

# CELL AND GENE CATALYST

ACCELERATING AUSTRALIA'S CELL AND GENE INDUSTRY

**Dr Marguerite Evans-Galea AM**  
Director, Cell and Gene Catalyst

## What is the Cell and Gene Catalyst?

- A joint venture of two industry-led peak bodies which aims to accelerate Australia's cell and gene industry.
- **AusBiotech:** Australian representative body for one of Australia's most innovative industries with a well-connected network of over 3,000 members in the life sciences industry.
- **Medicines Australia:** represents the research-based medicines industry and is committed to ensuring access for Australians to all innovative therapies that can extend and improve their lives.





## THE VISION

That Australian patients have access to world-class innovation sustained by a thriving Australian cell and gene therapy industry.

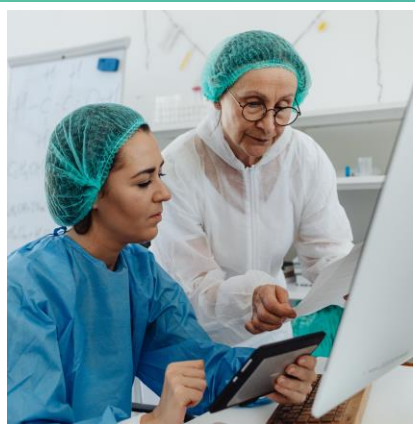
## THE MISSION

To create an end-to-end world-class value chain, that can discover, develop, and distribute cell and gene therapies, creating an Australian Hub to deliver jobs, commercialise research and benefit patients, exporting Australian therapies to the world.



CELL AND GENE CATALYST

## Strategic Goals



Attract, build and retain world-class talent



Collaborate across the value chain



Secure long-term investment in the sector



Create a clear market access pathway aligned to leading global markets



Build Australian capability and capacity across the CGT value chain

## Catalyst industry partners







## The Catalyst's **Expert Steering Group** advises on strategy and priorities:



**Dr Heather Donaghy**  
Scientific Engagement Manager  
Cell and Gene Therapies  
Therapeutic Innovation Australia



**Dr Jennifer Hollands**  
Government &  
Academic Liaison  
Cell Therapies



**Deniz Bagdadi**  
Business Unit Director  
New Products  
CSL Behring



**Caroline Ryan**  
Chapter Lead  
Medical  
Roche Products



**Lorraine Chiroiu**  
Chief Executive  
AusBiotech  
(Co-Lead)



**Elizabeth de Somer**  
Chief Executive  
Medicines Australia  
(Co-Lead)



**Anne-Maree Englund**  
Head, Strategic Policy  
Implementation  
Medicines Australia



**Sarah Greenbaum**  
Manager  
Policy & Public Affairs  
Pfizer








**Monique Jonson**  
Head  
Gene Therapy  
Novartis ANZ



**Dr Marguerite Evans-Galea AM**  
Director  
Cell and Gene Catalyst  
AusBiotech | Medicines Australia



# Catalyst Strategic Roadmap

<p>Mission</p>	<p>To create an end-to-end world-class value chain, that can discover, develop, and distribute cell and gene therapies, creating an Australian Hub to deliver jobs, commercialise research and benefit patients, exporting Australian therapies to the world.</p>				
<p>Goals</p>	 <p><b>Workforce development</b></p>	 <p><b>Connection and collaboration</b></p>	 <p><b>Funding</b></p>	 <p><b>Regulation and policy</b></p>	 <p><b>Infrastructure</b></p>
<p>Objectives</p>	<p>Attract, build and retain world class talent</p>	<p>Collaborate across the value chain</p>	<p>Secure long-term investment in the sector</p>	<p>Create a clear market access pathway to leading global markets</p>	<p>Build Australian capability across the value chain</p>
<p>Actions</p>	<p>Advocate for increased financial and structural incentives that encourage operations in Australia and attract individuals and groups with experience in commercialising therapies.</p> <p>Supporting stakeholders to improve information sharing across providers, clinicians and patients, especially around successful clinical models.</p> <p>Building activities aimed at improving health system readiness by working to embed CGT in standards and guidelines and as a medical speciality.</p>	<p>Building stakeholder engagement and mobilising resources to facilitate mentoring and networking programs across the value chain.</p> <p>Supporting efforts amongst stakeholders to ensure that commercial considerations are factored into early-stage research and to manufacturing capability.</p> <p>Advocating for and contributing to policy aimed at establishing a national coordinated approach to capability development (e.g. Clinical trials, site selection, etc).</p>	<p>Encouraging investment from governments and provision of broad economic incentives for private investment including a suite of targeted financing mechanisms.</p> <p>Mobilising private investment via international and domestic venture capital into Australia's biotechnology sector, including increasing institutional and retail investor understanding of CGT.</p> <p>Encouraging multinational companies to engage locally, to market their products in Australia and to provide expertise and partnering to SMEs located here.</p> <p>Encouraging more public-private partnerships (PPP).</p>	<p>Contributing to policy around expedited approval for CGT in Australia.</p> <p>Contributing to policy discussions that seek to create definitional and decision-making alignment across the different regulatory mechanisms.</p> <p>Advocating for Australia to have access to priority CGT clinical trials.</p> <p>Contributing to policy discussions on, and advocating for, the standardization of international quality control processes for CGT.</p>	<p>Mobilising resources, building stakeholder engagement and advocating for mechanisms that provide researchers early access to clinical-grade cell lines.</p> <p>Mobilising resources and advocating for a national stem-cell registry for researchers.</p> <p>Advocating for ongoing and increased government investment in domestic manufacturing capability and infrastructure through additional post-graduate training for the current workforce and undergraduate training for future workforce, and through support of current and emerging manufacturing infrastructure.</p> <p>Building stakeholder engagement and supporting activities aimed at improving health system readiness.</p>

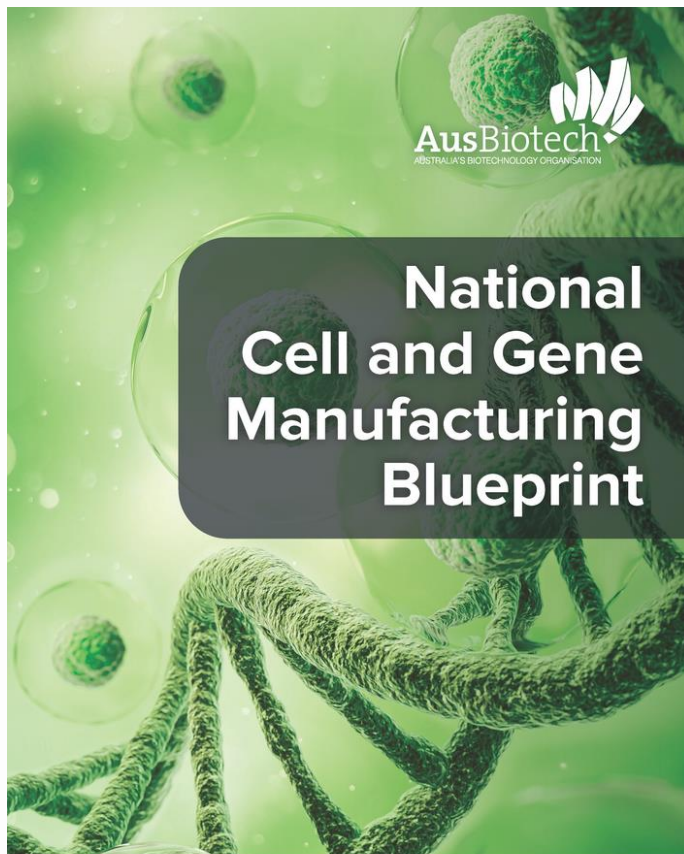
## Where to first?

### Over-arching priority areas for the Catalyst include:

- ❖ **Policy and advocacy** – reimbursement, manufacturing, long-term strategic investment.
- ❖ **Collaboration and knowledge-sharing** – meaningful opportunities to connect, exchange ideas, solve challenges.
- ❖ **Workforce development** – current and future workforce in healthcare, manufacturing and commercialization.

**Australia's Cell and Gene Catalyst** moves ahead, signalling the important next step in advancing cell and gene accessibility in Australia.





**National Cell and Gene Manufacturing Blueprint** – an industry-developed strategic approach for leveraging national strengths to overcome key challenges and to coordinate the growth of CGT manufacturing.

The blueprint provides:

- (1) A vision for manufacturing cell and gene products in Australia;
- (2) Outlines where we are now as a country; and
- (3) Provides a ‘blueprint’ of implementation strategies for manufacturing CGT locally.

#### **The vision**

To foster the development of the Australian ecosystem to a self-sustaining state, and to position Australia as a leader in the Asia-Pacific (APAC) region, it is crucial to establish a robust Australian capability in cell and gene manufacturing, prioritising quality, and reliability. In harnessing Australia’s strategic location within the APAC region, this reach can be expanded to encompass international markets.

The blueprint was developed in consultation with the sector and published by AusBiotech.



Australia:  
a self-sustaining C&G Manufacturing ecosystem  
that leads the APAC region

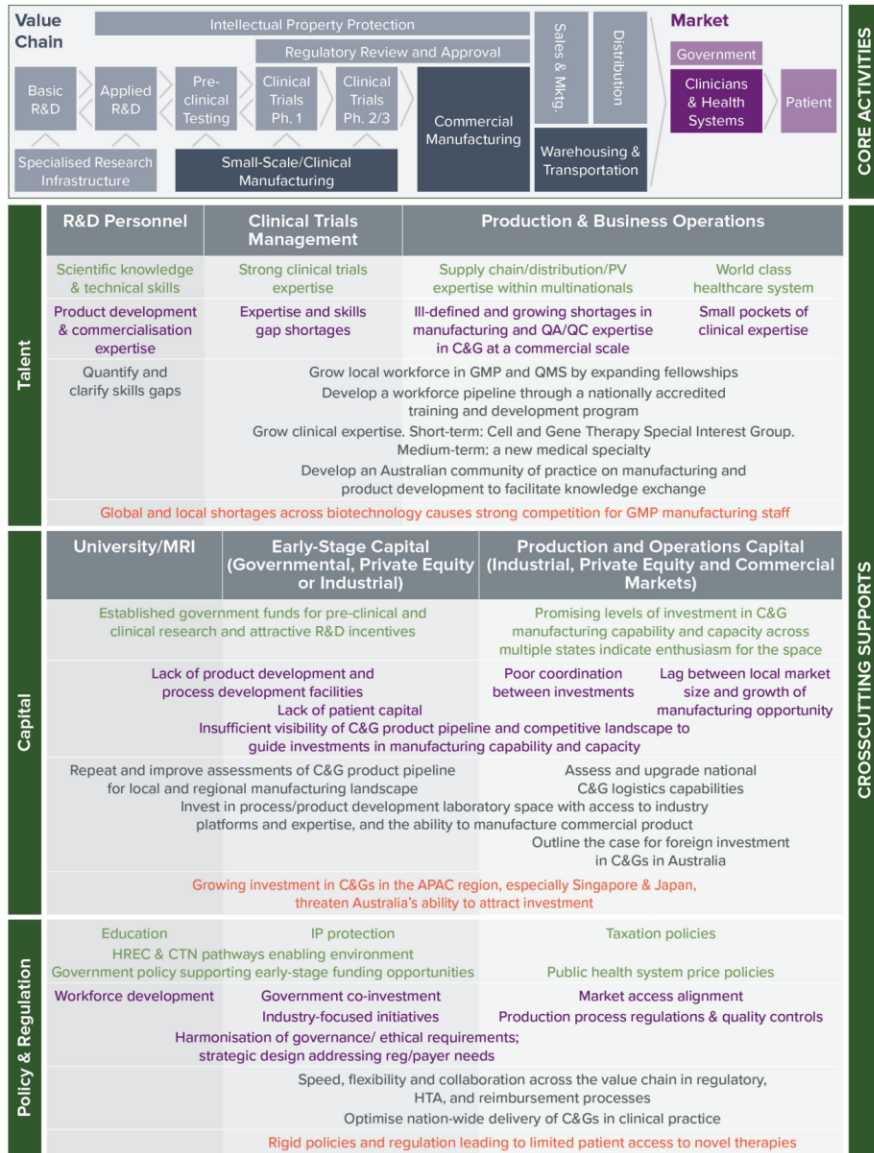
Challenges	Address critical and growing skills gaps	Build critical mass across the value chain	Optimise our pipeline contribution	Track and guiding industry growth
Key recommendations	1. Understand workforce requirements	4. Grow from existing strengths	6. Support translation of Australian Science	8. Communicate the high value opportunity and attractiveness of C&G
	2. Expand and improve the skill level of the developing workforce	5. Complete the manufacturing supply chain	7. Streamline running clinical trials	9. Monitor national ecosystem
	3. Share expertise and know-how			10. Scan the horizon
				11. Aid growth into international markets
Sector enablers	Funding opportunities			
	Existing infrastructure			
	Strong clinical trials capabilities			
	Strong public sector science			
	Networks, partnerships and collaborations			

The blueprint outlines four major challenges:

- (1) Address critical and growing skills gaps;
- (2) Build critical mass across the value chain;
- (3) Optimise our pipeline contribution;
- (4) Track and guide industry growth.

The Catalyst will play a major role in actioning the key recommendations made in the blueprint and tracking and monitoring their impact.

# CELL AND GENE CATALYST



Key: Strengths Weaknesses Opportunities Threats

## The blueprint aligns with the Catalyst's strategic goals



### Workforce development

Attract, build and retain world class talent



### Connection and collaboration

Collaborate across the value chain



### Funding

Secure long-term investment in the sector



### Infrastructure

Build Australian capability across the value chain



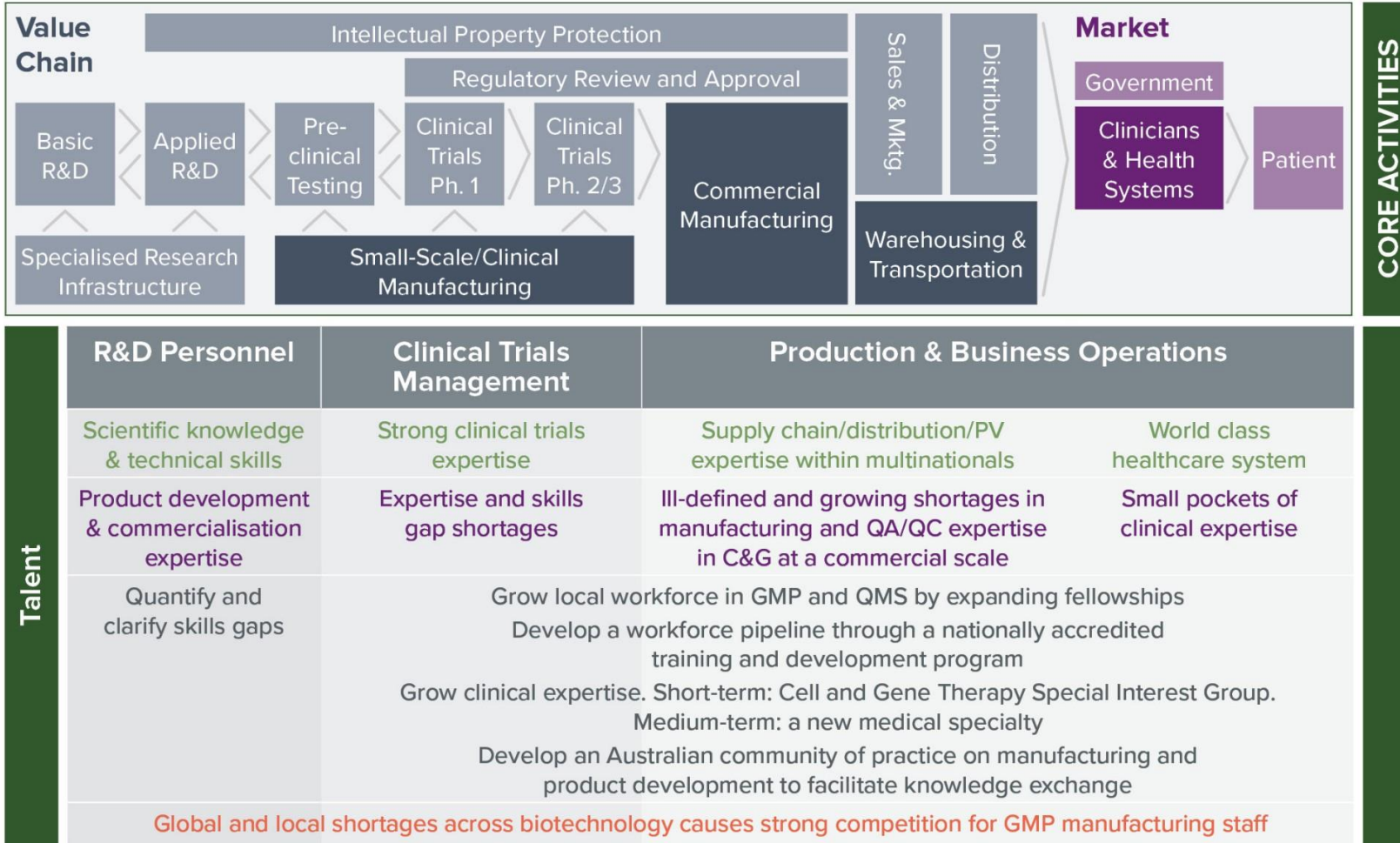
### Regulation and policy

Create a clear market access pathway to leading global markets





# CELL AND GENE CATALYST



Key:

Strengths

Weaknesses

Opportunities

Threats

## Talent



### Connection and collaboration

Collaborate across the value chain

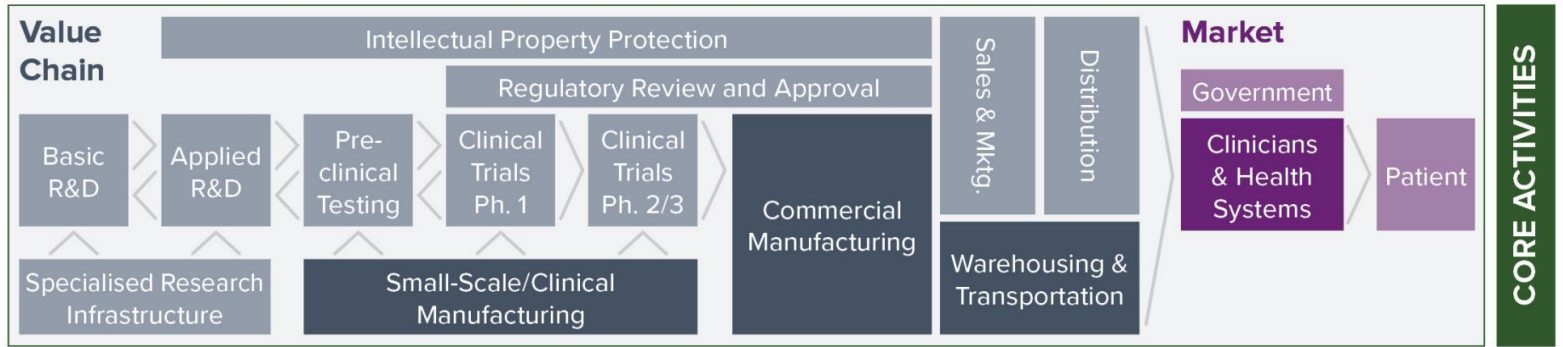


### Workforce development

Attract, build and retain world class talent



# CELL AND GENE CATALYST



Capital	University/MRI	Early-Stage Capital (Governmental, Private Equity or Industrial)	Production and Operations Capital (Industrial, Private Equity and Commercial Markets)
	Established government funds for pre-clinical and clinical research and attractive R&D incentives		Promising levels of investment in C&G manufacturing capability and capacity across multiple states indicate enthusiasm for the space
	Lack of product development and process development facilities Lack of patient capital Insufficient visibility of C&G product pipeline and competitive landscape to guide investments in manufacturing capability and capacity		Poor coordination between investments Lag between local market size and growth of manufacturing opportunity
	Repeat and improve assessments of C&G product pipeline for local and regional manufacturing landscape Invest in process/product development laboratory space with access to industry platforms and expertise, and the ability to manufacture commercial product		Assess and upgrade national C&G logistics capabilities Outline the case for foreign investment in C&Gs in Australia
	Growing investment in C&Gs in the APAC region, especially Singapore & Japan, threaten Australia's ability to attract investment		

**CROSSCUTTING SUPPORTS**

Key: Strengths Weaknesses Opportunities Threats

## Capital



**Funding**  
Secure long-term investment in the sector

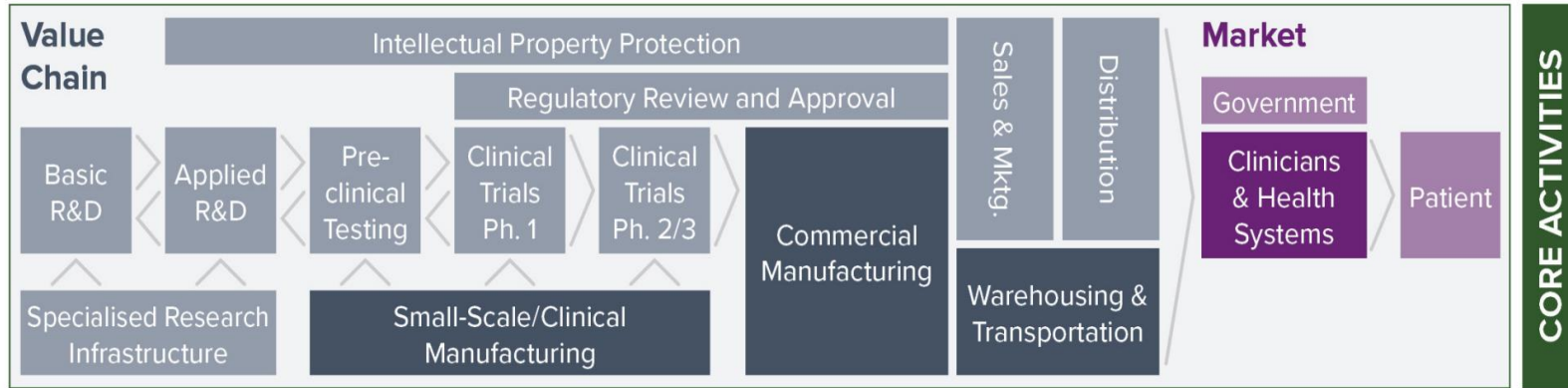


**Infrastructure**  
Build Australian capability across the value chain





# CELL AND GENE CATALYST



**CORE ACTIVITIES**

## Policy

<b>Policy &amp; Regulation</b>	<p><b>Education</b></p> <p>HREC &amp; CTN pathways enabling environment Government policy supporting early-stage funding opportunities</p>	<p><b>IP protection</b></p> <p>Government co-investment Industry-focused initiatives</p>	<p><b>Taxation policies</b></p> <p>Public health system price policies Market access alignment Production process regulations &amp; quality controls</p>
	<p>Workforce development</p>	<p>Harmonisation of governance/ ethical requirements; strategic design addressing reg/payer needs</p>	
		<p>Speed, flexibility and collaboration across the value chain in regulatory, HTA, and reimbursement processes</p>	
		<p>Optimise nation-wide delivery of C&amp;Gs in clinical practice</p>	
		<p>Rigid policies and regulation leading to limited patient access to novel therapies</p>	








**Regulation and policy**  
Create a clear market access pathway to leading global markets

Key: Strengths Weaknesses Opportunities Threats



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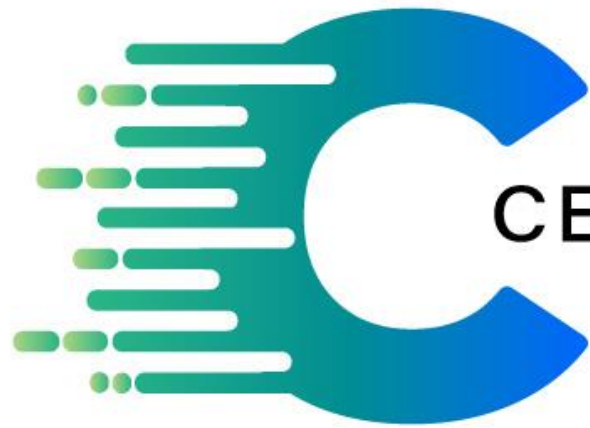
CELL AND GENE CATALYST



## Scan the QR code to:

1. Learn more about the Cell and Gene Catalyst.
2. Express your interest in serving on the Working Groups.
  - Policy and advocacy
  - Collaboration and knowledge-sharing
  - Workforce development

Email: [catalyst@ausbiotech.org](mailto:catalyst@ausbiotech.org)



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