

Welcome

- to -



R & D Day

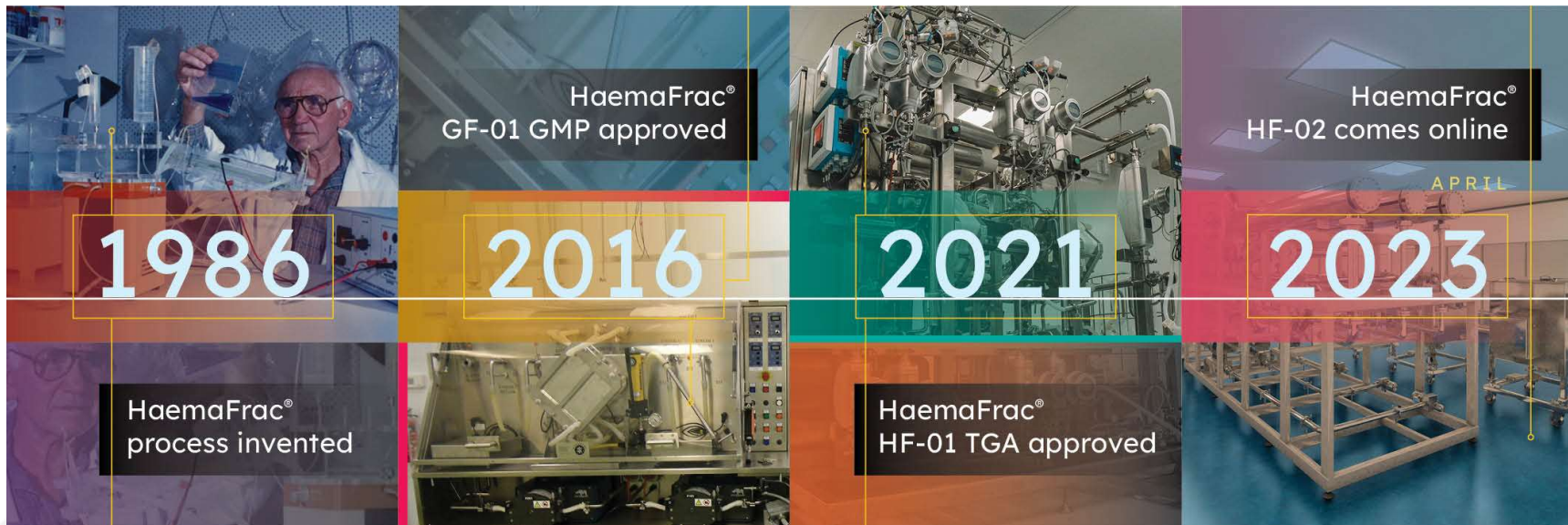
14th March 2023

Aegros – R&D Open Day Agenda

- ✚ Founders' Welcome – Profess Nair & John Manusu
- ✚ Ribbon Cutting – Mr Jerome Laxale MP (Bennelong)
- ✚ R&D Presentation – Emeritus Professor Stephen Mahler
- ✚ Medical Presentation - Dr Leon Rozen
- ✚ Engineering Presentation – Mr Damian Thornton
- ✚ Tour of 5 Eden Park Drive

Aegros – Australia's Leading Edge Fractionator

March 2023 Presentation Founders' Welcome



Aegros Solves IVIG Shortage in \$20B Therapeutic Plasma Market

✚ US\$20B Therapeutic Plasma market is limited by supply of raw material - Plasma.

Only two solutions:

1. Increase the collection of plasma;
Not viable as plasma comes from humans

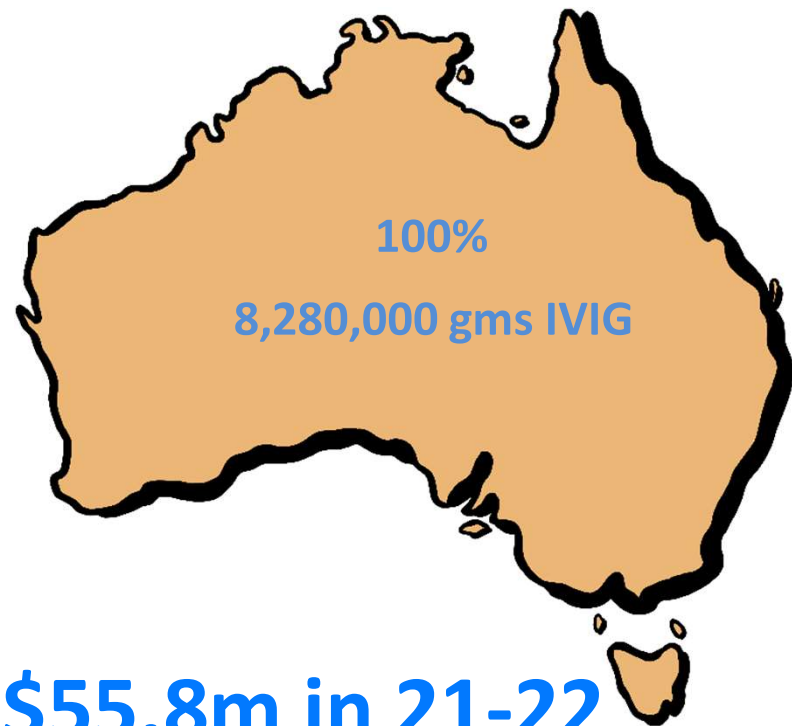
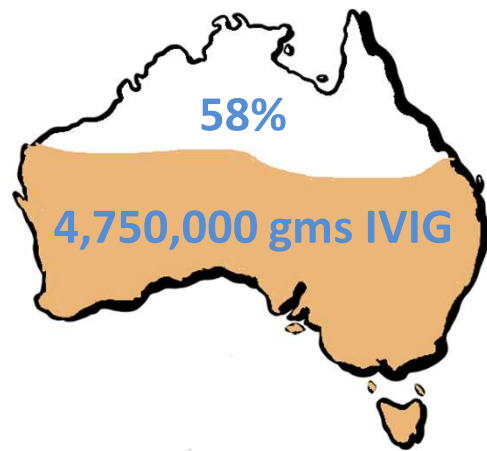
OR

2. Increase process yield.

Only solution - HaemaFrac[®] doubles yield

Australian Market - IVIG

- Monopoly Fractionator of Australian collected plasma provides 58% of Australian usage¹;



Saving the NBA over \$55.8m in 21-22

1. Based on data from the NBA 21-22 Annual Report

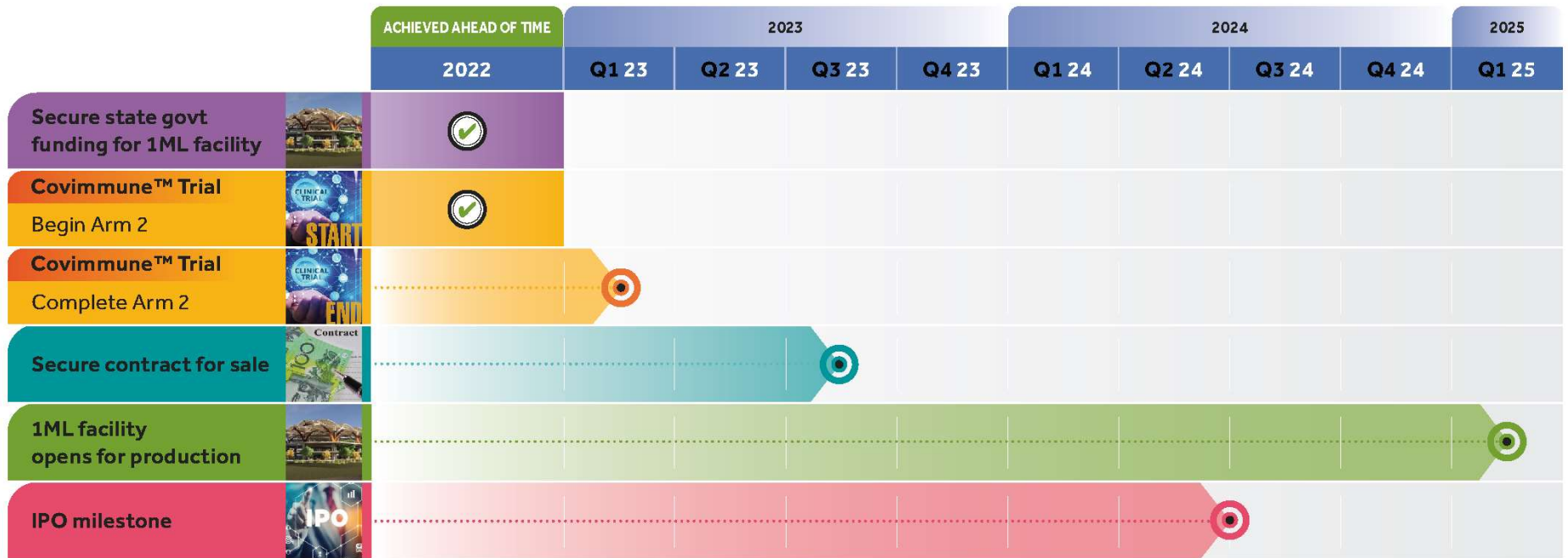
Aegros Copyright 2023



Achievements 2022 – Promised and Delivered

- ✚ TGA GMP approval of HaemaFrac[®] process;
- ✚ Successfully completed 1st arm of CHAT study;
- ✚ Qld Grant for 1M L HaemaFrac[®] Facility; and
- ✚ 1st Dosing of Covid-19 Hyperimmune.

Milestones for 2023/24



Covid-19 Hyperimmune – A product that won't Die

- ✚ Demand for Covid-19 Treatment is Accelerating;
- ✚ No viable solution for Immune Compromised Individuals;
- ✚ Outbreaks & Mutations continue;
- ✚ US Clinicians reaching out to Aegros;

Aegros Covid-19 Hyperimmune is the Answer



Upgrade 5 Eden Park to Process 100,000L pa

- ✚ Delivery of 100,000L HaemaFrac® in June
- ✚ Renovations of the Facility Layout to be completed in July;
- ✚ TGA Licensure Post an Audit by October;

1M L HaemaFrac[®] Qld Facility

- ✚ Selected a Site in the Springfield BioPark;
- ✚ Agreed a price for the 4.1Ha HaemaFrac[®] Site;
- ✚ Expect DA approval by June;
- ✚ Break ground in Q4 2023.

Update on Strategic Investor Process

- ✚ MacBank Managing this process;
- ✚ Engagement with a number of industry parties;
- ✚ Interest driven by:
 - ✚ Increase in yield by current market leader;
 - ✚ Difficulty in plasma supply;
 - ✚ Ability to become market leader.
- ✚ Expect this process to conclude in Q3 23.

GLOBAL MANAGEMENT TEAM



Professor Hari Nair,
Founding Executive Chair.



Mr John Manusu,
Founding Managing Director.



Ms Janet Bowen,
Executive Board Director
& Chief Regulatory and Quality Officer.



Mr Damian Thornton,
CEO Aegros Engineering &
Interim CEO Aegros Therapeutics



Mr Leighton Hopper,
CEO Aegros Consumables



Mr Alexander Stuke,
Chief Strategy Officer.



Emeritus Professor Stephen Mahler,
Global Chief Science & Technology.





Welcome
- to -

 **Aegros**

R&D Day
14th March 2023

 Aegros Copyright 2023

 **Aegros**



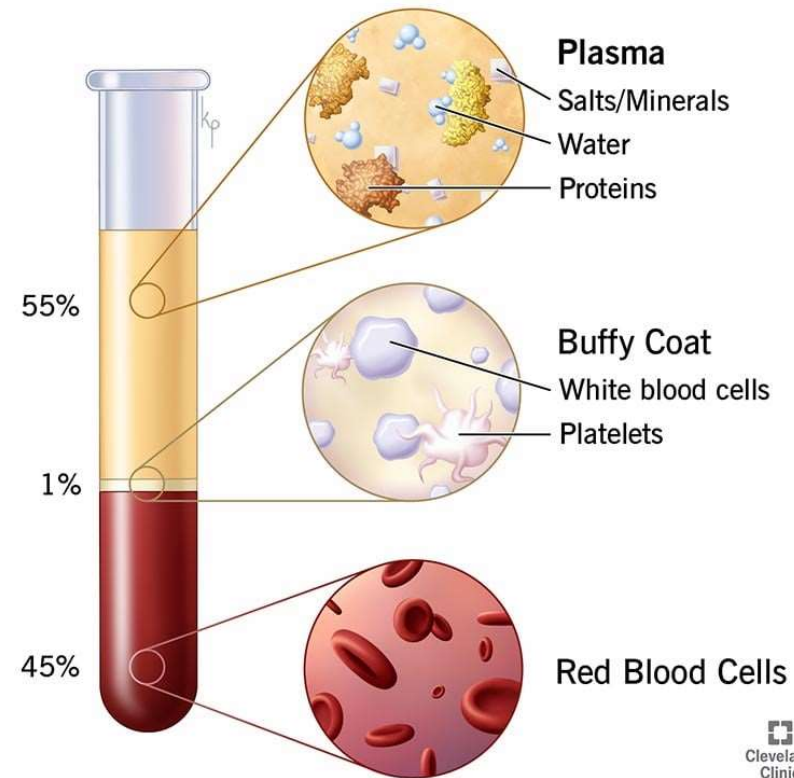
*Make therapeutic plasma products available and
affordable to the world*

R&D Presentation – Emeritus Professor Stephen
Mahler

 Aegros Copyright 2023

 **Aegros**

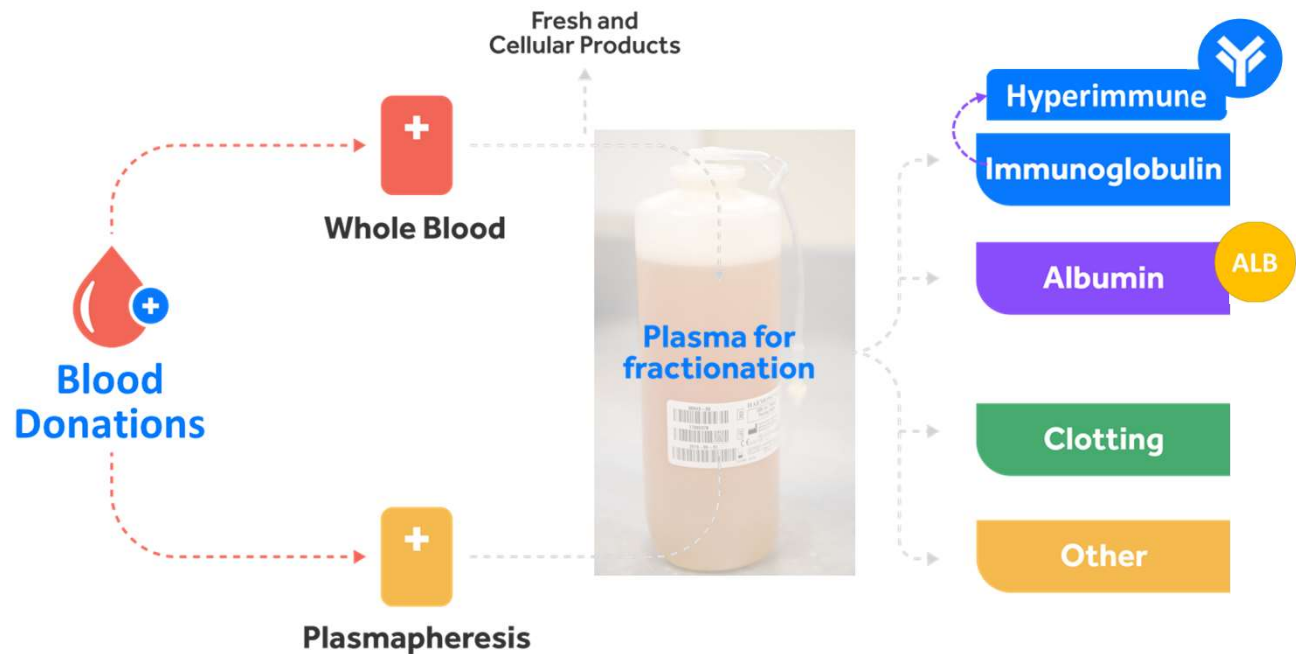
- Plasma is a straw-coloured liquid that makes up over 50% of whole blood volume.
- It is liquid medium by which nutrients are transported to cells and organs, and waste products removed around the body.
- It contains over 3,000 proteins, many of which in their purified form, provide life-saving medicines for a wide variety of medical conditions and disease indications.



Cleveland
Clinic
©2021

Aegros Copyright 2023 – Confidential

Therapeutic proteins found in plasma are separated, purified and concentrated into therapeutic doses which can be administered for various disease and medical indications





Aegros' groundbreaking HaemaFrac® plasma fractionation technology will revolutionise the industry.

HaemaFrac® technology is superior to the widely used Cohn fractionation process, with increased yields and an overall environmentally-friendly, more efficient process.

The main products derived from plasma fractionation are:

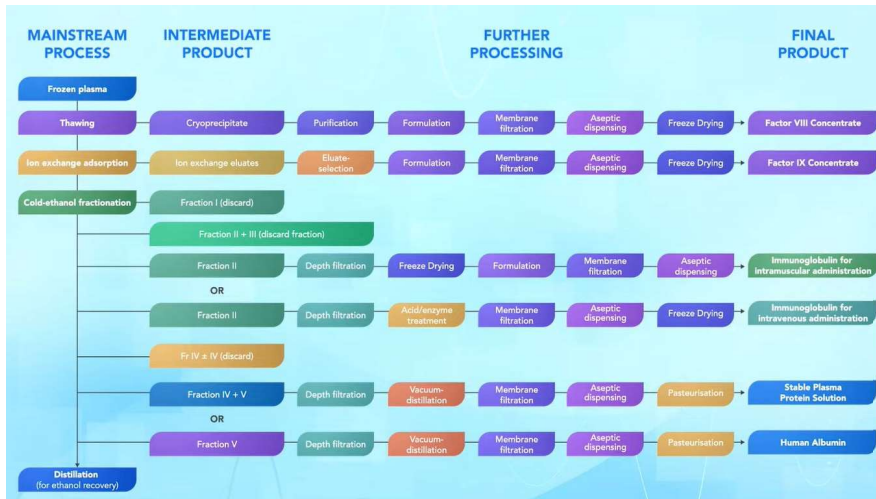
- ✚ IVIG (intravenous immunoglobulin)
- ✚ Albumin
- ✚ Fibrinogen

Centre of Excellence in Advanced Biomanufacturing

- ✧ In conjunction with major universities in Australia and internationally, Aegros is on the pathway to progressively build a Global Centre of Excellence in Advanced Biomanufacturing, focusing on bioseparations, driving innovation and leading to next-gen technology.

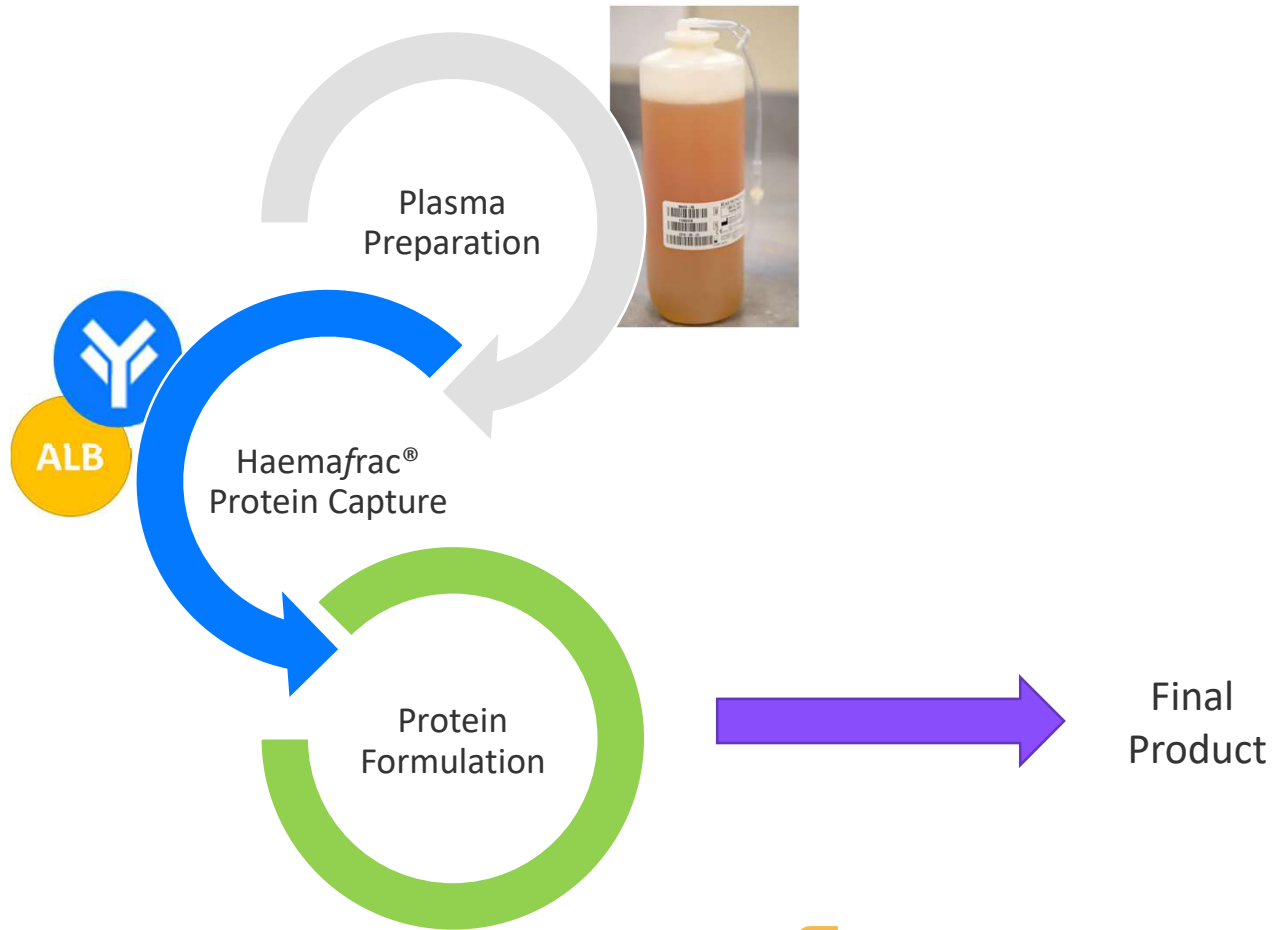
- 
- 
- ✧ Aegros operates out of its TGA-approved facility in Macquarie Park, Sydney.
 - ✧ Aegros is now in an expansion phase and will construct a 1-million-liter plasma fractionation facility in Southeast Queensland, to provide plasma products for both Australian and global export markets.
 - ✧ The facility will house state-of-the-art R&D laboratories and pilot-scale R&D biomanufacturing infrastructure

VS

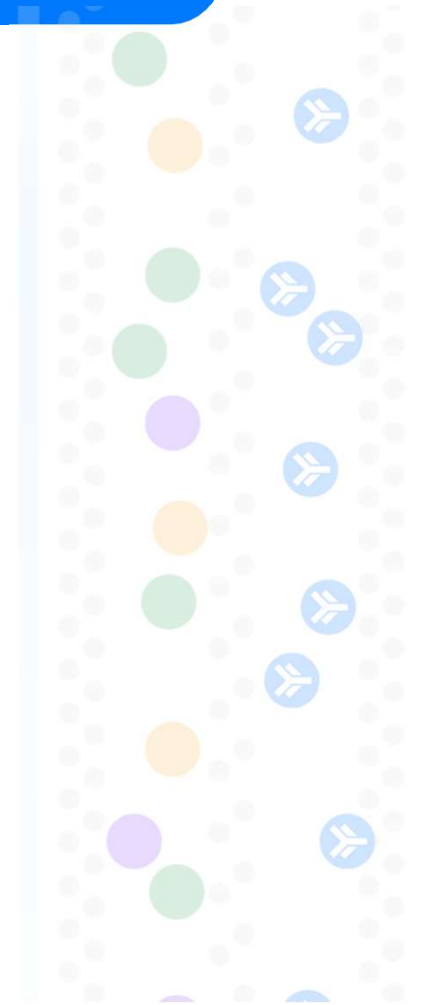


Aegros Copyright 2023

Haemafrac® Plasma Fractionation Bioprocess



 Aegros Copyright 2023



Research and Development



Blood protein purification and simultaneous removal of nonenveloped viruses using tangential-flow preparative electrophoresis

Richard E. Munnings^{1,2}, Nathan Munnings^{1,2}, Mark W. Horne^{1,2}
¹Department of Biological Sciences, Monash University, Clayton, Victoria, Australia; ²Centre for Blood Research, Monash University, Clayton, Victoria, Australia

1 Introduction

Ensuring the safety of biological products is the most critical of manufacturers and regulatory authorities worldwide. The widespread use of monoclonal antibodies (mAbs) in biopharmaceuticals has increased the need for effective purification and virus removal technologies.

Gradient flow technology allows rapid and high-capacity purification of proteins from complex mixtures and has been successfully demonstrated as a tool to purify mAbs. This article describes the use of a novel 2D, individual antibody purification (IAP) and a 3D, flow-through purification (FT) system to purify mAbs. The IAP system uses a novel 2D, individual antibody purification (IAP) and a 3D, flow-through purification (FT) system to purify mAbs. The FT system uses a novel 2D, individual antibody purification (IAP) and a 3D, flow-through purification (FT) system to purify mAbs.

2 Materials and Methods

Monoclonal antibody (mAb) purification was performed using tangential-flow preparative electrophoresis (TFPE). The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

3 Results

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

4 Discussion

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

5 Conclusion

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

6 Acknowledgements

The authors thank the following for their assistance: Dr. [Name], Dr. [Name], and Dr. [Name].

7 References

1. [Citation] 2. [Citation] 3. [Citation] 4. [Citation] 5. [Citation]

Journal of Biotechnology
Volume 300, Issue 1, 2014

science @ Elsevier
Journal of Biotechnology 300 (2014) 1–6

Fractionation of follicle stimulating hormone charge isoforms in their native form by preparative electrophoresis technology

Dalia Catalá¹, David Y. Chia¹, Peter G. Stanton¹, Peter P. Gray¹, Stephen M. Malhotra^{1,2}
¹Biotechnology Centre, School of Biotechnology, University of New South Wales, Sydney, NSW, Australia; ²Monash University, Clayton, Victoria, Australia

Abstract

Complex glycoprotein hormones, such as follicle stimulating hormone (FSH), consist of a single glycoprotein subunit to which several non-covalently bound glycoproteins are attached. FSH is a heterodimeric glycoprotein consisting of two subunits, α and β , and a carbohydrate moiety. The α subunit is composed of two polypeptide chains, A and B, which are linked by a disulfide bond. The β subunit is composed of two polypeptide chains, C and D, which are linked by a disulfide bond. The carbohydrate moiety is attached to the α subunit.

1 Introduction

Follicle stimulating hormone (FSH) is a heterodimeric glycoprotein consisting of two subunits, α and β , and a carbohydrate moiety. The α subunit is composed of two polypeptide chains, A and B, which are linked by a disulfide bond. The β subunit is composed of two polypeptide chains, C and D, which are linked by a disulfide bond. The carbohydrate moiety is attached to the α subunit.

2 Materials and Methods

FSH was purified from a complex mixture using preparative electrophoresis technology. The mAb was purified from a complex mixture using TFPE.

3 Results

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

4 Discussion

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

5 Conclusion

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

6 Acknowledgements

The authors thank the following for their assistance: Dr. [Name], Dr. [Name], and Dr. [Name].

7 References

1. [Citation] 2. [Citation] 3. [Citation] 4. [Citation] 5. [Citation]

Journal of Biotechnology
Volume 300, Issue 1, 2014

science @ Elsevier
Journal of Biotechnology 300 (2014) 1–6

Purification of recombinant human growth hormone from CHO cell culture supernatant by gradient flow preparative electrophoresis technology

Dalia Catalá¹, Helen Lavack^{1,2}, Chia P. Stanton¹, Peter P. Gray¹, Derek Van Dyl¹, and Stephen M. Malhotra^{1,2}
¹Biotechnology Centre, School of Biotechnology, University of New South Wales, Sydney, NSW, Australia; ²Monash University, Clayton, Victoria, Australia

Abstract

Purification of recombinant human growth hormone (rhGH) from CHO cell culture supernatant by gradient flow preparative electrophoresis technology. The mAb was purified from a complex mixture using TFPE.

1 Introduction

Recombinant human growth hormone (rhGH) is a heterodimeric glycoprotein consisting of two subunits, α and β , and a carbohydrate moiety. The α subunit is composed of two polypeptide chains, A and B, which are linked by a disulfide bond. The β subunit is composed of two polypeptide chains, C and D, which are linked by a disulfide bond. The carbohydrate moiety is attached to the α subunit.

2 Materials and Methods

rhGH was purified from a complex mixture using gradient flow preparative electrophoresis technology. The mAb was purified from a complex mixture using TFPE.

3 Results

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

4 Discussion

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

5 Conclusion

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

6 Acknowledgements

The authors thank the following for their assistance: Dr. [Name], Dr. [Name], and Dr. [Name].

7 References

1. [Citation] 2. [Citation] 3. [Citation] 4. [Citation] 5. [Citation]

Purification of monoclonal antibodies from cell culture supernatants by gradient flow preparative electrophoresis technology

Stephen M Malhotra^{1,2}, Sharon Leong^{1,2}, Andrew Gilbert^{1,2}, Fan Yang¹, Peter Gray^{1,2}, Derek Van Dyl¹, and Philip Booth¹
¹Biotechnology Centre, School of Biotechnology, University of New South Wales, Sydney, NSW, Australia; ²Monash University, Clayton, Victoria, Australia

Abstract

Purification of monoclonal antibodies (mAbs) from cell culture supernatants by gradient flow preparative electrophoresis technology. The mAb was purified from a complex mixture using TFPE.

1 Introduction

Monoclonal antibodies (mAbs) are used extensively in biopharmaceuticals for the treatment of a wide range of diseases. The mAb was purified from a complex mixture using TFPE.

2 Materials and Methods

mAbs were purified from a complex mixture using gradient flow preparative electrophoresis technology. The mAb was purified from a complex mixture using TFPE.

3 Results

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

4 Discussion

The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

5 Conclusion

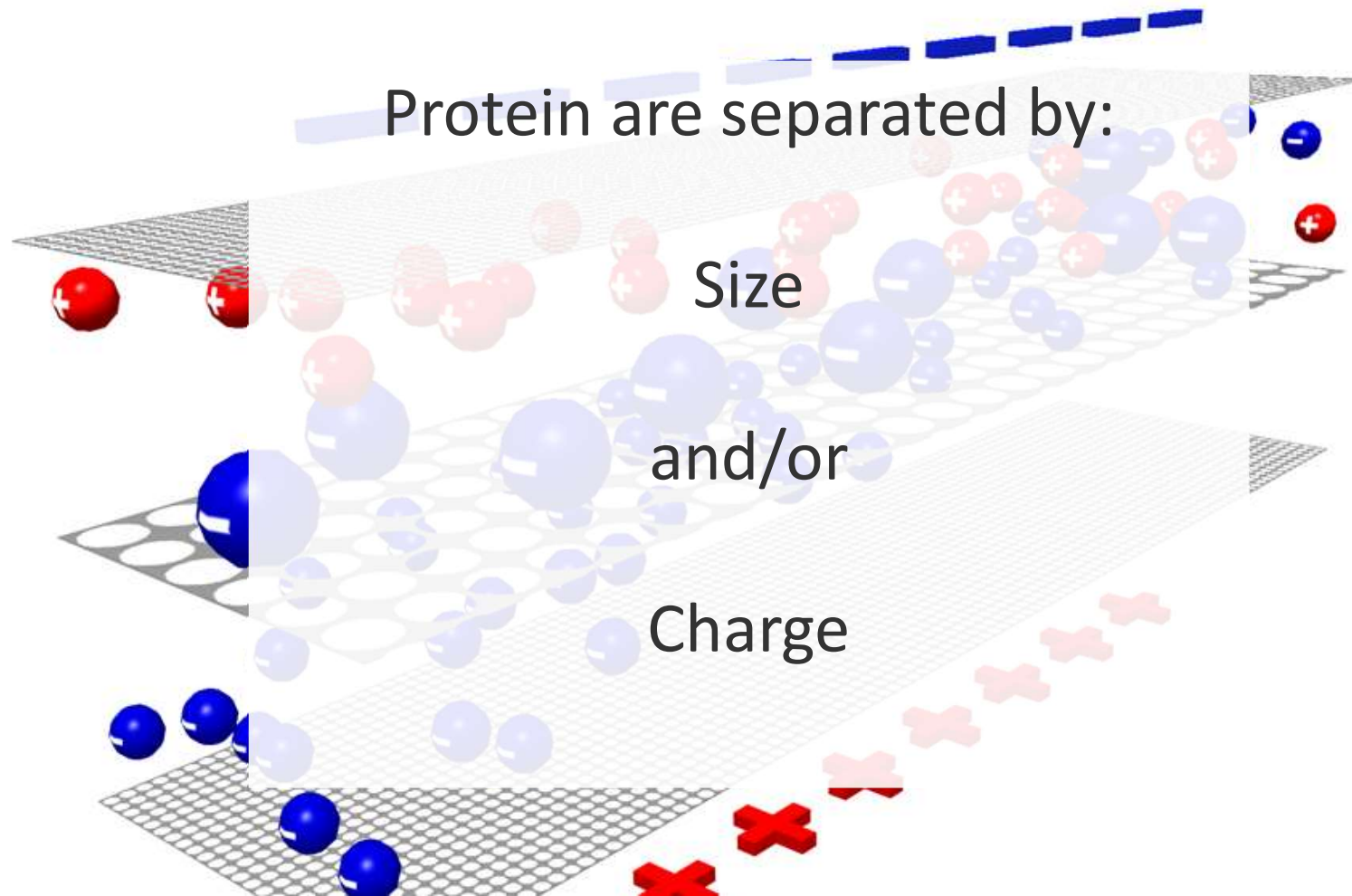
The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE. The mAb was purified from a complex mixture using TFPE.

6 Acknowledgements

The authors thank the following for their assistance: Dr. [Name], Dr. [Name], and Dr. [Name].




Separation by Tangential Flow Electrophoresis



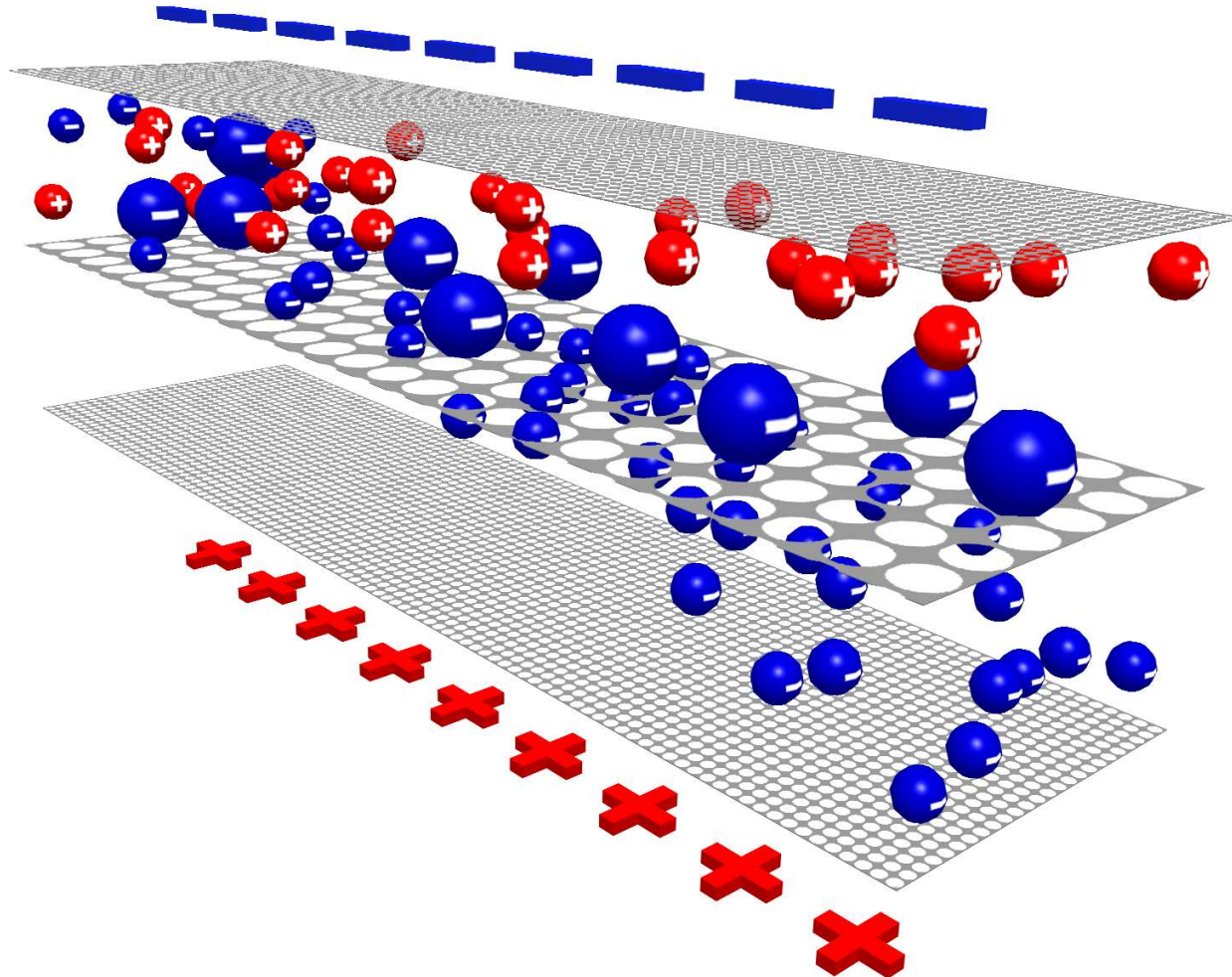
The BF400 R&D Separation Module



Small scale R&D
experimentation

 Aegros Copyright 2023

Separation Module



Cathode (negative electrode)

Restriction membrane

Stream 1 (feed stream)

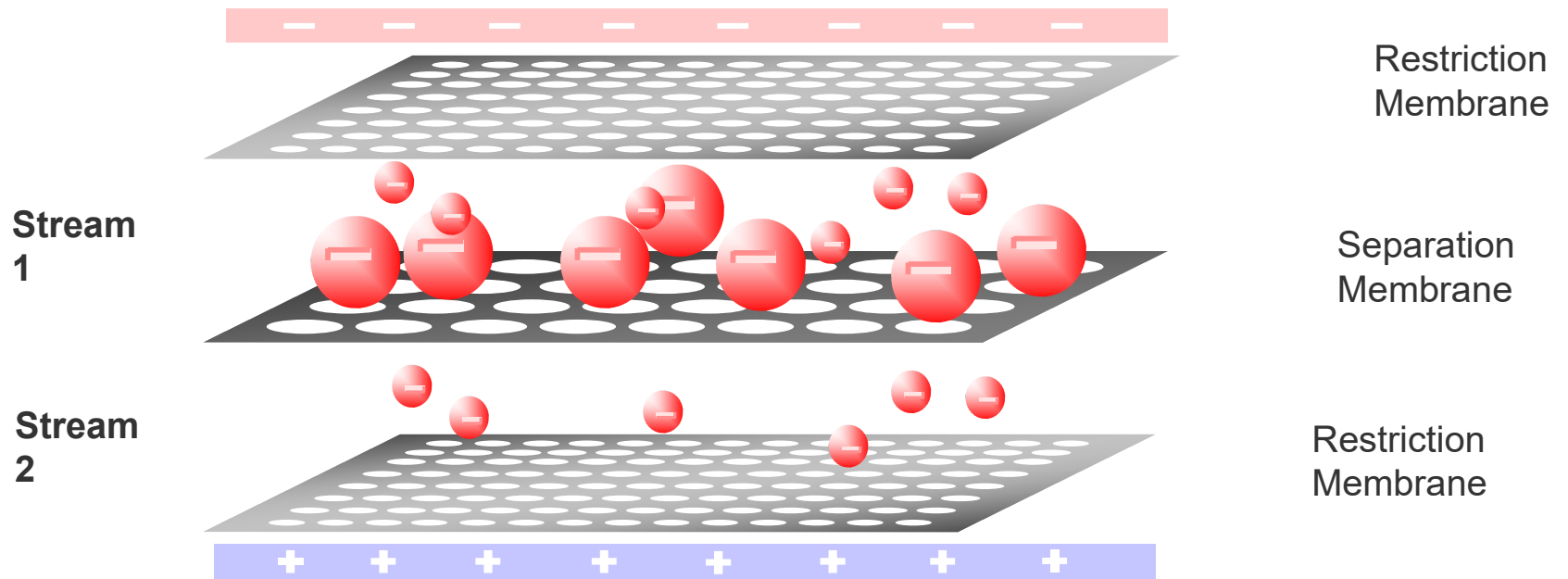
Separation membrane

Stream 2 (product stream)

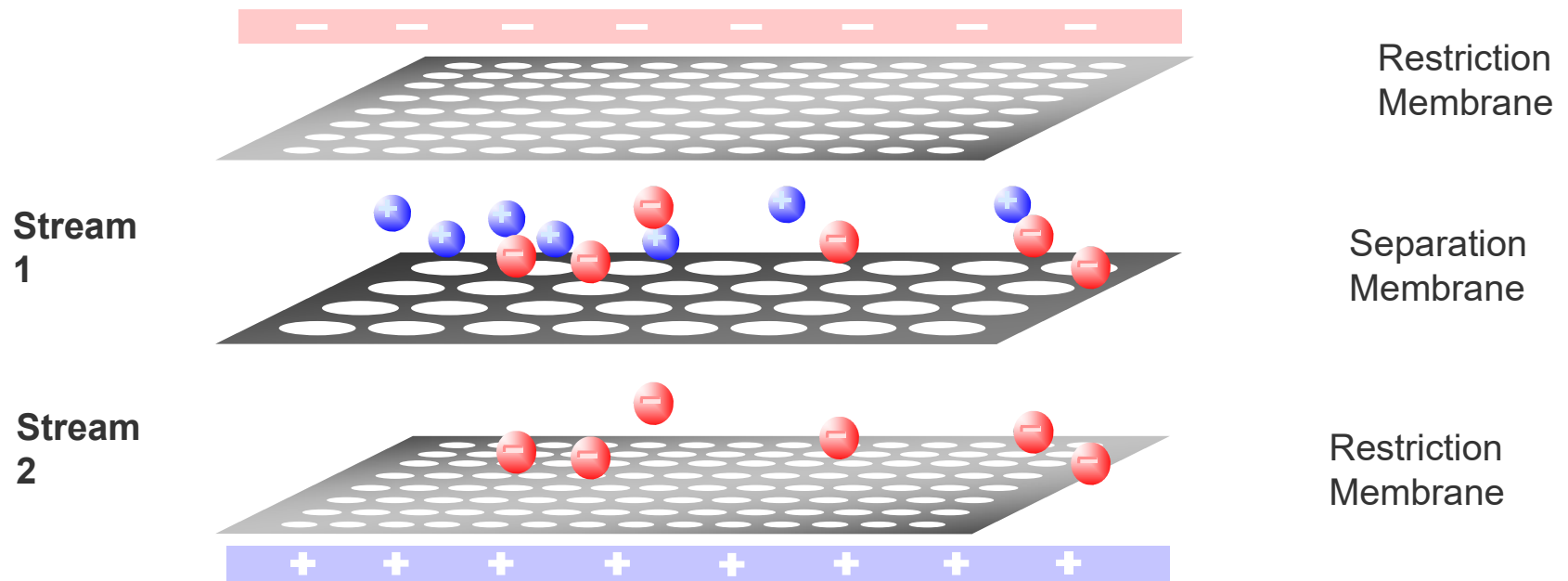
Restriction membrane

Anode (positive electrode)

Size separation



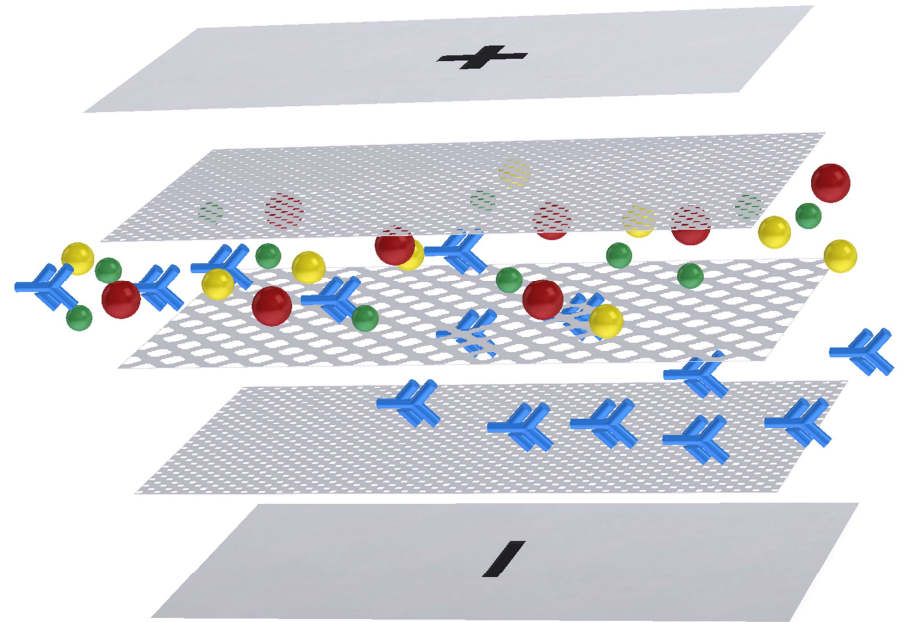
Charge Separation



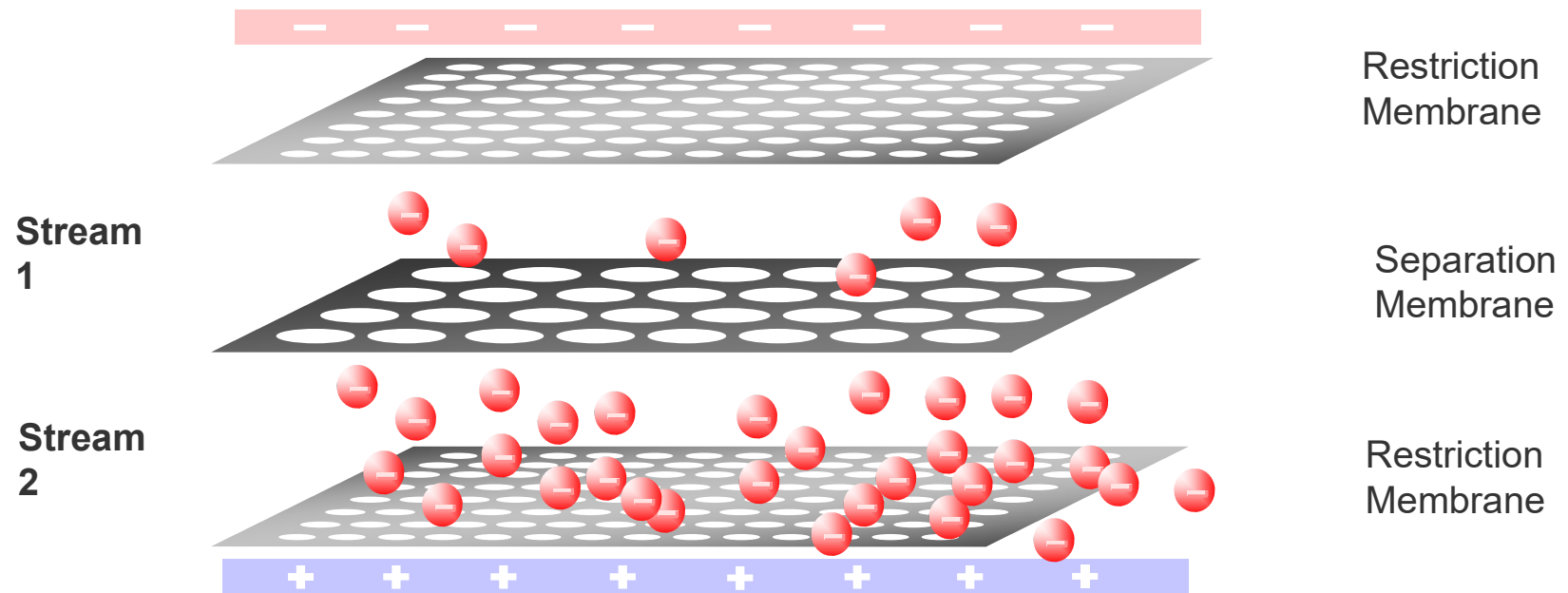
Aegros Products: Covimmune™

A hyperimmune IVIG preparation:



- Produced from human convalescent plasma from patients with preexisting antibodies to SARS-CoV-2
- IgG is fractionated using HaemaFrac® technology and is processed to produce an anti-SARS-CoV-2 hyperimmune IVIG preparation
- Currently undergoing clinical trial



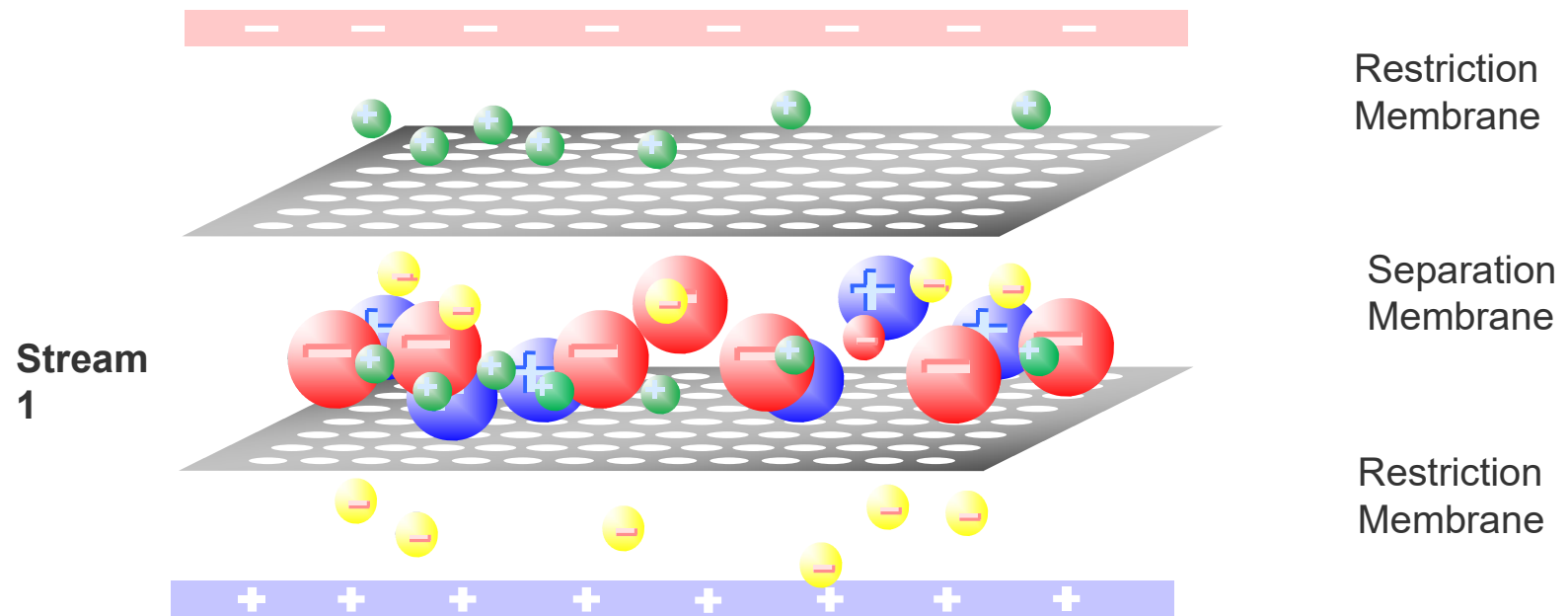
Concentration of Product




 Aegros Copyright 2023

- 
- 
- ✧ As well as a ground-breaking system for plasma fractionation, Aegros' TFE technology may have a variety of applications for the future.
 - ✧ The technology can be applied to concentrating product streams, in a similar way to conventional ultrafiltration

Dialysis



 Aegros Copyright 2023

Collaborations & Outreach



Australian Institute for Bioengineering and Nanotechnology



Australian Government



GUIDANCE ON INCREASING SUPPLIES OF PLASMA-DERIVED MEDICINAL PRODUCTS IN LOW- AND MIDDLE-INCOME COUNTRIES THROUGH FRACTIONATION OF DOMESTIC PLASMA



Policy

Engagement

Advanced
Biomanufacturing
Capability

Research and
Development
Partnerships



- ✚ Human plasma contains over 3,000 proteins, with just 20 proteins make up 99% of the total proteins by weight in plasma.
- ✚ The other 1 % of plasma proteins includes cytokines, growth factors, plasminogen and a host of coagulation factors. Due to their low abundance they are often difficult to separate from other plasma proteins.
- ✚ Aegros has innovative solutions for isolating and purifying these less abundant proteins of high net worth. Smart affinity membranes are able to selectively purify these membranes simultaneously with the purification of albumin and immunoglobulin

A photograph of two men in white lab coats standing in a laboratory. The man on the left is smiling and has his hands clasped. The man on the right is wearing glasses and has his hands on his hips. They are surrounded by complex industrial machinery, including pipes, tanks, and control panels. The scene is brightly lit, and the overall atmosphere is professional and scientific.

Share our **Passion**

What's next?



Strategic partnerships with both public and private sectors

New Products

Innovative Bioprocessing

Centre of Excellence

Research and Development

Global expansion

Sovereign self-sufficiency

International markets

The Future

 Aegros Copyright 2023

 **Aegros**

Welcome

- to -

 **Aegros**

R & D Day

14th March 2023

Aegros Medical Update

Medical Presentation - Dr Leon Rozen

Aegros Medical Update



Immunoglobulin

Albumin

Clotting

Specialty Products

80% of
future
business

Immune compromise and COVID-19

MELODY study

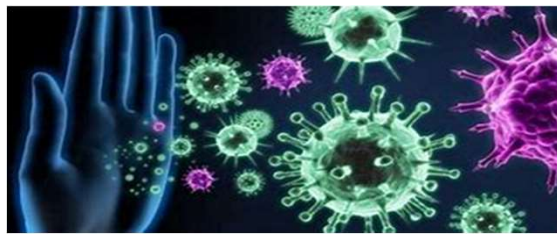
- ✚ UK registry - immune compromised patients and response to COVID-19 vaccine
- ✚ Solid Organ Transplant; Rare Autoimmune Rheumatic Disease; Lymphoid Malignancies
- ✚ Antibodies were undetectable in 20% of patients after at least three doses
- ✚ >70% had received four doses or more



It is estimated that there are **500,000** immune compromised patients in Australia

Convalescent Plasma (CP) and Prevention of Hospitalisation

- ✚ Convalescent plasma used in immune compromised patients
- ✚ Failed studies have been in treatment – eg Plasma Alliance, RECOVERY and an Australian study
- ✚ Also can use CP for prevention of hospitalisation in immune compromised patients
- ✚ Use of high titre CP early in the course of infection (first 5 days) as an outpatient reduces risk of hospitalisation by up to 50%
- ✚ The CDC suggests CP be considered as prevention of severe disease in immune compromised patients



COVID-19 Hyperimmune Aegros Trial (CHAT)

- ✚ To show COVID 19 Hyperimmune Immunoglobulin (hIVIg) provides similar COVID-19 antibody levels as compared to convalescent plasma (CP)
- ✚ hIVIg TGA registration study

Group 1

15 healthy volunteers - CP



Group 2

15 healthy volunteers - hIVIg



Group 3

5 immune compromised subjects



hIVIg – Ongoing Development

- ❧ hIVIg Immunodeficiency AegrOs (CIAO) Trial
- ❧ Multiple dose pharmacokinetics for hIVIg
- ❧ TBN (To Be Named)
- ❧ Prevention of hospitalisation in immune compromised patients compared to CP
- ❧ Institutions such as Mayo Clinic and Johns Hopkins (among others) now use convalescent plasma as standard of care for prevention of hospitalisation in immune compromised patients



Other Clinical Development

- ✧ Aegros Immune Replacement (AIR) Trial
 - ✧ Registration study for polyclonal IVIg product
 - ✧ Replacement therapy for Primary Immunodeficiency

- ✧ Development of niche products

- ✧ Other Hyperimmune globulins,

IgG3, plasminogen, fibrinogen, Factor XI



Welcome

- to -



R & D Day

14th March 2023

Aegros Australian Commercial Operations and International Expansion



**Aegros R&D Open
Day**

Tuesday 14/03/2023

Engineering
Presentation
Mr Damian Thornton



Aegros – Value Proposition

Three Areas of Value: 3 distinct growth phases:

- ✚ Provide Therapies to treat pandemics
 - ✚ 150,000L p.a. based in NSW
- ✚ Double Australian supply of IVIG & Albumin
 - ✚ 1,000,000L p.a. based in QLD
- ✚ Global self sufficiency in the supply of plasma products
 - ✚ Modular facilities for emerging markets



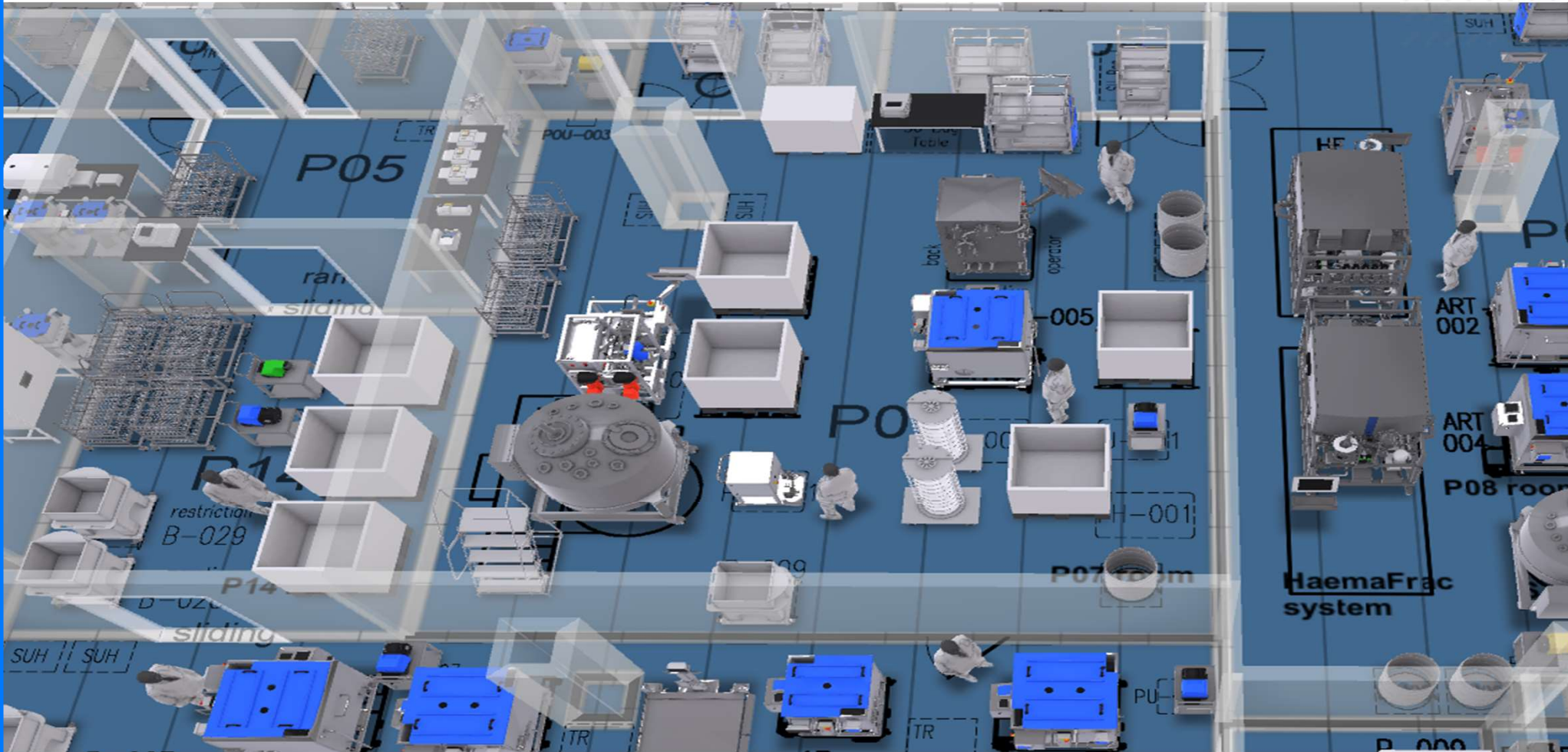
Phase 1: Pandemic Relief: 150,000L/yr Hyperimmune Facility – Macquarie Park



Phase 1: Renovation of 5 EPD to Process 150,000 L/yr of Hyperimmunes: New Facility Layout



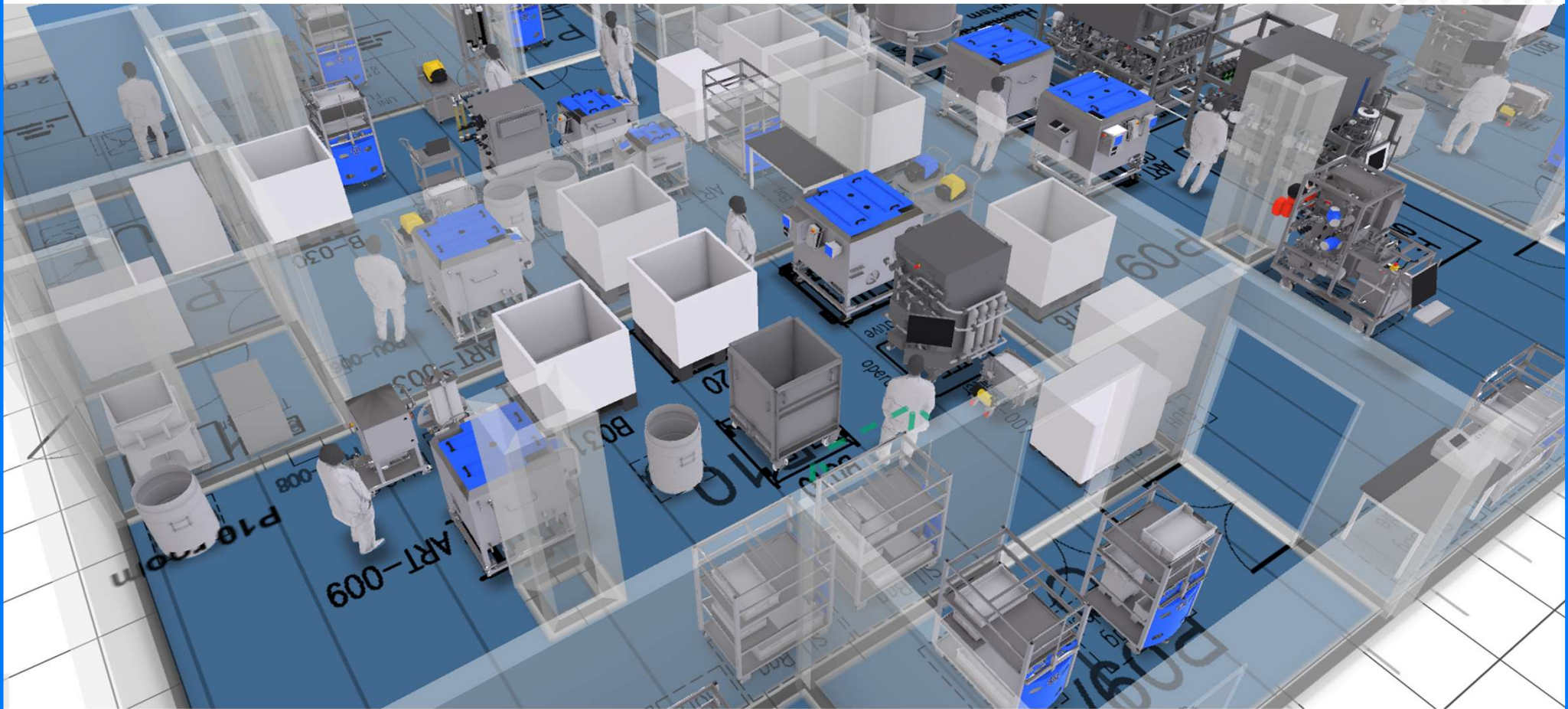
Plasma Thaw, Maturation and Desalting



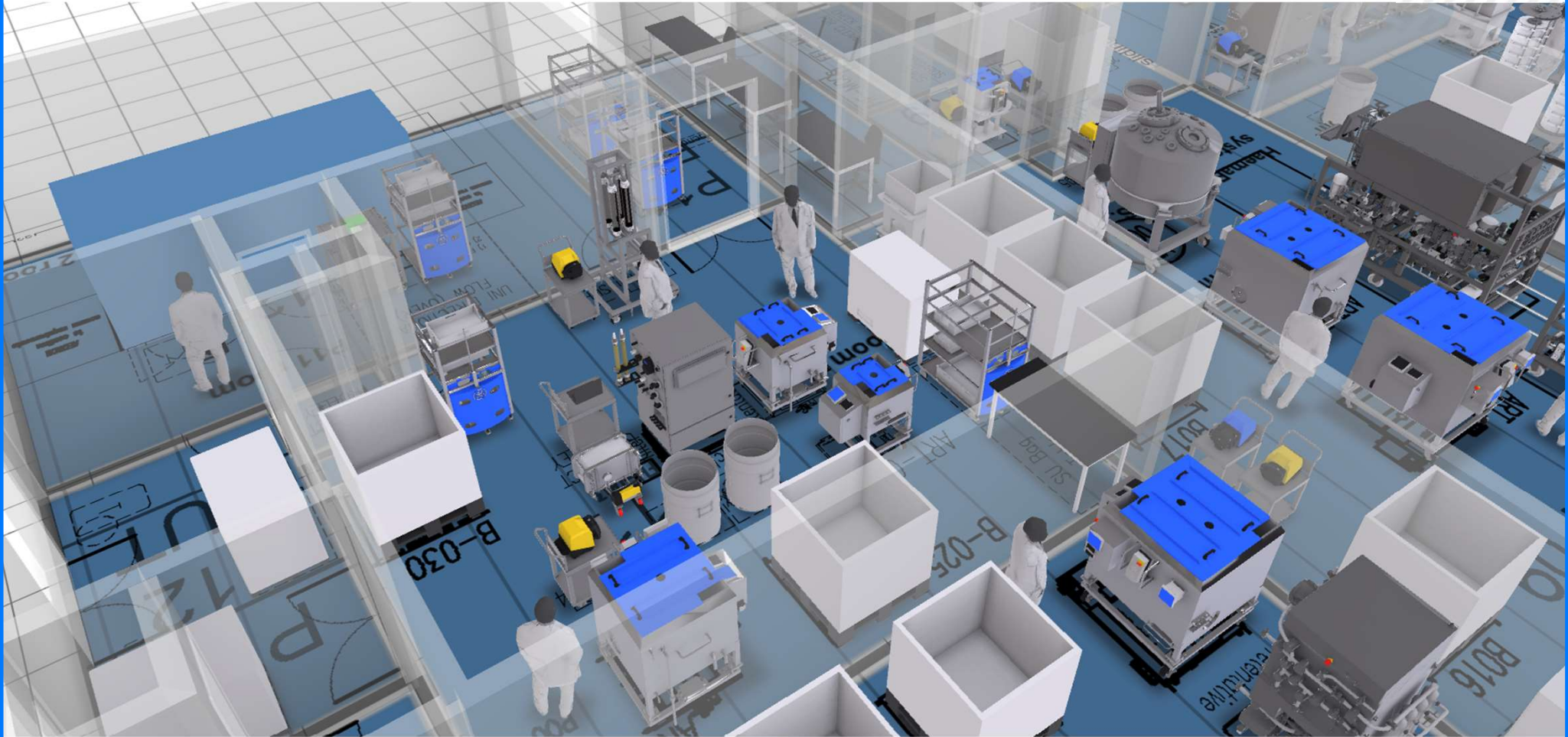
Fractionation



Concentration and Viral Filtration

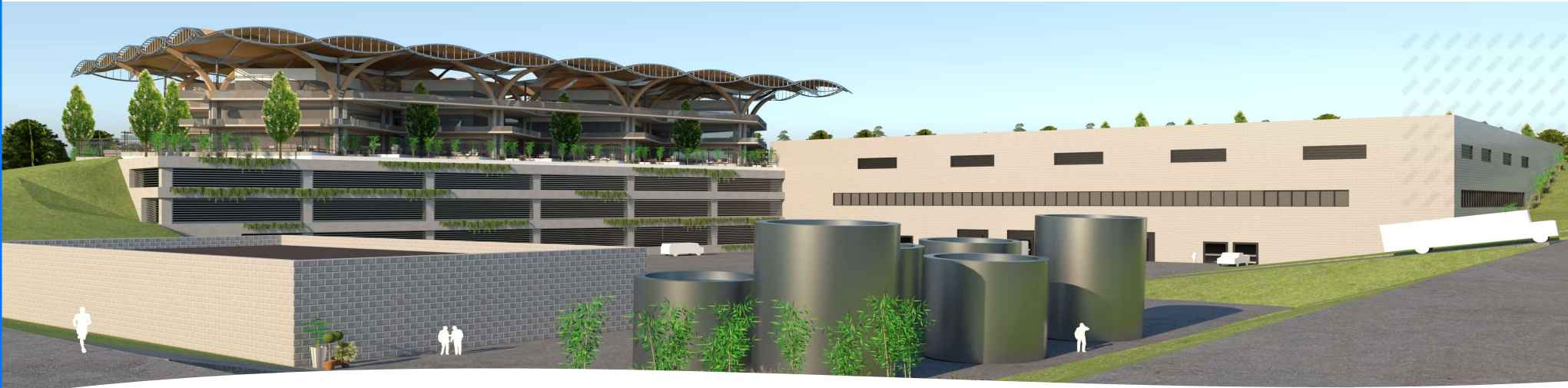


Diafiltration, Final Formulation and Filling



An architectural rendering of a large-scale plasma fractionation facility. The building features a prominent, undulating roof structure composed of multiple overlapping DNA double helix motifs, supported by a series of thick, curved columns. The building is multi-storied with glass railings on the upper levels. The facility is situated on a green lawn with several tall, slender trees in the foreground. The sky is a clear, light blue. In the top right corner, there is a decorative graphic of a grid of small, light blue squares.

**Phase 2: Large Scale Fractionation utilizing HaemaFrac[®]
Technology
1M L Plasma Fractionation Facility**



Queensland 1M L/yr Plasma Processing Facility includes:

- ❧ Two production trains manufacturing IVIG and Albumin: twice the output of a conventional Cohn facility
- ❧ Global R&D Centre of excellence for Bio-separations
- ❧ State of the art pilot plant and clinical trials facility
- ❧ Industrial membrane manufacturing facility for global supply
- ❧ Skid Manufacturing for HaemaFrac®
- ❧ Advanced Factory for Modular Fabrication

Aegros Queensland 1M L/yr Facility



 **Aegros**
Springfield, Queensland.

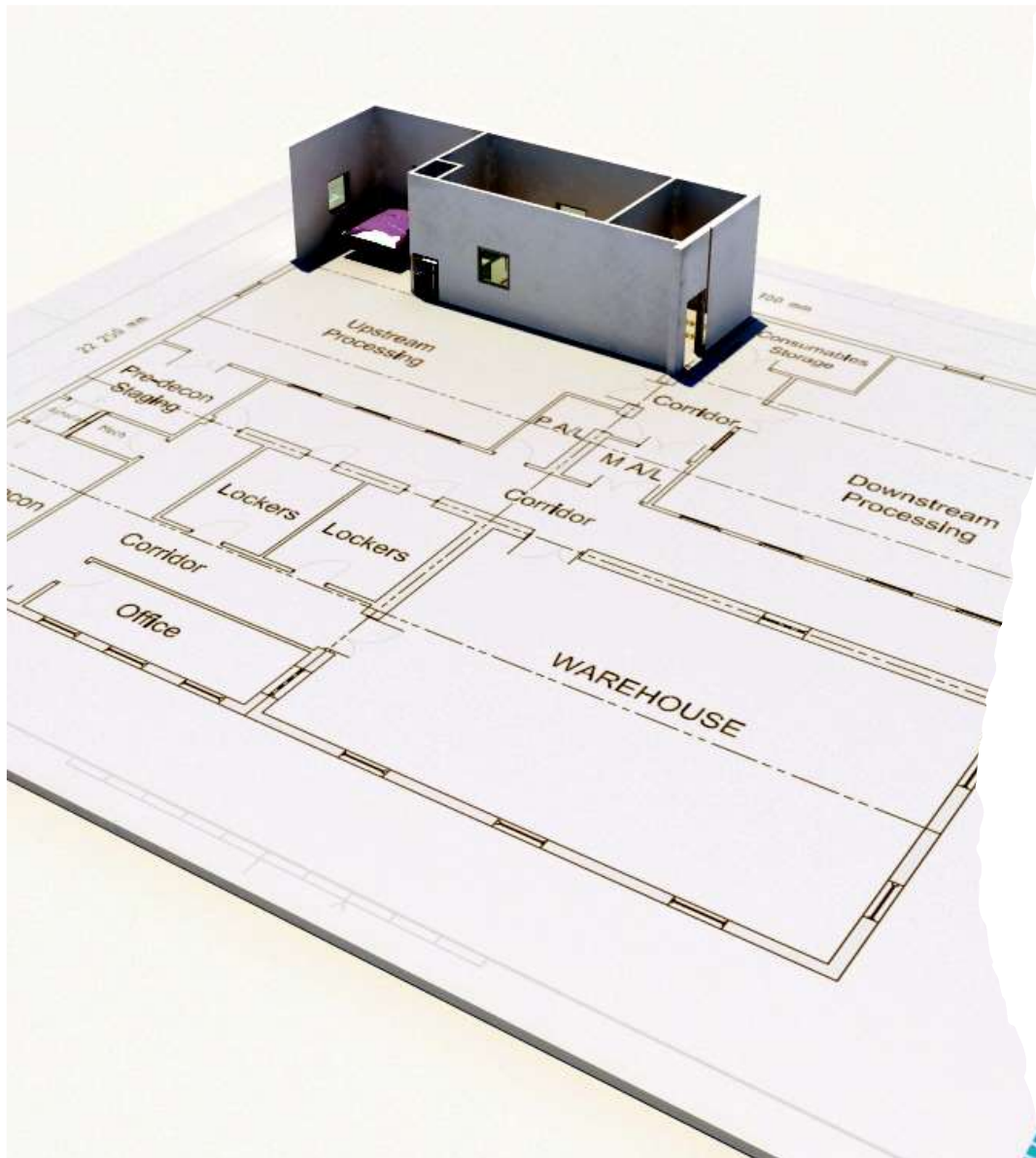

Niall M Byrne Architects Ltd
Ireland France Tel: +353 (0)53 900 8965
www.nmbarchitects.ie info@nmbarc.com

 **Aegros**



Phase 3: Aegros Modular Fabrication for Rapid Deployment: A 21st Century Technology for 21st Century needs



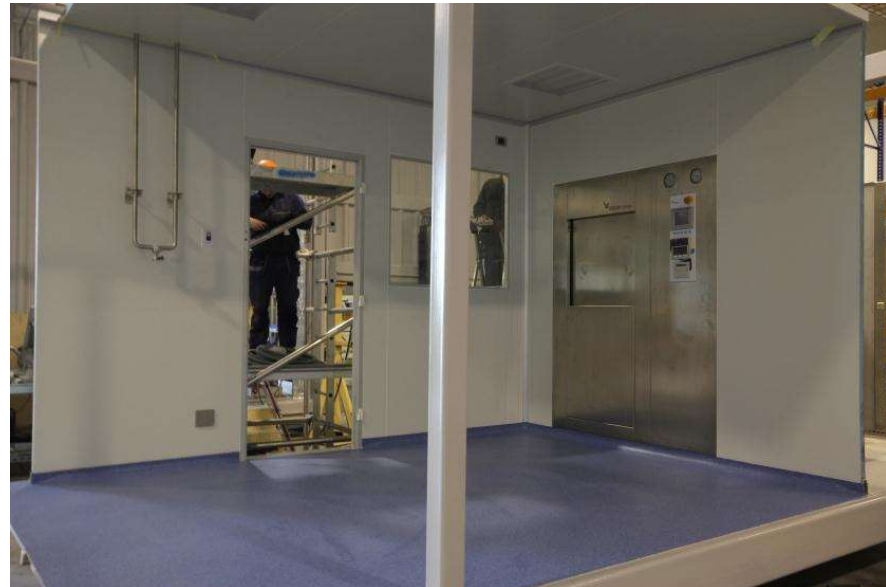
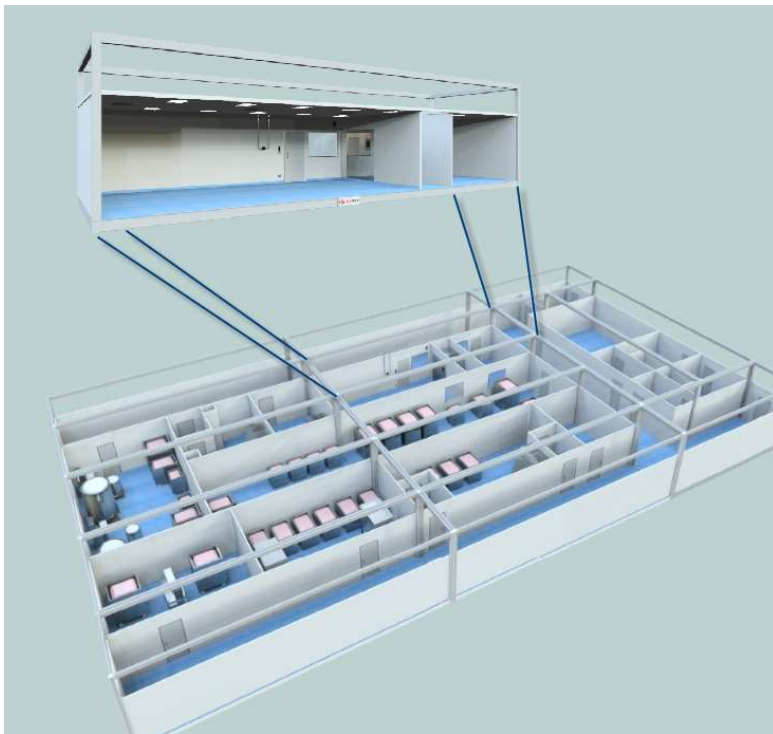


Phase 3: Aegros' Modular Solution for Global high yield Plasma Fractionation Facilities

- Standardized, Pre-engineered Modular Solution
- Facility designed for Capacity of 50,000 to 150,000 L/yr Plasma Processing with **No Additional Capex** required for manufacture
- Fast Delivery Time – 20-24 months from Project initiation to Bulk fill

Standard Building Module

Fully equipped; Length 13,35 m Width 4,45 m and height 4,1 m, panels with walkable ceiling





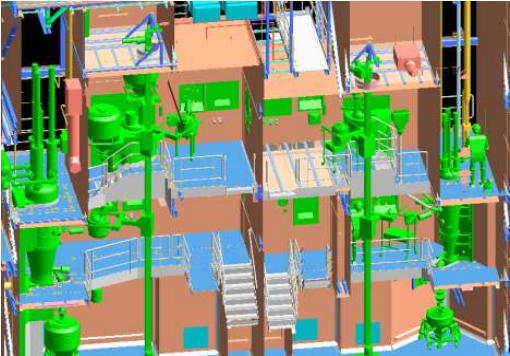
- **Phase 3: Aegros' Modular Solution for Global high yield Plasma Fractionation Facilities**



Phase 3: Aegros' Modular Solution for Global high yield Plasma Fractionation Facilities

Phase 3: Aegros' Modular Solution for Global high yield Plasma Fractionation Facilities

Engineering



Fabrication

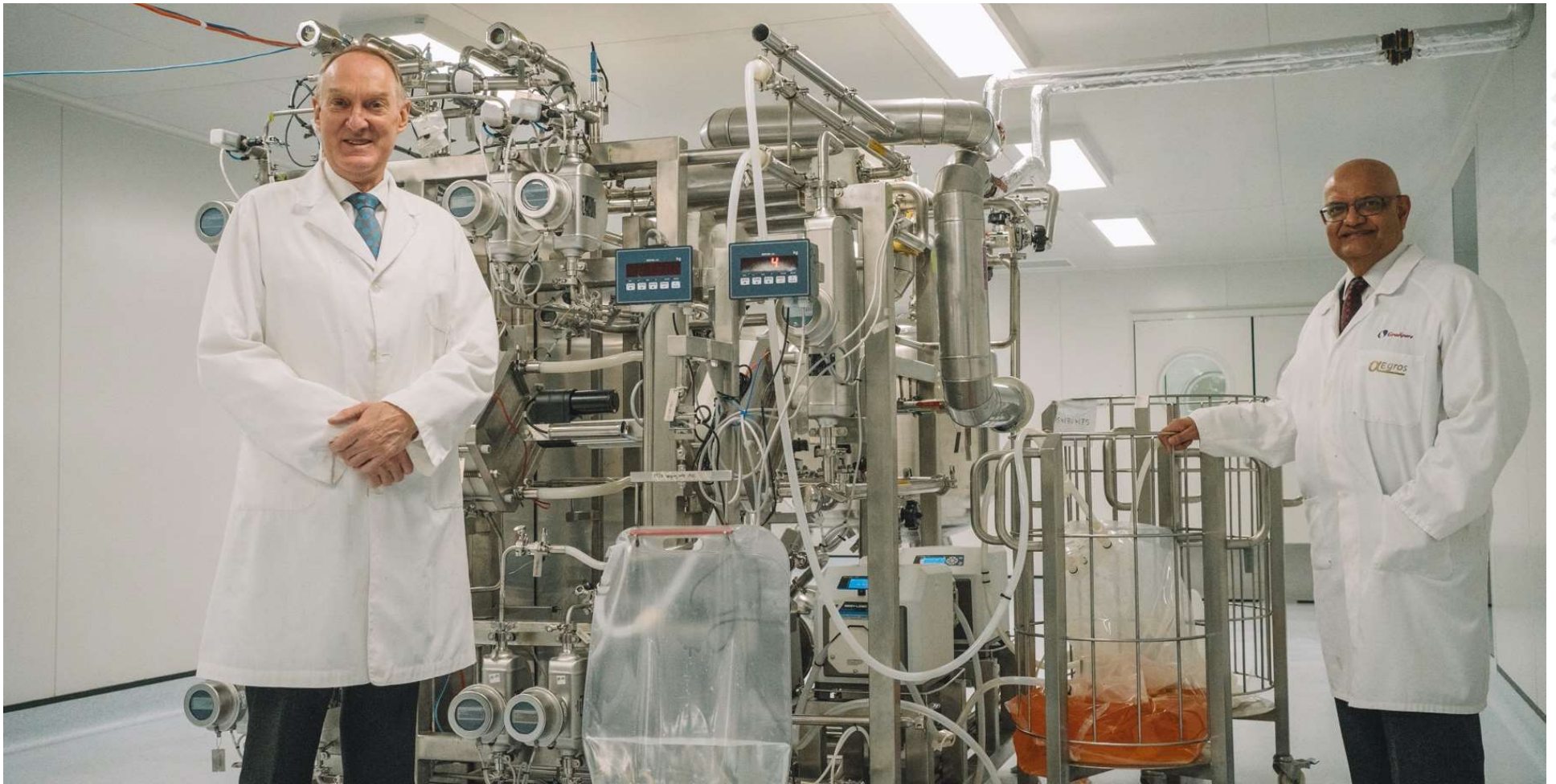


Delivery



Site Erection
&
Completion





Share our Passion

Welcome
- to -



R & D Day
14th March 2023