

Biomanufacturing

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Biomanufacturing highlights

Roadmap				Owner:
Scope				Suzanne Robb
	Top items	Analysis	Key insights	Contributors
Industry challenges	<p>The key challenges are:</p> <ol style="list-style-type: none"> Next generation therapeutics Food security and sustainability Optimised and sustainable biomanufacturing Materials, chemicals and circularity Biomanufacturing for diagnostics 	<p>Biomanufacturing industry challenges are focused in three key areas across all sectors, whether it is pharmaceutical, agricultural, chemical or food. They are:</p> <ul style="list-style-type: none"> new products and processes, process development and manufacturing optimisation scale up and pilot facilities. <p>The challenges range from clinical supply of novel modalities where new production methods are required and new products require new validation and regulations, to the adoption of automation and digitalisation in biomanufacturing to improve development pathways, increase sustainability and deliver validated manufacture.</p>	<ul style="list-style-type: none"> New products and processes required across sectors Digitalisation, automation and sustainable bio-manufacture accepted into regulatory environment The key challenges ensure UK resilience and tackle strategic priorities. 	David Bird, Simon Hawdon, Clare Trippet, Deepan Shah, Reza Ranjbar, Lois Hobson and others at CPI.
	<p>Industry requires the following key capabilities:</p> <ol style="list-style-type: none"> Food and feed production Alternative antimicrobials Sustainable and cost effective biomanufacturing Circularity of materials Skills development platforms 	<p>Translational biomanufacturing capabilities are needed to support the development of commercially viable products across sectors whether it is food, chemical or pharmaceutical.</p> <p>These capabilities support the development of processes suitable for the sectors and scales required from early research development to a marketable product through developing new processes and systems to support new products. Whether that is by supporting new process and bioreactor design, access to suitable scale up and pilot facilities, regulatory support, product and process characterisation and fast process development and optimisation.</p> <p>Improving biomanufacturing efficiency, cost effectiveness and sustainability by utilising digital and automation techniques to model and simulate process development phases, perform automated process control, perform process intensification, have in process characterisation and real-time release of the final product will support the UK's climate change goals.</p>	<ul style="list-style-type: none"> New processes and bioreactors to support new products and modalities Access to scale up and pilot facilities Cost is key Regulatory support across sectors for adoption of new modalities and processes Requirements across all sectors are very similar. 	<p>Validation:</p> <p>CPI, UKRI research councils, BIA, Jen Vanderhoven, James Miskin, Steve Bagshaw, Amanda Calvert, Andy Jones</p>
HVM Catapult developments	<p>HVM Catapult should focus on:</p> <ol style="list-style-type: none"> Novel manufacturing capability Digitally enabled biomanufacturing Public health and strategic priority response 	<p>Novel manufacturing includes new processes required for new modalities, new bioreactors, new processing or purification, new analytics, formulations and characterisation and scale up or scale out of manufacturing as required. It is translational manufacturing taking from early bench or shake flask scale to a scalable minimal viable product or process that can be demonstrated before being transferred and ultimately adopted into industry. Whether this is as an industry need or in response to a national strategic priority or public health imperative.</p> <p>Novel processes and manufacturing is underpinned by utilising digital capabilities to increase speed of development and increase sustainability, whether through automation and advanced process control to improve efficiency and quality, to process modelling, digital twins and AI to reduce development timelines and wet work required.</p>	<ul style="list-style-type: none"> Novel and translational manufacture from research to commercialisation Manufacturing or pilot scale facilities for novel products and processes. Digitalisation is required across biomanufacturing 	
		Other areas considered in the roadmap include current therapeutics and medicines, response to biothreats, downstream processing of materials, personalised medicine production, agreed standards, intensive and sustainable RNA and LNP production, consistent LCA for biomanufacturing, feedstock and supply chain resilience.		

Biomanufacturing roadmap

	Short term	Medium term	Long term
Industry challenges	Access to finance		
	Design of bio manufacture hardware		
	Economic bio recovery for R's		
	Next Generation medicines		
	Response to bio threats		
	Current generation medicines		
	Bio manufacture for diagnostics		
	Manufacturing scale up		
	Product assurance including regulatory understanding		
		Supply chain resilience for feedstocks	
		Food security and sustainability	
	Clean power manufacturing technologies		
	Develop a skilled workforce		
	Materials strategy		
	Materials and circularity		
	Supply chain		
	Faster and lower costs to market		
	Process		
	Digital manufacturing		
Technology capabilities	Consistent and improved application of LCA for cost/benefit		
	Digital simulation for development		
	High nutrition and appeal food/feed		
	Microbiome and phage		
	Modelling to speed developments		
	Platform approach to diagnostics		
	Skills development platforms		
		Space, transport etc.	
		Clinical supply of next generation materials	
		Host strain development	
	Automation and development of manufacturing		Organ replacement
	Circulatory of materials		

Biomanufacturing roadmap



HVM Catapult developments

Short term	Medium term	Long term
Downstream processing		
Robotic systems for labs		
Upstream bioreactor development		
	Recyclable polymers or methods to recycle	
Enabling investment		
Materials development		
Automated integrated viral vector system		
Develop continuous and perfusion culture methods for cultivated meat		
GMP manufacturing capability		
High throughput platforms for process development		
Intensive IVT system		
IVD components		
LCA standards		
Mapping supply chain		
Modular reactors		
Small scale automated production system for medicine		
	Agreed standards	
	Cell free production	
	Supply of - power, H2, Carbon	
	Universal host for phage	
Cross HVM Catapult collaboration		
Links to research		
Workflow and clinics trials		
Biological system modelling		
Data management		
Efficiency		
Digital twin platform		
Enzyme production platform. host sharing, DSP, high throughput assays		
Solvent extraction ria 20-50L scale 50-100L scale		
	Testing extremophiles for DB industry access	
Training		

