Stelis Biopharma

Collaborative, Agile, Compliant

Welcome to the world of Stelis, your trusted CDMO partner

Global Biopharmaceutical CDMO

Stelis Biopharma

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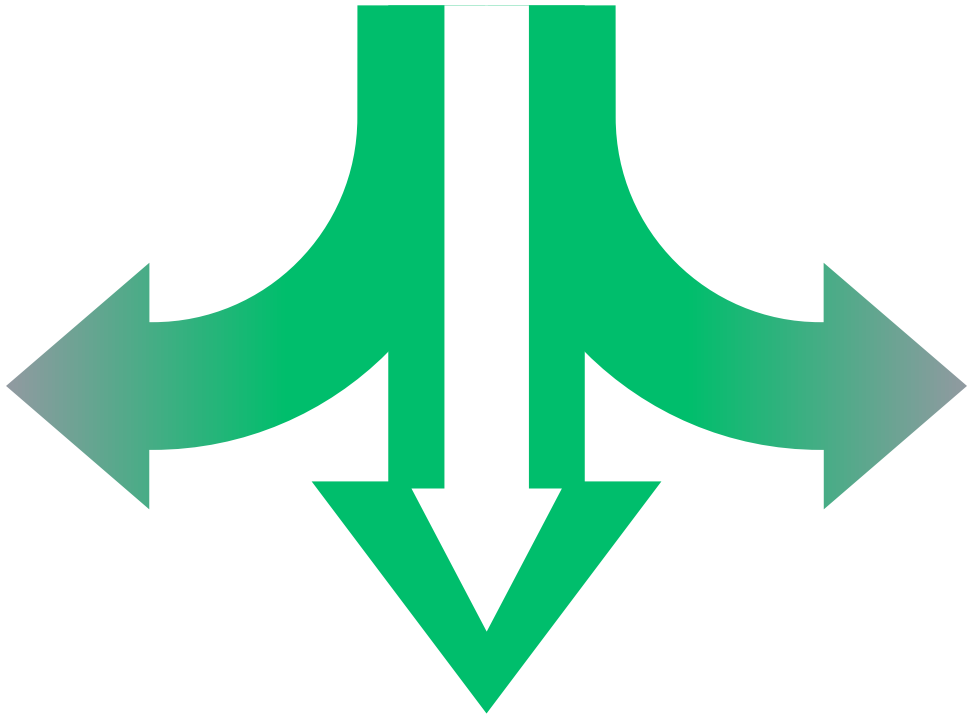
Our Mission

Reliably deliver our clients' biopharmaceutical programs on-time and in-full



Our Vision

Be globally recognized as the most trusted and reliable biopharmaceutical CDMO

Client Focused

Global Biopharmaceutical CDMO

Stelis Biopharma

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Our Difference,
Our Commitment

Collaborative

Working side-by-side with our clients as true partners, collaborating and closely communicating every step of the way

Agile

Proven ability to rapidly adjust or expand to meet the evolving needs and demands of our clients

Compliant

Established Stelis Quality Culture that enables us to always meet global quality and regulatory standards

Client Focused Global Biopharmaceutical CDMO

Stelis Biopharma

Collaborative | **Compliant** | **Agile**

Client's Expectations & Goals

Operational Execution & Excellence

Program Management

Recognized as Key Element to Client Satisfaction, Trust, & Success

Program Focused: Program Delivery On-Time & In-Full

Flexible Approach & Real Time Communication

Engagement, Planning & Mitigation

Client Focused Global Biopharmaceutical CDMO

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Our Experience, Your Solutions

- Talented Scientific Staff
- Cross-Functional Teams
- Diverse Experience
- Client Driven Protocol Design
- Proactive Troubleshooting
- Innovative Solutions

- ***Developed purification process*** for ***World's 1st*** plasmid DNA vaccine for covid-19
- ***Successful tech transfer and scale-up*** of an adenoviral vector process at 2000L scale
- ***Developed and established analytical methods*** (in-process, release and characterization) for ***mAbs and recombinant proteins***
- ***Authored and reviewed*** CMC module-3 sections of BLA and MAA dossiers for numerous submissions

Client Focused Global Biopharmaceutical CDMO

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- ***Knowledge & Experience***: across Multi-Modalities; Clinical to Commercial

Strong Technical Acumen

- ***Strategic Planning***: Growth & Investment

- ***Idea to Implementation:*** New, Validated facility in under 12 months

Experienced Leaders with Strong Biopharmaceutical Backgrounds

AGC Biologics | Apobiologix | aragen | Bayer | Biocon | Boehringer Ingelheim | Catalent

Dr.Reddy's | Enzene Biosciences Ltd. | eurofins | Genentech A Member of the Roche Group | INTAS | ipca A dose of life | Kinexum

Lonza | mAbxience From lab to life | Pfizer | Rentschler Biopharma | Syngene | Zydus dedicated to life

Selected companies where our leaders and technical experts have served

Successful Track Record

30+ Projects

across 14 global customers

20+ Projects

Under execution

15+ Projects

Filed for 5 customers | 3 approved in international market

15+ PFS **10+ Vials** **5+ DDCP**

Successful Track Record

22 Commercialization

13 in progress | 7 filed (US) | 2 approved

Ozempic
Wegovy
Abaloparatide
Teriparatide
Semaglutide
Acetylcysteine
Calcitonin
Methohexital
Sumatriptan
Mycophenolate
Levothyroxine
Methylene Blue
Lira- Saxenda
Remimazolam
Liraglutide
Octreotide
Leuprolide
Sincalide

4 Co-developed

DP, Tech transfer, manufacturing, submission and commercialization

Ozempic
Wegovy

1 NCE -1

DP, Tech transfer, manufacturing, submission

Semaglutide

Global Biopharmaceutical CDMO

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Worldwide Quality and Regulatory Focus

Q4 CY21

Licensed by Indian regulatory authorities to manufacture various products

Q1 CY22

EU certification received for DS (unit-1 Microbial) and DP unit-2 (all formats)

Q2 CY22

2 successful audits:

- EIR received in Sept'22 for small volume fill across all DP formats
- EIR received in Jan'23 for Drug Device Combination products (DDC)

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Quality Framework

ENABLERS

People
Process
Product
Facility

ARCHITECURE

Systems
Deployment
Improvements
Governance
Risk Mitigation
Metrics

QUALITY CULTURE

Proactive
Responsive
All Time Compliance

Our highly experienced quality and regulatory personnel help us meet the highest global quality standards, ensure compliance and guide our clients through the regulatory approval process

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State-of-the-Art Facilities

Mammalian & Microbial Process Development & Microbial Manufacturing

Mammalian & Microbial Manufacturing

Over ~550,000 square feet of development & manufacturing space for DS & DP

Our high-volume commercial use facilities were designed with USFDA consultation

Automated to increase accuracy, efficiency & Speed at every stage

Clinical & Commercial Capacity

Process Validation, Formulation, Analytics

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Best-in-class, highest among Indian CDMOs

Mammalian

- 4 X 2000L single-use trains
- Upstream Train: 50L→200L/500L→2000.

Microbial

- 1 X 1000L stainless steel fermenter train
- Upstream Train: 50L→300L→1000L

Amongst the highest CDMO capacity in APAC, including mammalian bioreactor suites to handle almost any level of client demand

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End-to-End Offering

Pre-Clinical → Phase 1 → Phase 2 → Phase 3 → Commercial

Drug Substance

Mammalian | **Viral Vector** | **Microbial** | **Regulatory Support**

Drug Product

Large & Small Molecules

Multi Format *(Liq & Lyo), PFS, Cartridge*

Drug Devices

Regulatory Support

Fully integrated CDMO, offering the complete spectrum of services, from cell line tech transfer to clinical and commercial manufacturing

Global Biopharmaceutical CDMO

End-to-End, Fully Integrated Offering

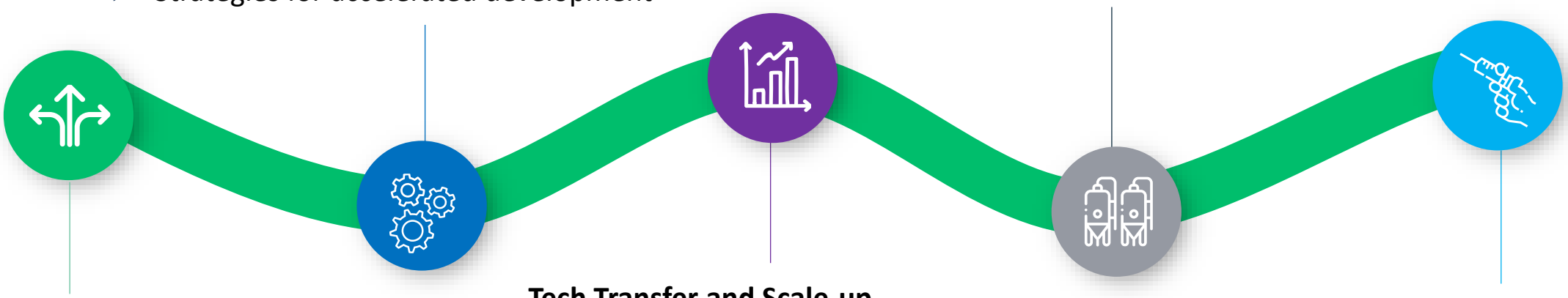
Drug Substance to Drug Product

Process Development & Analytics

- Industry-Leading Expertise
- High-throughput analytical automation
- Strategies for accelerated development

High Capacity

- Mammalian & Viral Vector: Single Use Bioreactor (SUB)'s
- Microbial: Hybrid Model; Stainless steel fermenter for upstream and single-use or stainless-steel systems for downstream
- Cost-effectiveness for any volume demand



Flexible infrastructure

- Multi-modalities
- Versatile Starting Points: Upstream/Downstream

Tech Transfer and Scale-up

- Robust approach for scale-ups and scale-down models
- Process characterization
- Control strategies for successful PPQ campaigns and commercial Mfg.

Integrated Fill/Finish

- Multiple fill/finish formats
- Extensive experience delivering a diverse range of client programs

Flexible Infrastructure

Mammalian

- Monoclonal antibodies
- Fusion proteins
- Vaccines

Viral Vector

- Adenovirus, Adeno-associated virus and Lentivirus Mfg.
- Suspension cell culture processes

Microbial

- Recombinant proteins – including Fabs, Insulin analogues and peptides
- Plasmid DNA
- Protein subunit vaccines

Experienced with:

Multiple cell lines; CHO DG44, CHOK1, HEK293, Sp2/0

Adeno virus (Serotype AD5 and AD26), Lentivirus and Baculovirus (Sf9 platform)

Multiple expressions systems such as *E. coli*, Pichia and Saccharomyces

We're Always Ready to Develop a New Process or Optimize or Adopt an Existing Process, at the Scale You Need

Rapid Single Cycle Development & Tech Transfers Enabling Successful Clinic & Commercial Outcomes (1/2)

Clone Selection & Characterization

- **High throughput screening** and characterization of top clones to finalize the lead and backup clone with **optimal yield and desirable product quality attributes**
- **Preparation of cell banks** (MCB and WCB) and **full-scale characterization** using qualified network of CROs

Drug Substance Development

- Expertise in development of upstream processes **(mammalian and microbial)** to maximise productivity and optimize product quality
- Significant **experience in resin screening and developing efficient unit operations** with high recovery, increased resin utilization and optimal purity
- Reliable transfer and **optimization of client's drug substance processes** across different hardware platforms

Rapid Single Cycle Development & Tech Transfers Enabling Successful Clinic & Commercial Outcomes (2/2)

Drug Product Development

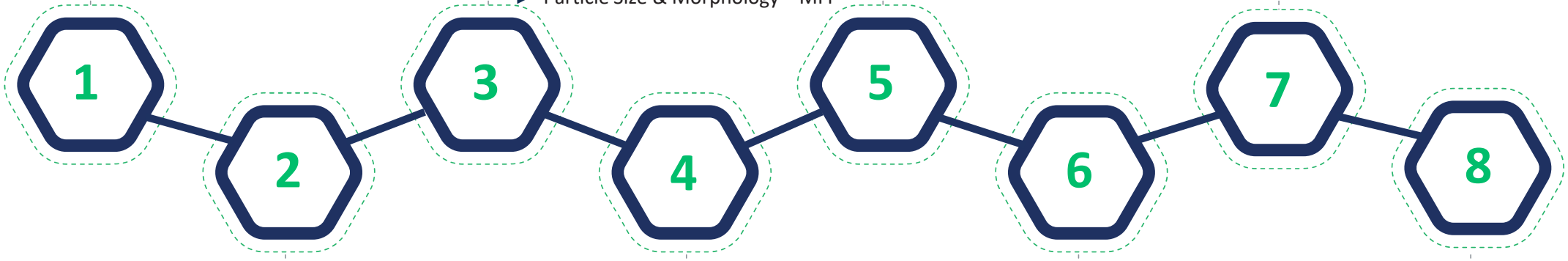
- **Rapid excipient screening studies** using Design of Experiment (DOE) principles and container closure system selection and stability studies to develop non-infringing formulations
- Fully integrated, **phase-appropriate solutions** to drug product formulation, process, and primary packaging
- Significant experience in development of **drug/device combination products** and support studies for regulatory submissions

Tech Transfer & Scale-up

- Experience in **tech transfers from the client sites** and **process scale-up** for both microbial (up to 1KL) and mammalian (up to 2KL) platforms
- Expertise in developing **scale down models** for process characterization and defining robust **control strategies** leading to successful PPQ campaigns and Mfg. troubleshooting
- Use of **data analytics and template approaches** for client communication to ensure streamlined technology absorption

High-throughput analytical infrastructure allows us to cover **over 95%** of testing in-house across different modalities (mAbs, recombinant proteins, viral vectors)

Standard analytical development offerings for different therapeutic modalities



1 Primary Structure
- Intact Mass
- Peptide Map LC/MS/MS
- NR Peptide Disulfide Map
- Free Sulfhydryl

2 Secondary & Tertiary Structure
- Far UV CD
- FT-IR
- Near UV CD
- Fluorescence
- DSC

3 Size
- SEC-MALLS
- DLS
- NR CE-SDS
- R CE-SDS
- SV-AUC
- Particle Count Light Obscuration
- Particle Size & Morphology – MFI

4 Charge
- CEX-HPLC
- cIEF
- Peptide Map LC-MS

5 Glycosylation
- HILIC-HPLC Glycan map Gal, Man, Aruco
- Peptide Map LC/MS/MS Aglyco
- HILIC-HPLC Glycan Map siallc ACld
- Intact Mass

6 Accelerated Stability & Forced Degradation
- 37C
- 55C stressed
- Forced oxidation
- pH shift
- Photostability

7 Biological Characterization
- Competitive Binding ELISA
- Cell based Potency
- Biacore Kinetics & Affinity
- FcRn, FcGR
- ADCC/CDC

8 Impurity Clearance
- HCP (by ELISA) HCONA (by qPCR)
- Protein-A leachate (kit based)
- Other process related Impurities

High Capacity

Modality	Process Development	Process-Scale UP	Process Validation & Commercialization
Mammalian	2L & 10L USP & DSP	200L USP & DSP	4 x 2000L Single Use Trains USP Train: 50L > 200L/500L > 2000L
Microbial	5L & 10L USP & DSP	50L USP & DSP	1 x 1000L SS Fermenter Train USP Train: 50L > 300L > 1000L

Integrated Drug Product Fill/Finish

High speed aseptic liquid filling lines for all formats: Vials (Liquid and Lyo), PFS, Cartridge and Device

Fully automatic packaging line

High-capacity warehouse:
1526 m. sq. and 392 pallets

100% visual inspection

Cold rooms for storage of product

Track and trace systems

Tertiary packaging area
(Shippers, Cold Packs etc.)

Pen device and Auto Injectors assembly capabilities

Integrated Drug Product Fill/Finish

Formats & Capacities

Format	Site	Equipment	Fill Volume	Annual Capacity
Vials, Liquid & Lyo	Unit 2	Tofflon filling line integrated with isolator and Lyophilizer	1 – 100 mL	12M Vials
Pre-filled Syringes & Auto Injector assemblies	Unit 2	Bausch Strobel filling line integrated with isolator. Mikron assembly line	0.5 – 10 mL	28M
Cartridges and Pen Device assemblies	Unit 2	Bausch Strobel filling line integrated with isolator. Mikron assembly l	1.5 – 3 mL	40M
Isolater Based Filling: Multi-Format (Vials, Cartriges, PFS)	Unit 1	Filling Machine: Colanar (Germany) Isolator: Bectochem (India)	V (5), C (3.5), PFS (1) mL	Clinical & Tox

Your Trusted CDMO Partner

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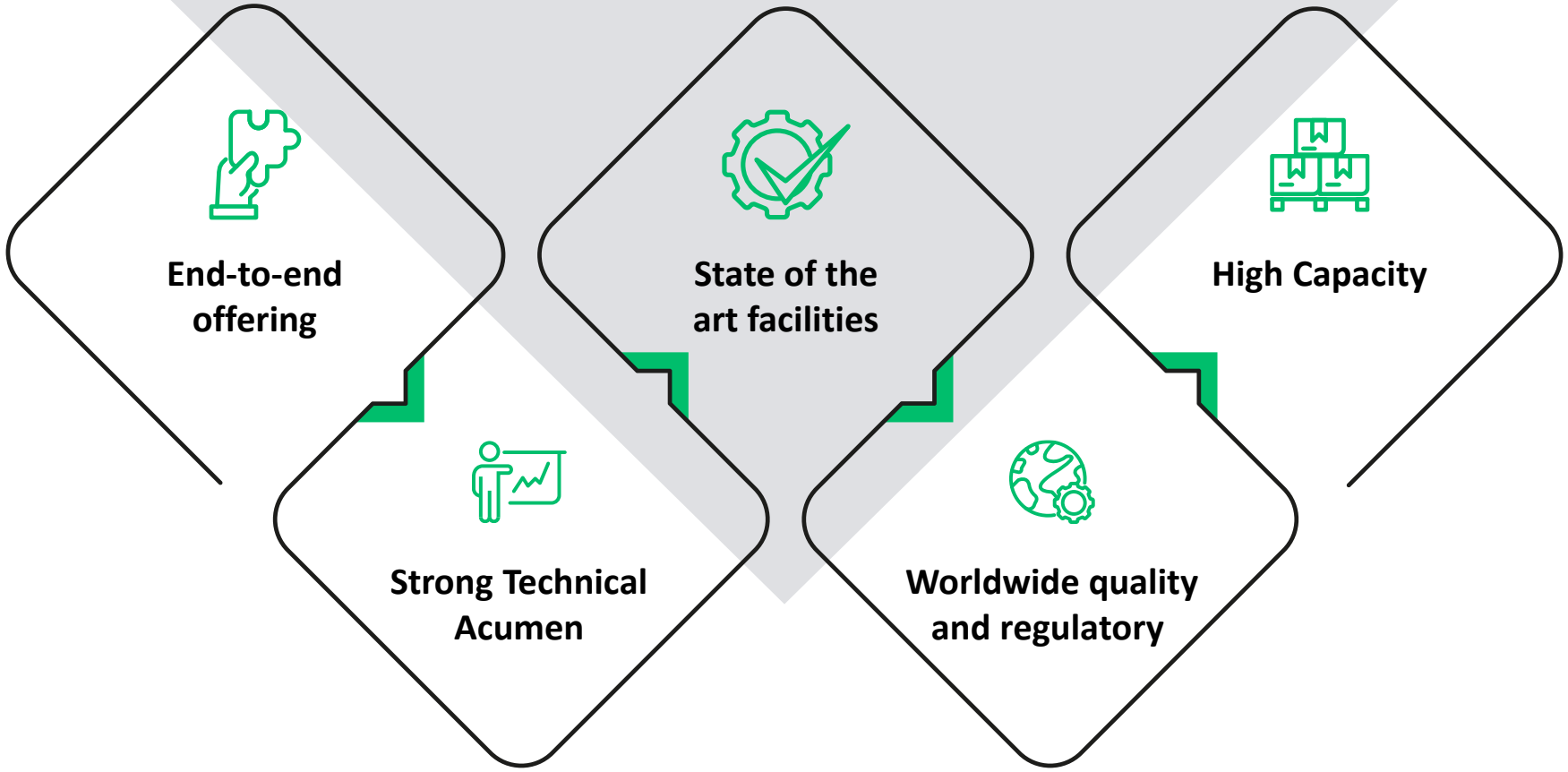

Our Key Differentiators

Collaborative

Compliant

Agile

Thank You !

Contact:
Sarat Patanaik
Sarat.Patanaik@stelis.com

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