



Your Agile CDMO Partner.
From Clinical to Commercial.

50+ Years of History

1980 Origins

- Perth: Delta West founded
- BFS and Oncology Packaging Introduction
- Adelaide: Bresagen established

1990 Global Integration

- Perth acquired by Upjohn → Pharmacia
- First Cytotoxic Product launched

2015-2018 Pfizer Era

- Hospira acquired by Pfizer
- Facility Upgraded
- New Vial Line Commissioned

2003-2013 Global Expansion & Modernization

- Perth: **Pfizer's center of excellence for oncology and BFS manufacturing**
 - RABS and oncology line major upgrades
 - Rommelag BFS line commissioned
- Adelaide: **cGMP biologics facility established, TGA-licensed; later Hospira-acquired**
 - Large-scale purification systems added

BridgeWest Era

- Acquired by BridgeWest, forming BioCina (Adelaide) and NovaCina (Perth)
- Adelaide: US-FDA pre-approval and cGMP inspection
- Next-generation mRNA and pDNA manufacturing launched

Two Sites. One Global CDMO.

- BioCina and NovaCina Merger

A Legacy of Global Excellence, now united under BioCina.

Powered by BRIDGEWEST GROUP



Trusted Science,
Backed by Strong Capital



Flexible Innovation
Across the Value Chain

- Global investment firm with US\$3B+ in assets
- Strong capital support driving site growth and innovation
- Proven track record in scaling biotech and tech enterprises
- Long-term ownership enabling sustainable CDMO growth
- Strategic network of 40+ portfolio companies enhancing capabilities

Biomanufacturing

Biologics & Injectable CDMO



Drug CRDMO



Chromatography



Digital

Healthcare AI



Healthcare Training AI



Pharmaceutical Supply AI



Therapeutics

Pharmaceuticals



CAR-T



CAR-T for Solid Tumors



Conditionally Active Biologics



Ophthalmic Therapeutics



Oncology Therapeutics



Dx & Device

Immunodiagnosics



Diagnostics



Surgical Tools NZ and Australia



BioCina: Advancing Therapies Through Trusted Partnership

Committed to building enduring client partnerships, aligning on strategic objectives, and applying deep expertise across small molecules and biologics.

We Listen. We Solve. We Deliver. On-Time, In-Full.



Partnership. Aligned.

Dedicated teams provide **flexible, solution-focused support**, understanding priorities through **open, transparent collaboration**.



Delivery. On-Time.

Industry-leading >95% on-time-and-in-full (OTIF) performance with supply to **more than 100 countries** worldwide.



Quality. Trusted.

Trusted and inspected by leading global health authorities, including **US FDA, EMA, TGA, and others**.



Expertise. Proven.

400+ specialists with an **average tenure of 15 years**, showcasing deep technical and operational mastery built over decades.

Manufacturing Sites

Drug Product (Perth)

- ▶ 14,000 m² (150,695 sq. ft.) Facility
- ▶ 10 State-of-the-Art Filling Lines
- ▶ > 600 Drug Product Approved
- ▶ > 1B+ Sterile Units Manufactured



Drug Substance (Adelaide)

- ▶ 8,400 m² (90,417 sq. ft.) Facility
- ▶ 4 Key Modalities Across Dedicated Suites
- ▶ > 100 Products Cloned & Expressed
- ▶ 3 Commercial Products Developed

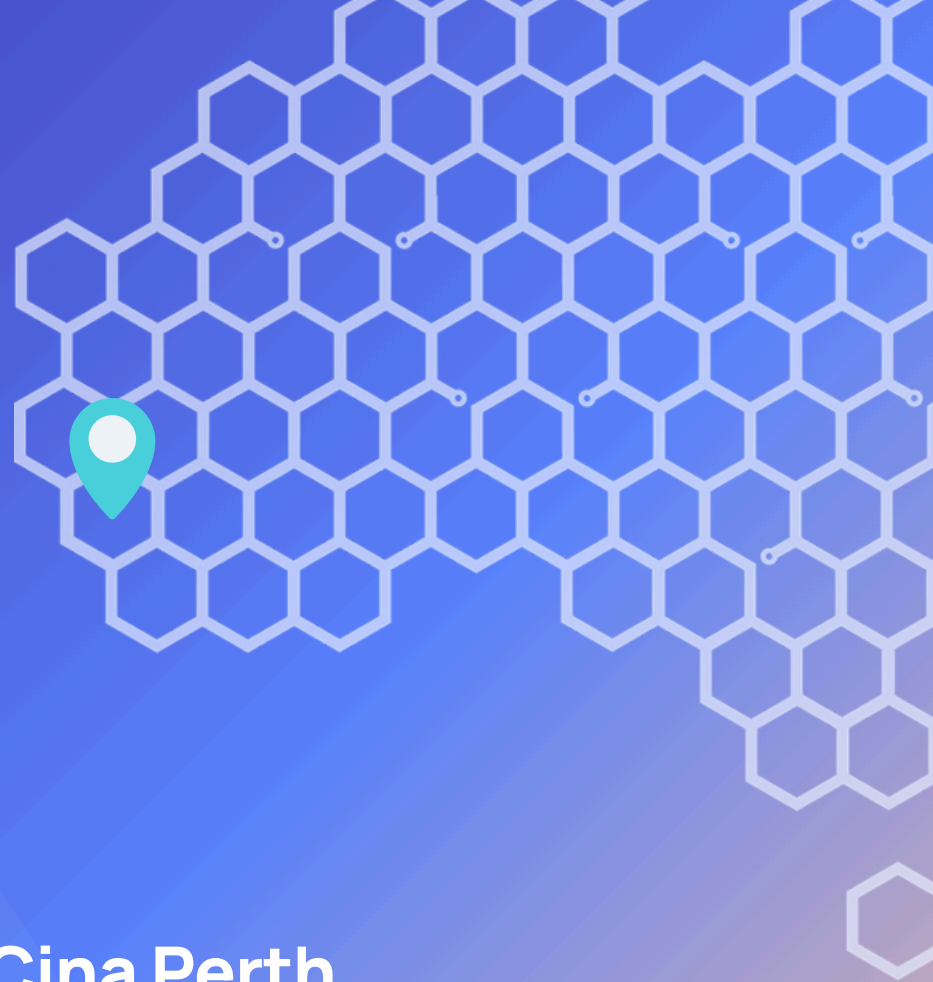
Manufacturing Capabilities Overview

Drug Substance

	STAGE	EQUIPMENT	YIELD
Microbial	Process Development	2 L Fermenter x8	YIELD Up to 5 g / L
	Scale-Up	30 L SS Fermenter	
	cGMP	435 L SUB Fermenter 750 L SS Fermenter	
pDNA	Process Development	2 L Fermenter	YIELD 50 - 200 mg
	cGMP	435 L SUB Fermenter 750 L SS Fermenter	YIELD 5+ g
mRNA	Process Development	WAVE 25 Reactor NanoAssemblr (Spark / Ignite / Blaze)	YIELD Up to 2 g / batch Up to 20+ L formulated
	cGMP	WAVE 25 Reactor NanoAssemblr (NCFS)	YIELD Up to 100 g / batch Up to 1000+ L formulated
LNP	Process Development	NanoAssemblr (Spark / Ignite / Blaze)	YIELD Up to 4 L
	cGMP	NanoAssemblr (NCFS)	YIELD Up to 40+ L

Drug Product

FORMAT	FILL VOLUME	EQUIPMENT	ANNUAL CAPACITY
Blow-Fill-Seal	1-30 mL	Blow-Fill-Seal	200M + units / yr
Vials	1-100 mL Polypropylene	RABS	10M + units / yr
	20-100 mL Glass · Polypropylene	Terminal sterilization	10M + units / yr
	2, 6, 10 mL Glass	Isolator workcell	5M + units / yr
Pre-Filled Syringes	1, 5 mL Glass	Isolator workcell	5M + units / yr
Cartridges	3 mL Glass	Isolator workcell	5M + units / yr
PET Bottles	100-200 mL	Farmomac	1M + units / yr
SPECIALIST CAPABILITIES			
Cytotoxic Injectables	1-100 mL	Dedicated cytotoxic suite (RABS)	10M+ units / yr
Controlled Substances	All applicable fill volumes	Applicable to all lines	



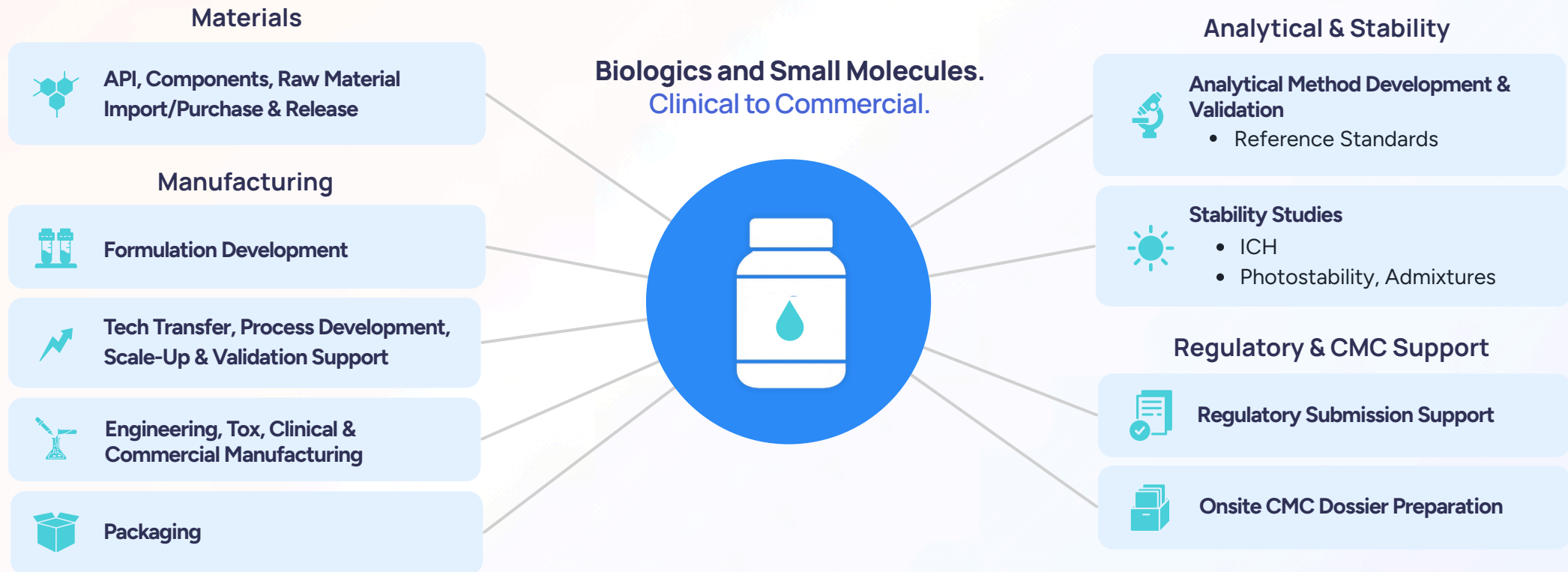
BioCina Perth

**Our Integrated Drug
Product Operations**



Fully Integrated Drug Product Manufacturing

50 Years of Sterile Manufacturing • 10 Aseptic Lines • 225M+ Units Annual Capacity



Formulation and Analytical Development

Formulation Development

- **End-to-end formulation support** for lead candidates
- **Reverse engineering** for ANDA / 505(b)(2) product pathways
- **Solubility, stability,** and **compatibility** strategies
- **Terminal sterilization** and **filter assessment** studies
- **Non-cGMP stability screening programs**
- **Scale-Up support**
- **Seamless transition** into cGMP manufacturing

Analytical Development & Characterization

- **Analytical method development, optimization,** and **validation** (ICH-aligned)
- **Stability-indicating** and **impurity profiling**
- **Compatibility, extractables/leachables (E/L),** and **container-closure** studies
- **Forced degradation** and **stress-testing**
- **Full analytical packages** supporting ANDA / NDA submissions
- **Method transfer and re-validation** for cGMP release & stability programs

Integrated scientific expertise to accelerate your drug product pathway.

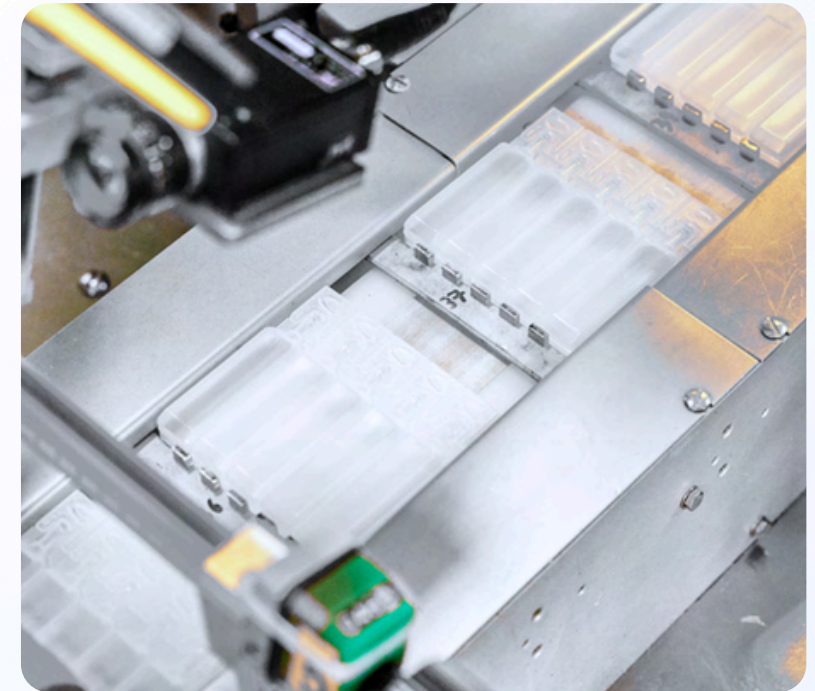
Blow-Fill-Seal (BFS) Ampoules

200M+ Unit Annual Capacity. 40+ Presentations. Aseptically Filled.

- Ideal for **ophthalmic, inhalation, and single-use sterile liquids**
- Suitable for **preservative-free** or **sensitive formulations**
- Scalable for **high-volume hospital** products
- Fully enclosed aseptic forming and filling (no glass breakage risk)

Key Technical Capabilities

- **7 BFS production lines**
- **1–30 mL** fill-volume range
- Batch sizes from **105 L to 25,000 L**
- Multiple head-mold formats:
 - Luer – Direct Fill With Syringe (1–10 mL)
 - Non-Luer Amp – Draw With Needle (5–20 mL)
 - Inhalation (1–2.5 mL)
 - Irrigation (30 mL)



High Potent Cytotoxic Drug Products

10M+ Vial Annual Capacity. Plastic. Aseptically Filled.

- Designed for **cytotoxic, oncology**, and **highly potent liquid injectables**
- Full containment for operator and product protection via **Restricted Access Barrier System (RABS)**
- Ideal for **high-value, high-risk** products requiring enhanced safety

Key Technical Capabilities

- **1–100 mL** fill-volume range
- Batch sizes from **15 L to 1,180 L**
- Polypropylene vials (clear and amber)
- Complete visual inspection and support for oxygen-sensitive products
- Approved by FDA, EMA, TGA, ANVISA, and other major authorities



Multiformat Injectables

10M+ Vial Annual Capacity. Plastic and Glass. Terminally Sterilized.

- Suitable for a broad range of **liquid sterile** products
- Supports **oxygen- and metal-sensitive** formulations
- Ideal for products requiring **terminal sterilization**
- Flexible container options for global clinical and commercial supply

Key Technical Capabilities

- **20–100 mL** fill-volume range
- Batch sizes from **15 L to 2,400 L**
- Dedicated terminal-sterilization vial line
- Polypropylene and glass vials (clear and amber)
- Disposable filling assemblies, including needles
- Vacuum draw and nitrogen introduction capability
- Teflon-coated transfer line for sensitive products



Isolator Filling Workcell (SA25 Cytiva)

5M+ Vial Annual Capacity. Vials, Pre-Filled Syringes, Cartridges.

- Ideal for **small-to-medium clinical batches** needing high aseptic assurance
- Supports **glass vials, prefilled syringes (PFS)**, and cartridges
- Excellent for **oxygen-sensitive** and other **delicate** formulations
- **Annex 1 compliant**

Key Technical Capabilities

- **0.5–50 mL** fill-volume range
- **Flexible batch sizes** from clinical to commercial
- Fill formats include:
 - Vials: 2 mL, 6 mL, 10 mL
 - Syringes: 1 mL, 5 mL
 - Cartridges: 3 mL
- Fully automated aseptic filling with nitrogen overlay and vacuum stoppering
- Headspace O₂ < 5% achievable
- Handles viscosities from 1 cP to 40 cP



Farmomac Liquid Filling

1M+ Bottle Annual Capacity. PET & HDPE Bottles.

- Supports **controlled** and **non-controlled** substances
- Ideal for **oral** and **liquid non-sterile** products
- Multiple colours for **light-sensitive** formulations (amber, white, clear)
- **Tamper-evident and child-resistant** closure options

Key Technical Capabilities

- **100–200 mL** fill-volume range
- Controlled-substance batch size: **up to 1,700 L**
- Unrestricted batch size for non-controlled products
- PET bottles with secure, compliant closures
- Consistent fill accuracy and packaging performance
- Licensed handling: US/UK Schedule I–V; Australia Schedule 8



Summary of Fill-Finish Capabilities

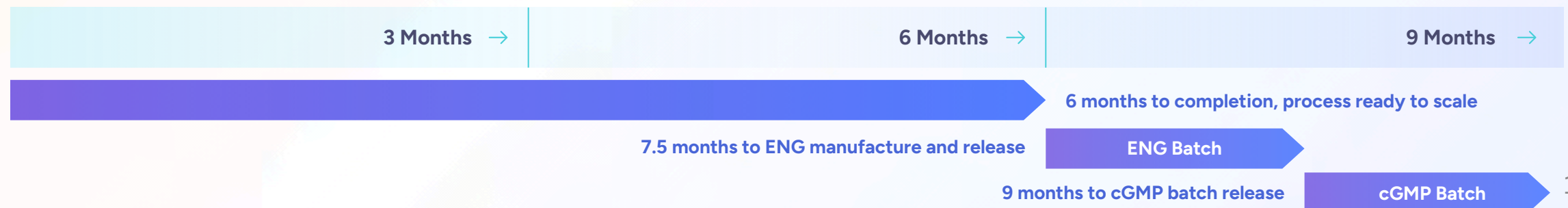
Drug Product Development and Manufacturing



Sterile DP Development and Manufacturing Scales

Equipment / Type	Fill Volumes	Batch Sizes	Presentations	Annual Capacity
Blow Fill Seal Ampoules	1 - 30 mL	105 - 20,000 L	Multiple Head Formats	200 M+
High Potent Cytotoxic Drug Products	1 - 100 mL	15 - 1,180 L	Polypropylene Vials	10 M+
Multiformat Injectables (Terminal Sterilised)	20 - 100 mL	15 - 2,400 L	Polypropylene, Glass	10 M+
SA25 Cytiva Workcell	0.5 - 50 mL	Flexible Batch Sizes	Vials, Syringes, Cartridges	5 M+
Non-Sterile / Oral Administration	100 - 200 mL	Up to 1,700 L	PET, HDPE Bottles	1 M+

Typical Development and cGMP Manufacturing Timelines





BioCina Adelaide

Our Drug Substance Hub



Drug Substance Manufacturing

50+ Years of Fermentation Experience • 4 Key Modalities • >40 Batches per Year



Microbial Fermentation

Diverse Molecule Types We Produce

- Recombinant proteins, enzymes, cytokines, and interleukins
- Antibody fragments including scFv, Fab, and Nanobodies (VHH domains)
- Subunit antigens, recombinant vaccine antigens, and diagnostic proteins
- Plasmid DNA and mRNA
- Toxoids



Therapeutic Areas Supported

- Oncology, including immunomodulators and targeted biologics
- Infectious diseases, including bacterial and viral vaccine antigens
- Autoimmune and inflammatory disorders, leveraging cytokines, interleukins and antibody fragments
- Rare and metabolic diseases via enzyme and protein therapies
- Applications also spanning regenerative medicine, hematology, diagnostics, and more

Microbial Fermentation

Comprehensive Microbial Expression & Manufacturing Capabilities

Manufacturing Expertise

- **Escherichia coli (E. coli)**
- Yeast platforms: *Pichia pastoris*, *Saccharomyces cerevisiae* (Baker's yeast)
- *Streptococcus pneumoniae* and *Salmonella enterica*



Key Technical Capabilities

Fermentation Scale-Up

- **400 mL–1 L parallel bioreactors**
Rapid strain screening and early process definition
- **20 L development fermenters**
Process optimisation, characterisation, and scale-up refinement
- **Up to 500 L cGMP fermentation**
cGMP-scale production of drug substance

Chromatography Development & Scale-Up

- **Lab-scale method screening (ÄKTA)**
Resin selection and purification strategy definition
- **Pilot → cGMP-scale purification**
Fully scalable workflows suitable for tech transfer

TFF (Tangential Flow Filtration)

- **Development-scale TFF**
Membrane selection and operating-parameter setting
- **Pilot-scale optimisation (QbD-aligned)**
Robustness and process refinement
- **cGMP-scale TFF**
Consistent DS concentration, diafiltration, and quality

Summary of Microbial Capabilities

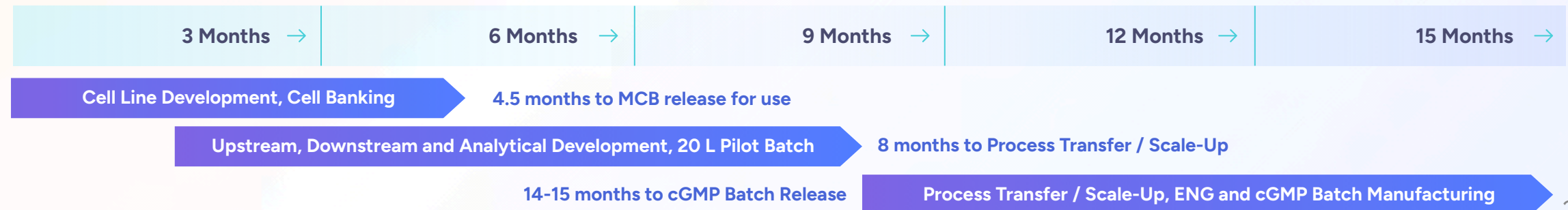
Microbial Manufacturing Process



Microbial Development and Manufacturing Scales

Stage	Equipment	Working Volume	Yield
Process Development	2 L Fermenter x 8	400 mL - 1 L	Up to 5 g per L
Scale-Up	30 L SS Fermenter	6 - 20 L	
cGMP Manufacturing	435 L SUB Fermenter 750 L SS Fermenter	65 - 300 L 200 - 500 L	

Typical Microbial Development and Manufacturing Timelines



Plasmid DNA

Diverse Molecule Types We Produce

- **Cell & Gene therapy plasmids** supporting gene replacement, CRISPR/Cas9 editing, and functional gene delivery
- **DNA vaccines** encoding viral, bacterial, or tumor antigens
- **Starting material for virus production**
e.g. AAV rep/cap, helper plasmids, and GOI plasmids
- **Templates for mRNA production**
Used in vaccines and protein replacement therapies

Phase-Appropriate Options



Early-Phase & Preclinical Supply (5-200 mg)

Ideal for preclinical studies, research-grade applications, and process development activities



Full cGMP Manufacturing (≥5 g per batch)

Enabling Phase I-III clinical supply with scalable processes designed for eventual commercial readiness

Plasmid DNA

Flexible Development Pathways

- **Start Anywhere** from your plasmid sequence, existing process, or partial workflow
- **Fast, Seamless Onboarding** of client-developed methods
- **Tailored Process Development** for feasibility, optimization, and scale-up
- **Deep Microbial Expertise** guiding efficient upstream and downstream refinement

Key Technical Capabilities

Strain Selection & Optimization to identify high-yield, high quality plasmid producers

cGMP-Aligned Cell Banking including master and working cell bank generation

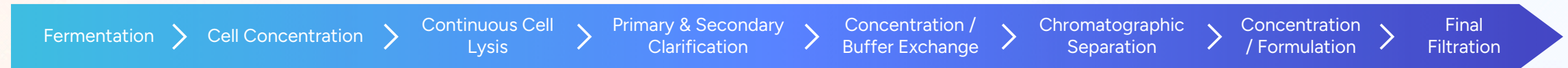
Dedicated Process Development Labs for fermentation, lysis/clarification, and purification workflow design

Scalable Purification Platforms supporting high supercoiled content and tight impurity control

Process Characterization & Comparability aligned with global regulatory expectations

Summary of Plasmid DNA Capabilities

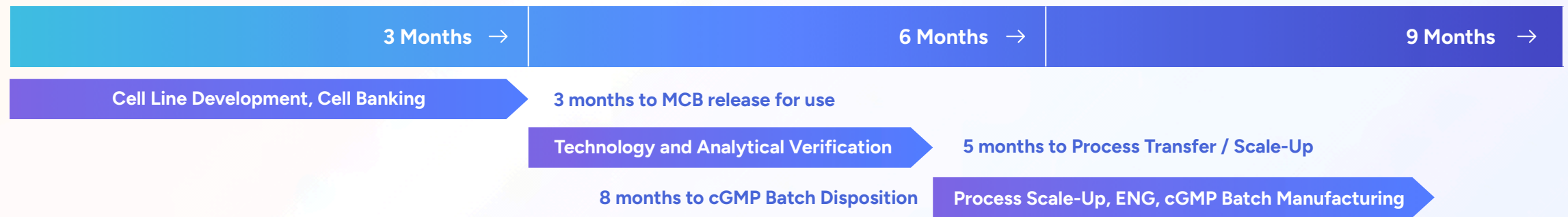
Large-Scale Plasmid DNA Manufacturing Process



Development and Manufacturing Scales

Stage	Equipment	Working Volume	Yield
Process Development	2 L Fermenter	Up to 1 L	50 - 200 mg
cGMP Manufacturing	435 L SUB Fermenter 750 L SS Fermenter	65 - 500 L	5+ g

Typical Plasmid DNA Development and Manufacturing Timelines



mRNA

Diverse RNA Modalities We Support

- **Non-replicating mRNA** for vaccines, protein expression, and therapeutic applications
- **Self-amplifying (saRNA) and trans-amplifying RNA (taRNA)** for enhanced expression at lower doses
- **Circular RNA (circRNA)** for stability-enhanced, long-duration expression
- **Antisense oligonucleotides (ASO) and RNA aptamers**
 - Sequence-based support depending on project design
- **tRNA and other RNA formats** for emerging therapeutic platforms

Phase-Appropriate Options

Process Development & Scale-Up

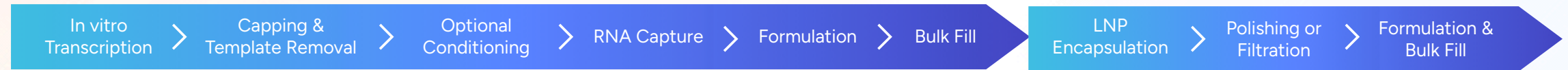
- **Up to 2 g** Formulated mRNA (per batch) at PD scale
- Sequence-to-material development for early research and feasibility studies

Full cGMP Manufacturing

- **Up to 10 g** Formulated mRNA (per batch) depending on construct complexity and process requirements
- End-to-end readiness for future LNP, fill-finish, and release testing integration

Summary of mRNA Capabilities

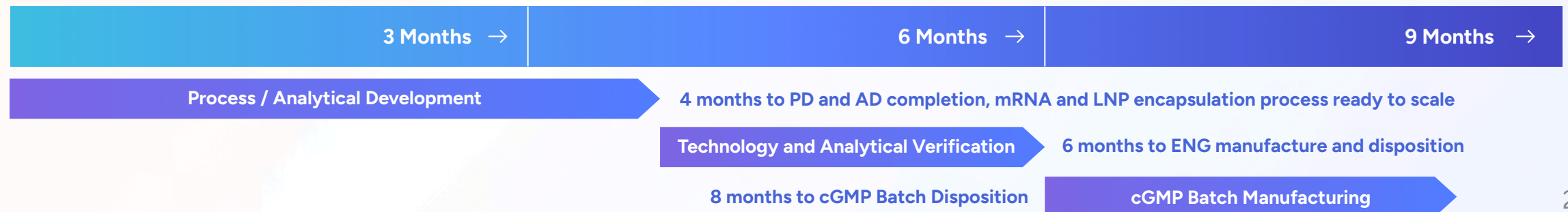
mRNA Manufacturing



mRNA Development and Manufacturing Scales

Stage	Equipment	Working Volume	Yield
Process Development	WAVE 25 Reactor NanoAssemblr (Spark/Ignite/Blaze)	Up to 25 L 20 µL - 1 L (Pre-Dilution)	Up to 2g Formulated mRNA Per Batch Up to 20+ L Formulated mRNA
cGMP Manufacturing	WAVE 25 Reactor	Up to 25 L	Up to 10g Formulated mRNA Per Sub-Batch; Up to 100g Per Full Batch
	NanoAssemblr (NCFS)	Up to 600 L (Pre-Dilution)	Up to 1000+ L Formulated mRNA

Typical mRNA / LNP Development and Manufacturing Timelines



Encapsulation

Modality-Agnostic Encapsulation

- Encapsulation for **mRNA, saRNA, circRNA, pDNA**, recombinant proteins, small molecules and **peptides**
- Fully flexible with **client-supplied lipids, proprietary systems, or open-platform formulations**
- Flexible approach enabling **multi-modality therapeutic and vaccine programs**

Key Technical Capabilities

Production Capacity

- Process Development (up to 4L)
- cGMP manufacturing (up to 40L)

Microfluidic Mixing Using Precision Nanosystems (PNI) Technology

- **Advanced, non-turbulent microfluidic technology** for precise particle size control and high encapsulation efficiency
- Scalable system configurations suitable for PD and cGMP batches

Integrated Purification & Formulation

- TFF-based concentration, buffer exchange, and polishing
- Formulation refinement guided by stability and product-quality requirements
- Ready for seamless progression into sterile filtration and fill-finish

Flexible Development Pathways

- Feasibility and optimization tailored to client payloads and lipid systems
- Efficient transfer of existing processes into BioCina platforms

Summary of LNP Capabilities

Drug Substance Source

Recombinant Proteins / Peptides, pDNA, mRNA

LNP Encapsulation

LNP Encapsulation



Polishing or Filtration



Formulation & Bulk Fill

LNP Development and Manufacturing Scales

Stage	Equipment	Working Volume	Yield
Process Development	NanoAssemblr (Spark/Ignite/Blaze)	20 µL - 1 L (Pre-Dilution)	Up to 4 L
cGMP Manufacturing	NanoAssemblr (NCFS)	Up to 600 L (Pre-Dilution)	Up to 40+ L

Typical mRNA / LNP Development and Manufacturing Timelines



Project Management



At BioCina, we **simplify complexity** so you can focus on science while we **deliver on-time and in-full**.

Expanding Capacity. Advancing Innovation.



Commercial-Scale RNA Manufacturing

Large-scale commercial RNA manufacturing train in our Adelaide facility footprint (currently we offer Process Development and small-scale manufacturing capabilities for RNA)

Timing: Ready for client service by Q4 2026



Blow-Fill-Seal Manufacturing Line

Higher capacity (3x) Blow-Fill-Seal (BFS) manufacturing line in our Perth facility to significantly increase throughput for an aseptic liquid filling line

Timing: Ready for client service by Q4 2026

Regulatory Excellence Trusted Worldwide History



- Facilities are licensed by the TGA for **cGMP Clinical and Commercial** manufacture
- Product approvals from the **US FDA, EMA, Health Canada, Japan, China, Latin America, Africa, Middle East, Asia Pacific, Australia, and Brazil**
- **600+ approved products in 100+ countries**
- Comprehensive licenses including **US / UK Schedule I-V** and **Australia Schedule 8**
- Always compliant and inspection-ready, meeting the highest global regulatory standards
- Uncompromised quality assurance throughout the entire manufacturing process



● BioCina Global Product Reach

Why BioCina?

Built Around Your Program



Partnership

- **Seamless collaboration** across time zones
- **Flexible solutions** tailored to your program needs
- **Dedicated teams** driving success at every stage



Reliability

- **Globally trusted:** FDA, EMA, TGA, and many others
- **Consistent on-time, in-full** delivery (>95% OTIF)
- **Stable, long-term** partner for continuity



Expertise

- **End-to-end CDMO services** from development to commercial supply
- **Proven commercial success** with small molecules and biologics

Why Australia?

A stable, compliant, and globally connected partner location.

Global Gateway

Strategic bridge between Asia-Pacific and Western markets for **global program scalability**.

Stable & Secure

Western democracy with political stability, **robust IP protection**, and trusted legal frameworks.

Globally Aligned

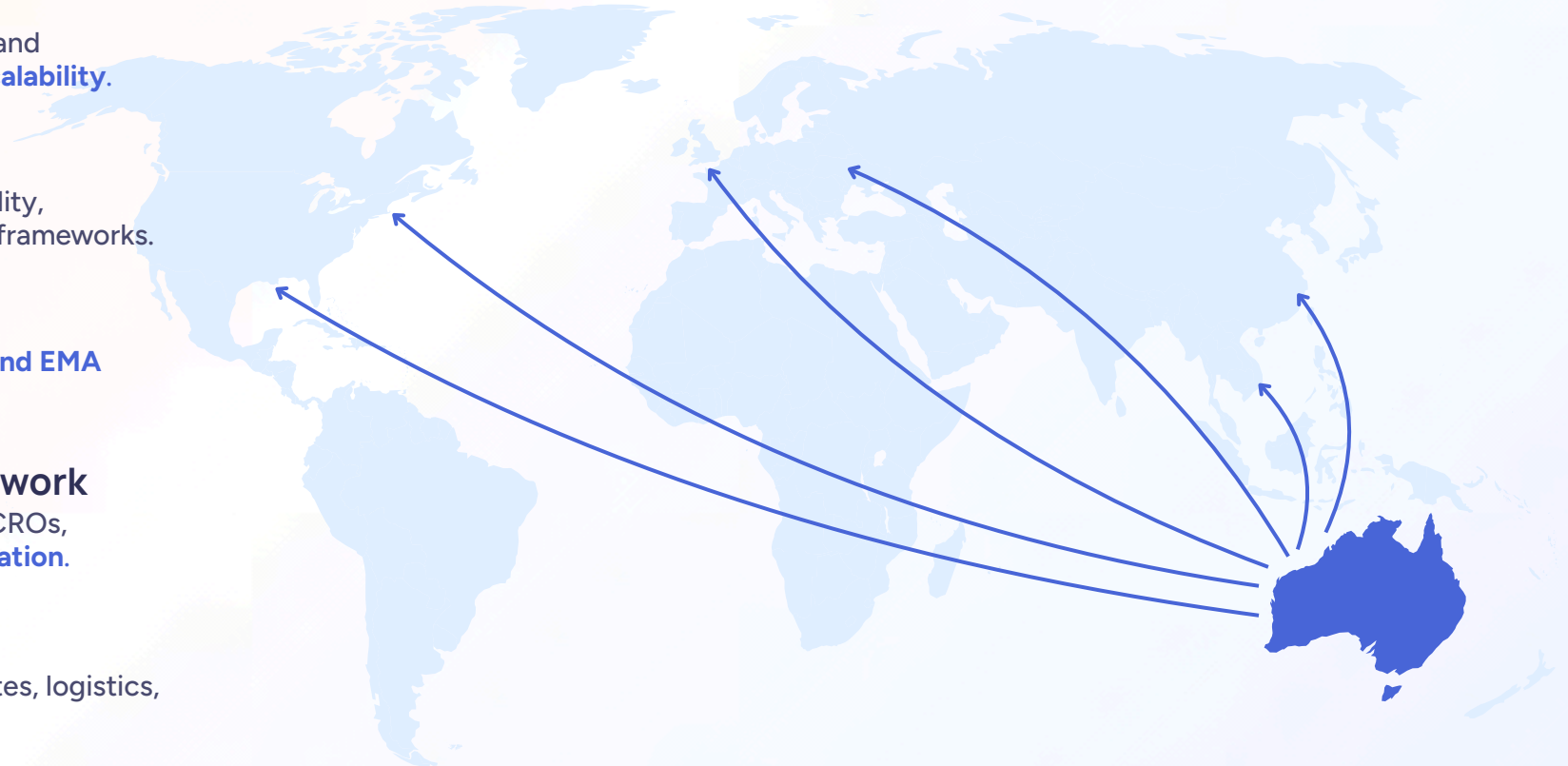
TGA standards **harmonized with FDA and EMA** for seamless global compliance.

Connected Clinical Trial Network

Fast-growing ecosystem of hospitals, CROs, and trial sites enabling **rapid study initiation**.

Thriving Biotech Ecosystem

Integrated network of research institutes, logistics, and skilled scientific talent.



Rapid cGMP-to-Clinic Pathway with No IND Requirement

Why no IND?

Australia's Therapeutic Goods Administration (TGA) allows early-phase trials to begin without a full IND through its streamlined Clinical Trial Notification (CTN) pathway.

What is CTN?

- Ethics approval is obtained through a Human Research Ethics Committee (HREC).
- A simple online CTN notification is submitted to the TGA with no full regulatory review required for most investigational products.
- Trial initiation often possible within 6-8 weeks of submission*

*Source: Australian Clinical Trial Handbook, TGA, updated 3 October 2024

What it Means for Your Programs

- ✓ cGMP Drug Substance and Drug Product manufactured at BioCina can move into clinic as soon as they are released.
- ✓ Earlier human data **de-risks development**, **sharpens clinical strategy**, and **strengthens your position for licensing, fundraising, and portfolio prioritization**.
- ✓ CTN clinical data are fully acceptable to FDA and EMA for later submissions.



Start human dosing faster. De-risk your development program. Scale globally with confidence.

Cost-Effective End-to-End DS & DP Development, Leveraging Australia's Tax Incentive

Up to 43.5% Cash Back Through a Refundable Tax Incentive

Eligible R&D spend can return almost half your investment, offering a globally leading innovation incentive.



Do More With the Same Budget

Redirect refunded capital into extra batches, added studies, or expanded scope without seeking new investment.



Strengthen Your Balance Sheet

Annual refunds boost cash flow, reinforce financial stability, and support long-term planning.



Advance More of Your Pipeline

Greater liquidity helps you progress more candidates, reach milestones sooner, and lower development risk.

Eligibility

Australian Entity Required

Set up an Australian entity with ease to access the R&D incentive.

R&D Conducted in Australia

Work conducted in Australia from pre-clinical through Phase 3 can be eligible.

Comprehensive Technical Records for Your Projects

BioCina provides robust documentation to support your R&D claims.

BioCina Helps You Navigate Eligibility

We connect you with trusted experts to support discussions around eligibility.

LumaCina™, A BridgeWest Portfolio Company



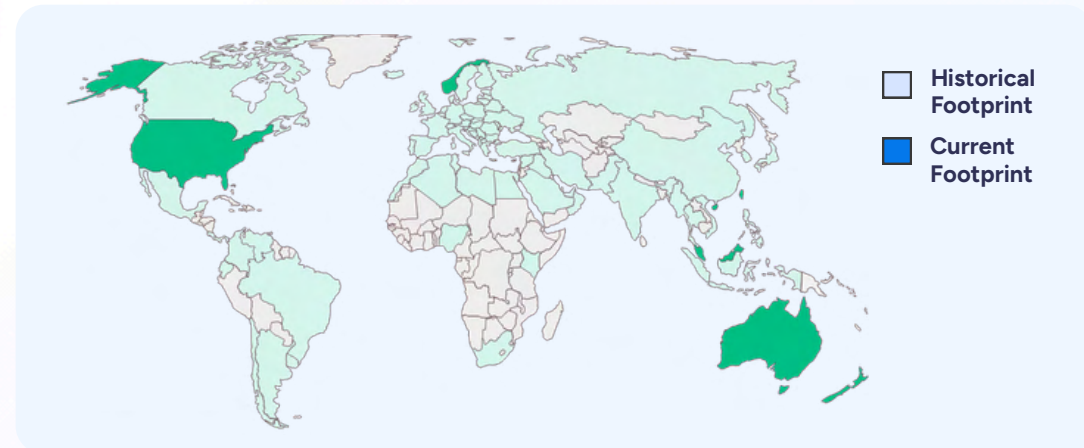
Established Product Portfolio

Export-ready medicines supplying hospitals and healthcare systems globally:

Portfolio Segment	Products in Segment
 Controlled Oral Liquids	Morphine Oral Solution in 200 mL
 Irrigation and Topical Solutions	Chlorhexidine in 30 mL Chlorhexidine + Cetrimide in 30 mL Saline Irrigation in 30 mL Povidone Iodine in 30 mL
 Sterile Injectable	Lidocaine 5 mL and 20 mL Sodium Chloride 0.9% 5, 10, 20 mL Water for Injection 5, 10, 20 mL

Worldwide Distribution Footprint

- Supplied to **98+ countries** across APAC, Europe, Americas & emerging markets
- Supported by **FDA, EMA, PMDA** and other major regulatory approvals
- Long-standing hospital and government supply relationships



- Scalable manufacturing and distribution of hospital and specialty medicines
- Ready-to-ship portfolio enabling faster market access and revenue growth

Proven Hospital Medicines. Manufactured by BioCina. Distributed Worldwide by LumaCina.

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