Evaluating policy and legislative toolboxes in other priority areas such as chips and batteries will be a significant support for biomanufacturing and help shape the right strategy.
Europe has been at the forefront of innovation in all areas of science and technology. It is well-recognised that great ideas and inventions only make a difference when they are implemented, and done so at scale. In the global context, visionary targets and timing of action to enable this transfer of innovation into the market are extremely important to maintain (or recapture) a leadership position and insure the achievements of key targets for Europe’s economy and wellbeing of its citizens.

Biomanufacturing innovation and scaling face more barriers within the EU than in other fast-growing regions. Initiatives such as public-private partnerships have been laudable in bringing players together, identifying hurdles and addressing them collaboratively.

Europe has a strong position for biomanufacturing that can transform healthcare and create sustainable industries however this position cannot be taken for granted. The current legislative pathways linked to Europe’s strategies for health, sustainability and competitiveness need to ensure that all actors are able to mature.

SMEs are the vehicle for innovation and more can be done to bring SMEs and larger industrial players together through collaboration to support scaling and absorption of innovation. This is linked to the ability of Europe to attract and encourage the deployment of large capital investments, in addition to a positive environment for higher risk strategic R&D and go-to-market decisions on specific products.
Biomanufactured goods and therapies face unresolved challenges on the policy front. Other global regions are developing more fit-for-purpose regulatory frameworks and incentives, enabling the transition away from petrochemical derivation.

A level playing field that addresses biomass use and carbon pricing would make market entry fairer for products and support the green transition. This should be accompanied by continued collection of evidence of how biomanufactured products have a positive impact on the environment and the economy.

European institutions recognize the important of industry for cohesion and democracy. These institutions should place biomanufacturing and biotechnologies higher on the political agenda if they want to reach important targets.

Europe has invested substantially in research and innovation within the biotech space over decades. By not being ambitious and strategic now, Europe risks a decline in innovation, with accelerated exit of intellectual property to other regions. This will result in reduced research-driven economic growth, poorer options for consumers, limits in capacity to hit strategic political goals and weakened rather than strengthened resilience. Europe must decide whether it is a pilot in the cockpit or a passenger for the delivery of innovation.

Europe’s legislative framework is the key to enabling biomanufacturing. The pharma legislation is an example of this, as a tremendous opportunity for Europe to be recognised globally for bringing advanced innovation to patients as an originator and a destination of advancing healthcare.

The biotech industry is by its own nature heterogeneous and fragmented. Yet a clear voice has emerged through biomanufacturing and is further taking shape to guide policy makers towards ambitious, yet feasible frameworks in the biomanufacturing space across sectors and to the benefit of European citizens.
Biomanufacturing Recommendations

Europe needs to create a cross-sectoral biomanufacturing roadmap reflecting global positioning and targets.

- Recognise cross-sectoral biomanufacturing within high level European strategies, such as EU Industrial Strategy, Pharma Strategy, Bioeconomy Strategy and Green Deal Industrial Plan.

- Coordinate at a policy level the alignment between R&D focus, industrial priorities, and commercial applications towards delivering sustainable products and processes through biomanufacturing.

- Address alignment across legislation to address unintentional barriers to biomanufacturing scale up for Europe.

- Recognise Europe’s resilience improvement resulting from biomanufacturing capacity for healthcare preparedness and supply chain resilience across sectors.

- Create a skills pathway for biomanufacturing and advanced manufacturing to ensure access to critical re-skilling and up-skilling in all European countries.

- Create targets for increase of biomanufacturing within the EU economy, supported by policy strategies that identify and recognise its economic, social and environmental contributions across sectors.

- Recognise and address critical points and vulnerabilities within biomanufacturing value chains to improve European competitiveness.

- Position regulatory frameworks and resources for product rather than process-driven criteria to increase agility and accelerate Europe’s green transition.

- Support the uptake of European innovation converted into value-added businesses and economic development and incentivise investment into start-ups and SMEs to scale-up biomanufacturing within Europe.

- Ensure a global level playing field for transition to sustainable biomanufacturing processes and products.
Summit Participant Organisations

- 21st.Bio
- Abolis Biotechnologies
- Asociación Española de Bioempresas
- BASF SE
- BIO Deutschland
- Bio.be
- BioPharmaChem Ireland
- Biotechnology Innovation Organization (BIO)
- CECIMO
- Circular Biobased Europe JU
- Council of European BioRegions
- Cytiva
- DG AGRI, European Commission
- DG GROW, European Commission
- DG RTD, European Commission
- DSM
- EIT Health
- EIT Manufacturing
- Eli Lilly and Company
- EUREKARE
- European Parliament
- Evonik Operations GmbH
- Flanders Investment & Trade
- Fréget Glaser & Associés
- Galician Innovation Agency
- German Association of Biotechnology Industries
- GIP Genopole
- HollandBIO
- Ibec
- IFF
- Lallemand
- MabDesign
- Merck Group
- Merck Life Science
- MSD
- National Institute for Bioprocessing Research and Training (NIBRT)
- Novartis
- Novo Nordisk Foundation
- Novozymes
- OECD
- Orgalim
- Pfizer
- Puratos NV
- regenold GmbH
- Roal Oy
- SwiftPharma
- Takeda Belgium
- VCLS
- Vertex Pharmaceuticals