



Rodon Biologics

Express your needs

> 20 years in development and manufacturing supporting discovery, research, preclinical and clinical development



1997

Biosimilars

E.coli expression technologies
Fermentation
Purification
Analytics
Capabilities

Labs in IBET (Oeiras)

1999

CDMO Services

E.Coli and yeast cell line, process development, scale-up, transfer and manufacture (CMC)

2002

Mammalian Cell Line, Process Development, Cell Based Assay and Antibody Capabilities

Facilities in Lagoas Parque (Oeiras)

2006

Antibody Engineering
Multispecific formats
T cell engagers

2011

Tribody™ development

2013



Tribodies



acquired by Iberfar
Facilities to Barcarena Park
Relaunch
CDMO Services

Tribody™ sold to Chiome (JP)

2018

2020

Biosynthetics/
Cannabinoids
Capabilities

- Engineering, producing, analysing, characterising, and delivering processes, products, CMC / quality documentation and consultancy to support discovery, early stage and preclinical research, industrialization, CMO selection, process transfer, manufacture, INDs and IMPDs.
- mAbs, antibody based formats e.g. scFv, Fabs, VHH, multi specifics (Bites, Tribody, Bibodies, Diabodies, Bi/Tri specifics), monovalent IgGs, Fc-fusions, cytokines, growth factors, vaccine antigens, novel fusion formats, biosynthetics, cannabinoids

Success stories with many customers / collaborations



Projects for small, mid and large-size biotech/pharma on an international level
Collaboration with CMOs, Universities, Institutes and technology providers

Testimonials

"Our lead Biologics presented several challenges to the development of a Cell Line and Manufacturing Process. Rodon, through years of experience, came up with effective solutions to these challenges. They successfully delivered a cell line and scalable manufacturing process to produce our product with a higher than expected yield and quality for clinical development. Rodon showed a high level of professionalism, dedication and attention to detail which made them a pleasure to work with."

"Rodon Biologics helped us find the appropriate expression system, develop the cell line and process and transfer this for manufacture of our novel lead product. The teams experience, proactivity and enthusiasm were crucial to complete these activities in timely manner".

"Rodon Biologics achieved a timely delivery on budget, a flawless execution and commitment to our project. They always went the extra-mile in finding successful solutions to complex problems. At the end of the project their reports breath quality as deliverables. In fact one the best I have seen so far in over 23 years of my life in the business. Clearly the reliability of the team and consistency of results together with the long standing track-record of their team was an asset for our project."

Where we fit



Biology

- Molecular engineering
- Process prototyping
- Small Scale Productions (mg-grams)
- Analytics / Characterisation

Analytics

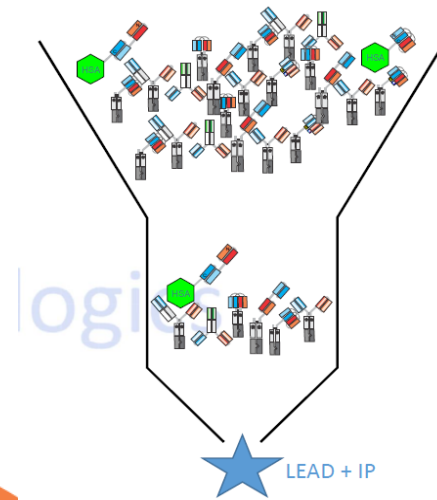
- Methods development
- Cell Based Assays
- Analysis and Characterization

Process (CMC)

- Cell-line Development
- Formulation Development
- Process Development / Optimisation
- Characterisation / Qualification / Industrialisation⁶
- Scale-Up, Transfer and cGMP Manufacture



- Half life extension, format optimisation, manufacturability, stabilisation
- Bi and multispecifics multivalent formats:
 - formats (Tribodies, Diabodies ect..)
 - Fc fusions (scFv , nanobodies, diabodies, novel binding domains)
 - Albumin and albumin binding fusions
 - Immune cell engagers e.g CD3 multispecifics
 - Modulators e.g. check point multispecifics



Wide screening
(16-44 molecules)

Formats
Configurations
Sequences
Linkers etc..

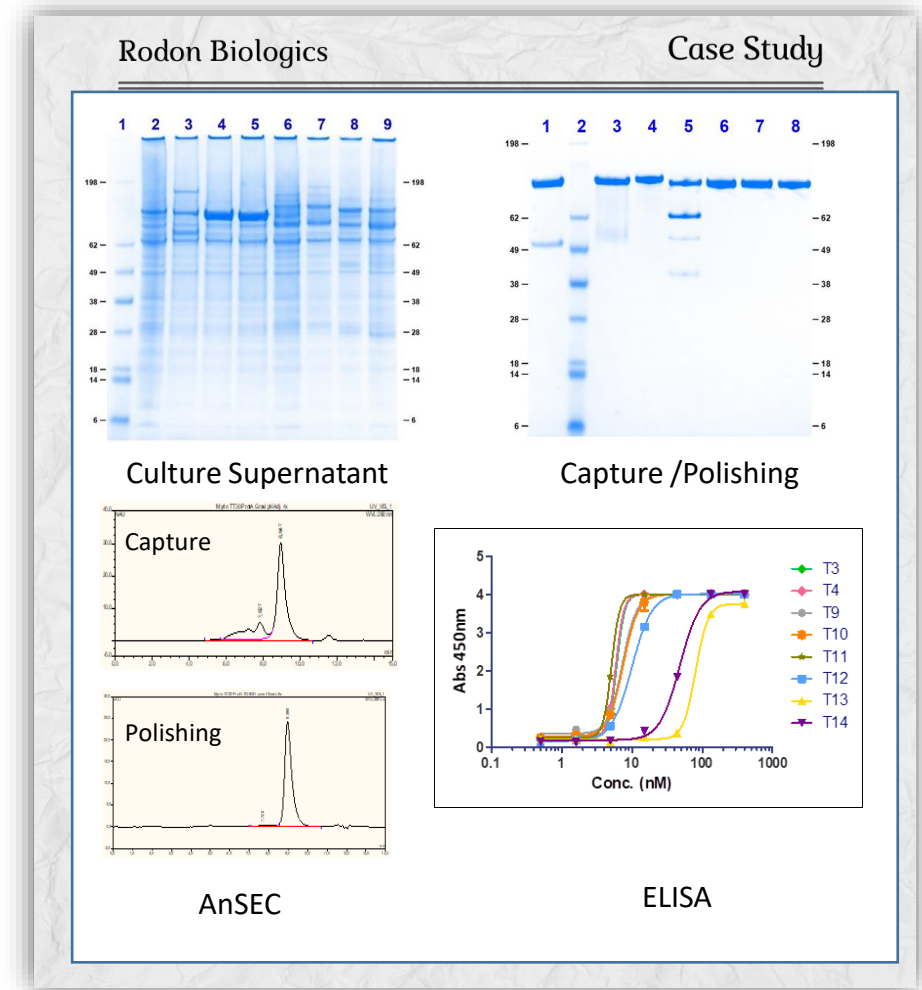
Yield
Mw
Conformation
Purity
Binding
Activity
Stability

Vectors

- Fc fusions
- Bispecific (KiH)
- fcy silenced
- Linkers
- Tags

Methods

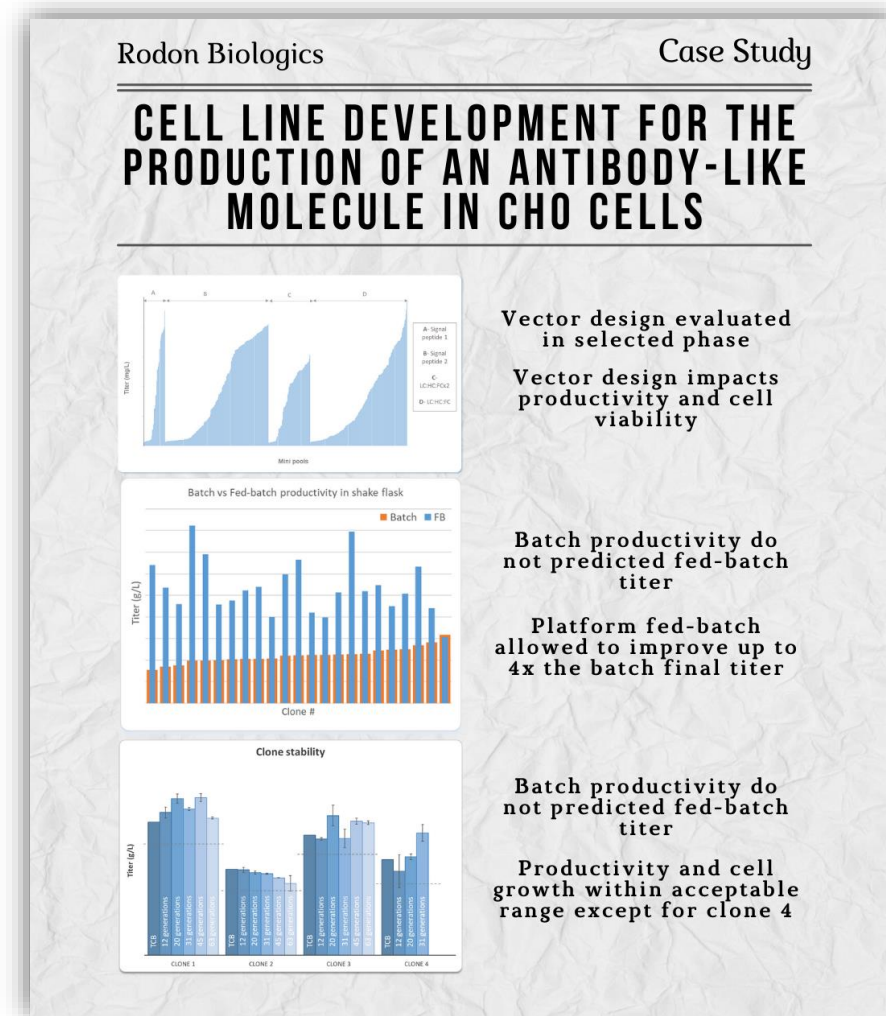
- Transfection
- Culture
- Affinity Capture
- Polishing
- Analysis





Expression Technologies

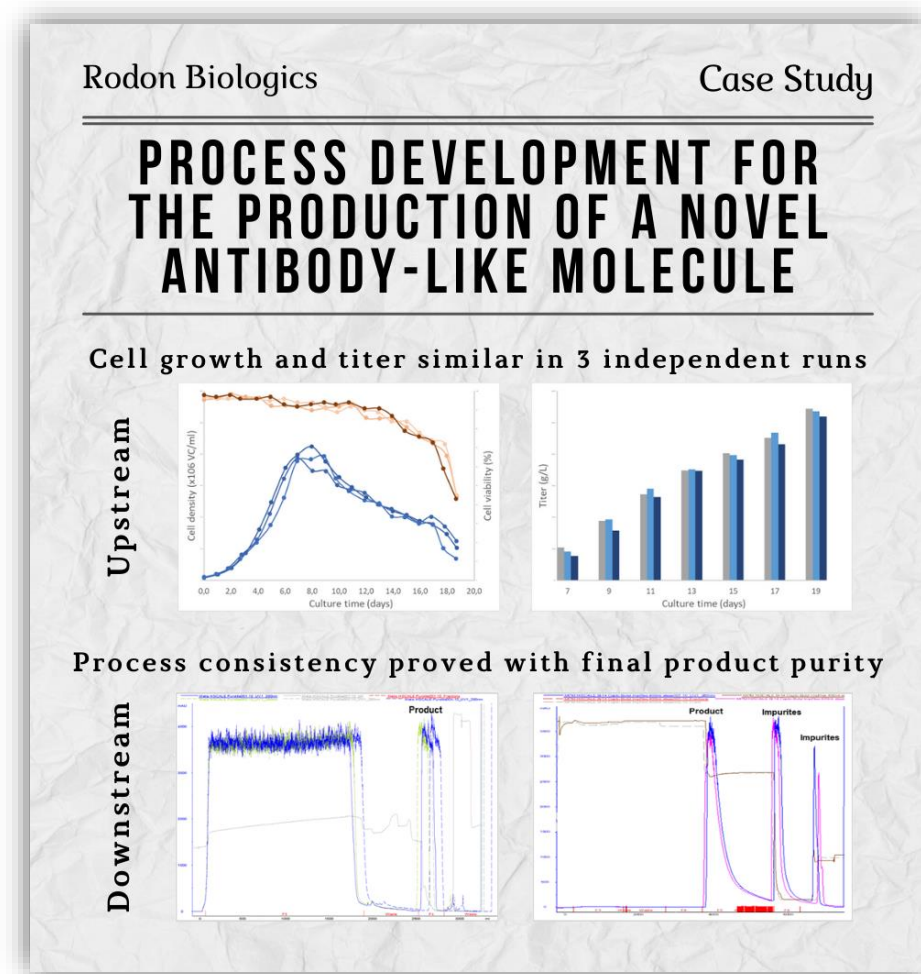
- HEK293, CHO, *E.coli*, *S. cerevisiae*, *Pichia*
- Production
 - Rodon or client tech/protocol
 - Screening and/or production
 - ml to several liters (plates, shake flasks, bioreactors)
 - mg – grams
- Manufacturing Cell Lines
 - Stable (stability assessment)
 - grams per liter in fed batch processes





Process

- **Fermentation and Cell culture**
 - fermenters / bioreactors
 - 2, 5, 10 benchtop, to 50 and 200 litres
- **Chromatography**
 - Akta systems
 - Affinity, Ion-X, HIC, MMC, RP, membrane
- **Filtration**
 - Cross Flow System
 - Depth, Micro, Ultra, Nano, Viral
- **Localisation**
 - Cytoplasm, periplasm, secreted
 - Inclusion bodies (refolding)
- **Cell disruption**
 - High Pressure Homogeniser
 - 2000 bar
- **Spray Drier**
- **Rota Vap**





Purity

- SDS-PAGE
- HPLC (RP, HIC, SEC, IonX)
- DNA (qPCR)
- HCP (ELISA)
- Microbiological
- Endotoxin – LAL

Potency

- Concentration assays
 - ELISA, UV, HPLC
- Binding and affinity
 - ELISA, Flow Cytometry
 - SPR

Identify

- Appearance
 - pH
 - Melting Temps
 - Peptide fingerprint
 - Western Blotting
 - IEF
 - cIEF / ceSDS
 - Amino acid analysis
 - Mass spectrometry
 - Glycan profiling
 - Peptide mapping
 - Sequencing
 - CD, DSC

Stability

- Formulation
- Stress/accelerated testing
- Real time testing
- DLS/Vis/sub-vis particles



*Outsourced



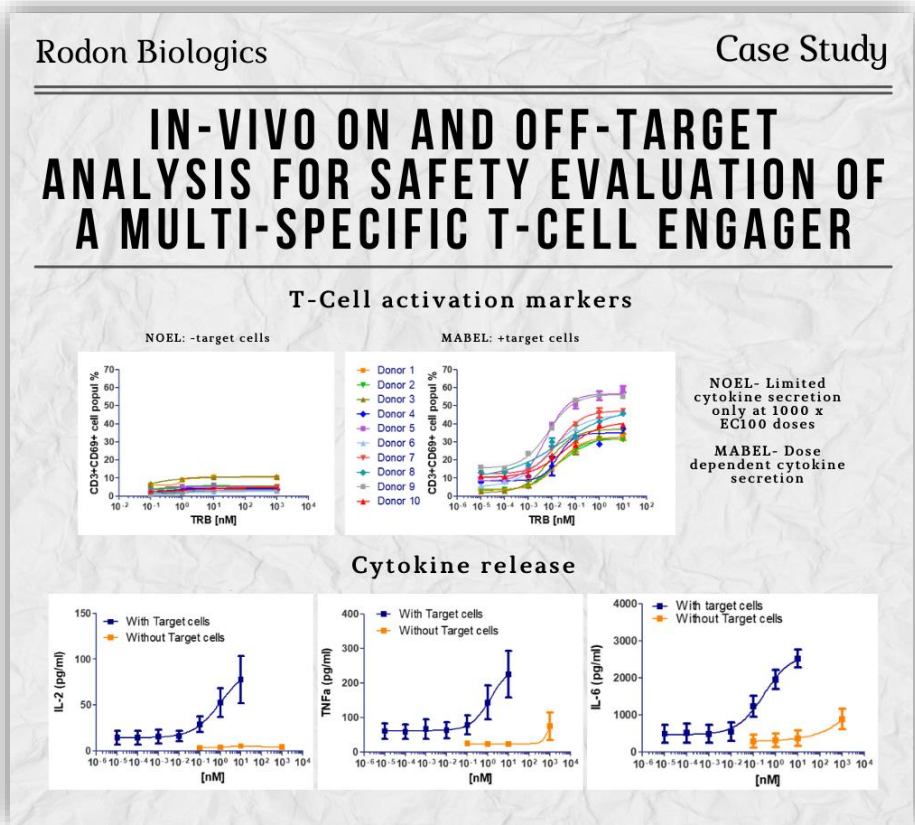
Cell Based Assays

Preclinical Assessment

- Off and on-target activity
- Cytotoxicity
- Cytokine Release
- Activation Markers
- MABEL
 - Minimum Anticipated Biological Effect Level
- NOEL
 - No-observed-effect level

Cell Based Assays

- Cell Lines
 - Commercial or Clients
- Cellular ELISAs
- Cytometry
- Pro and anti-Proliferation
- Cytotoxicity
- Immune system engagement
 - ADCC / CDC
 - PBMCs
 - T or NK cells





Manufacturing: Industrialising in mind

- **Materials**
 - non animal derived
 - history in Biologics manufacture
 - preferentially readily available (Off the shelf)
- **Scalability of Unit Operations**
- **Single use technology where available**
- **Identify and target CQAs**
- **Optimise Operating parameters**
- **Identify CPP, NOR, PAR**
- **Record Keeping and detailed documentation**
 - facilitate transfer
 - support regulatory filings
- **CMO selection**
- **Close collaboration into manufacture**



Operations Management

Resources

Finance

Quality

Traceability

Health and safety

Environmental

Project Management

Service Agreement and Work programs

Planning and organization of tasks

Procurement and allocation of resources

Execution and documentation

Ongoing monitoring and review

Regular and open communication with client

Project Adjustments (change orders)

Reports

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**PASSIONATELY COMMITTED
TO ACHIEVE YOUR GOALS**

