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Life Sciences Services and Products

From gene to biotherapeutics

Target Validation to Lead optimisation

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- Philippe FUNFROCK, founder and CEO
- French company located in Strasbourg, **14 years** of existence
- **One stop solution from Gene to Diagnostics / Biotherapeutics**, Food enzymes, or Veterinary products…

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Antibody drug market

- Major class of biopharmaceutical products worldwide
- First in 1986 (Muromonab-CD3)
- USD 85.4 billion in 2015
- More than 500 in the clinic

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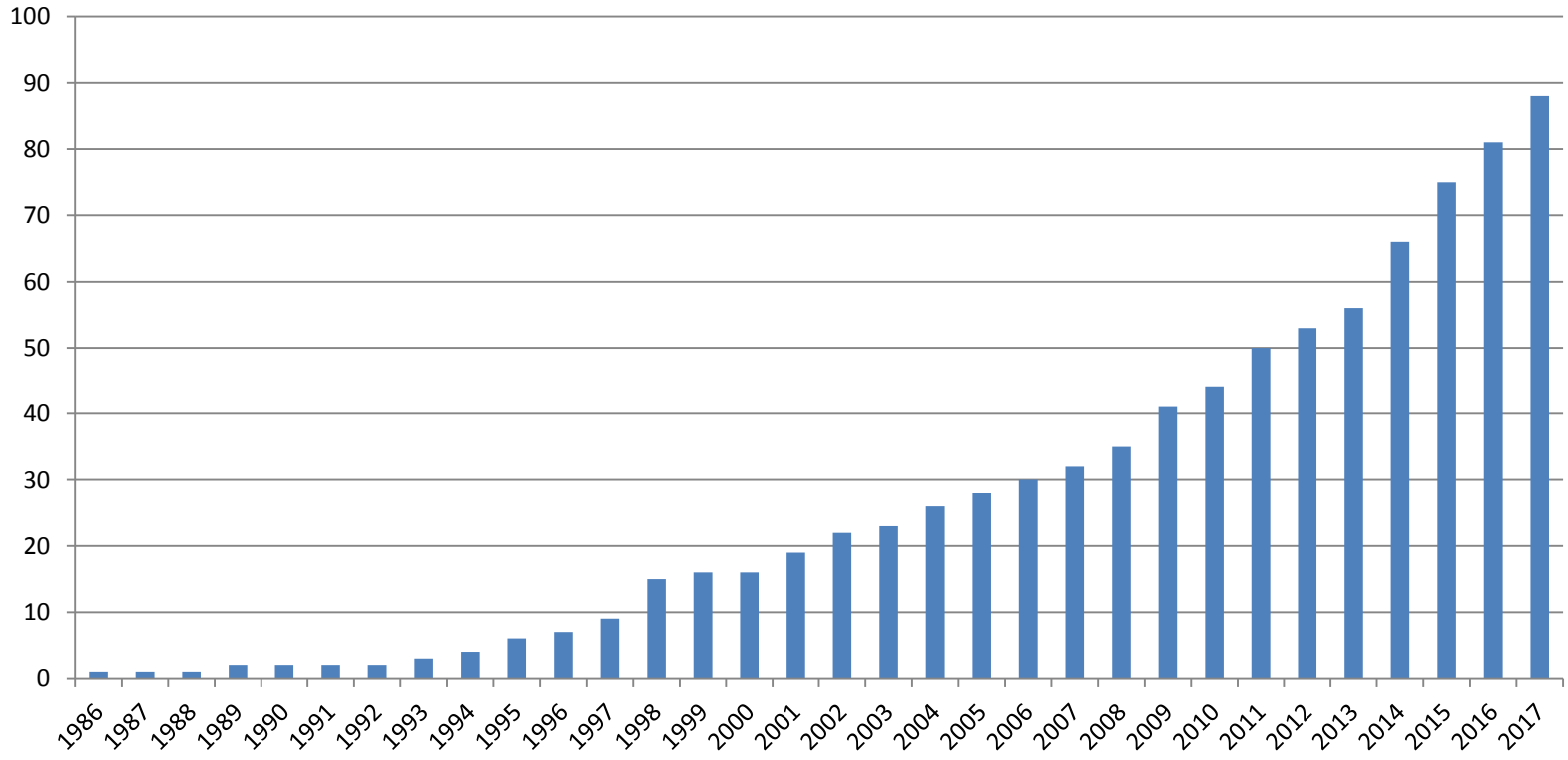
Number of therapeutic antibodies and immunoadhesins on the market



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Context

- Antibody drug discovery → sophisticated process
- Time to the market increase
- Significantly more costly to develop and produce
- *Begin with the End in Mind.* Stephen R. Covey

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Context

- The better the hit antibody initially meets the specifications → the higher the probability to make it to the market
- These antibody properties depend on how the antibody is developed

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Specifications of a therapeutic ab

- Format (100+)
- Functionality (activating, inhibiting, blocking)
- Specificity
- Species cross-reactivity (mouse, monkey)
- Stability / solubility
- Affinity
- Productivity
- ADA response

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Formats

- Full-length mAbs
- Bi-specific mAbs
- ADC
- sdAb (VHH)
- Other (ScFv, Fab, polyclonal, Fc-fusion proteins…)

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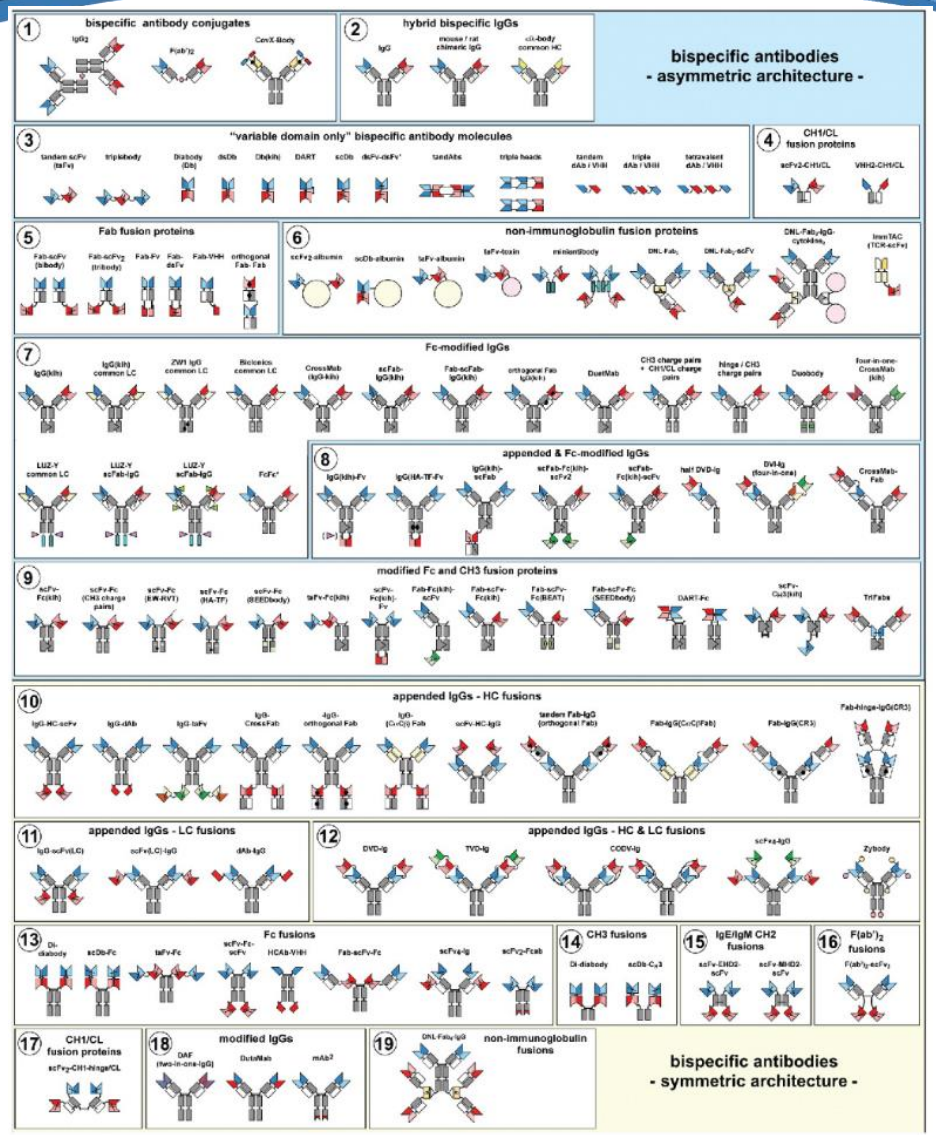
100+ BsAb Formats

International experts



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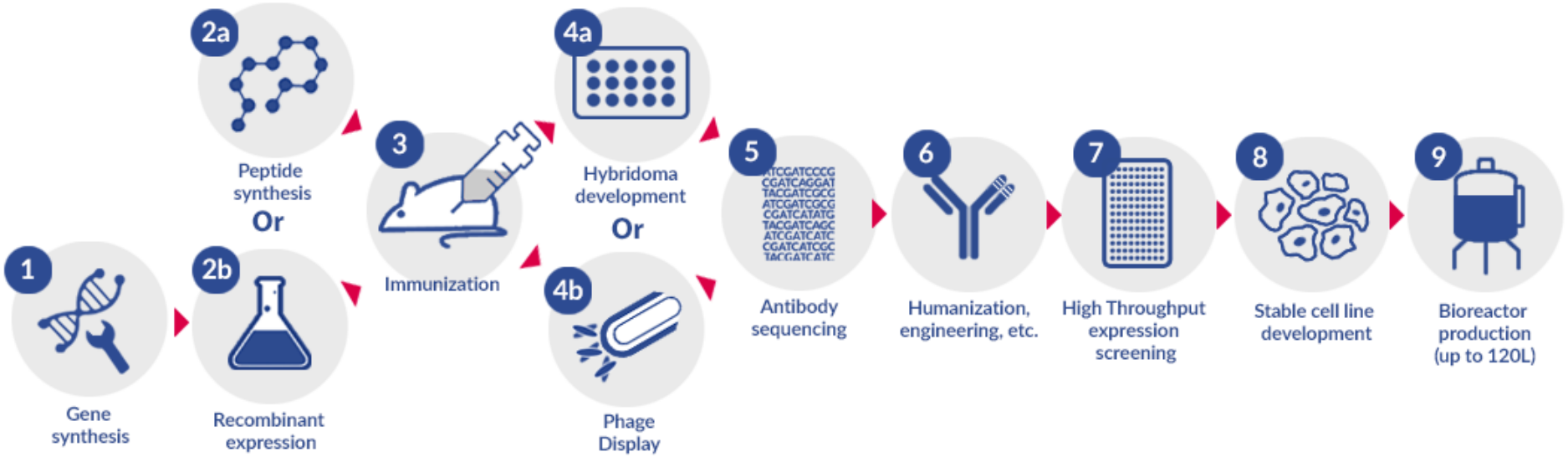
How to develop therapeutic mAbs FlowChart example



Antigen (Target) choice

- The choice of the right antigen is decisive
  - Functionality, affinity and specificity
- Native Protein, Recombinant protein, peptide, DNA (Genetic immunization)
  - Endogenous protein highest similarity
- Full-length, fragment…

Gene synthesis
To produce the antigen (target)

- Define the expression system
  - cDNA optimization
- Vector choice
  - Promoter, leader sequence
- Full-length vs fragment
  - Domain to produce, SIP, tag position, cleavage site

Antigen (target) production

- Cell line (HEK293, CHO)
- Tricky proteins → High throughput
  - SIP, tags, medium, culture conditions, feeding

Antibody development (hybridoma)

- Large number of clones required
  - Mice and fusions. Higher probability of having the expected featu
- Testing at parental stage
  - Subclone best clones
- Screening in several applications
- Hybridoma sequencing

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Antibody development (hybridoma)

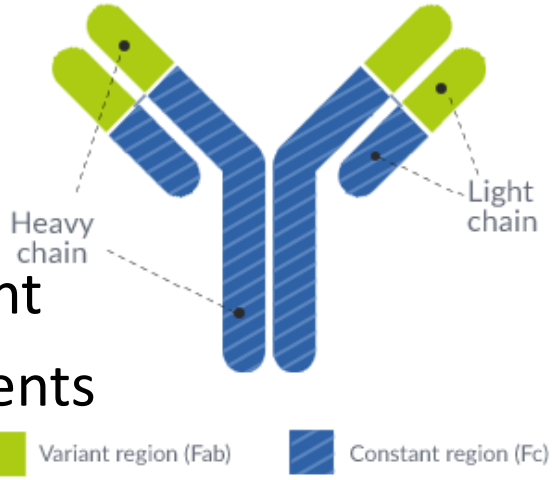
- Produce the recombinant version in HEK293, CHO cells or E.coli
- Compare affinity and functionality of hybridoma and chimeric recombinant version

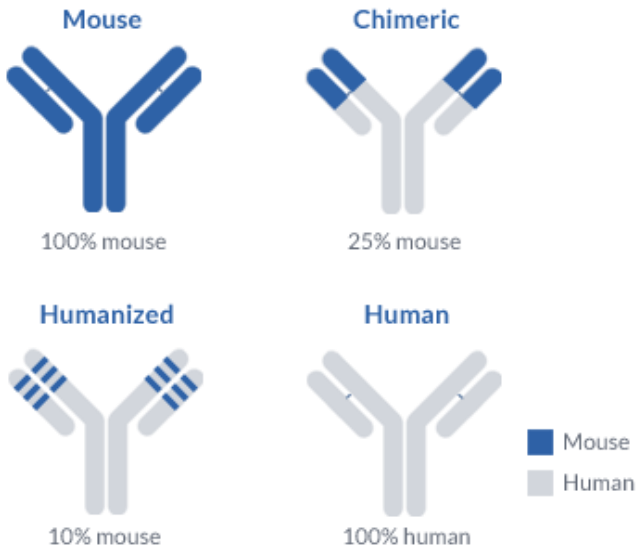
Antibody library screening
Phage display

- Pros: Selection of Human/VHH and recombinant, time, efficiency, toxic molecules
- Cons: affinity
- Naïve or Immune library screening (Fab, ScFv, VHH, species…)
- Key factor: quality (diversity) of the library

Antibody engineering

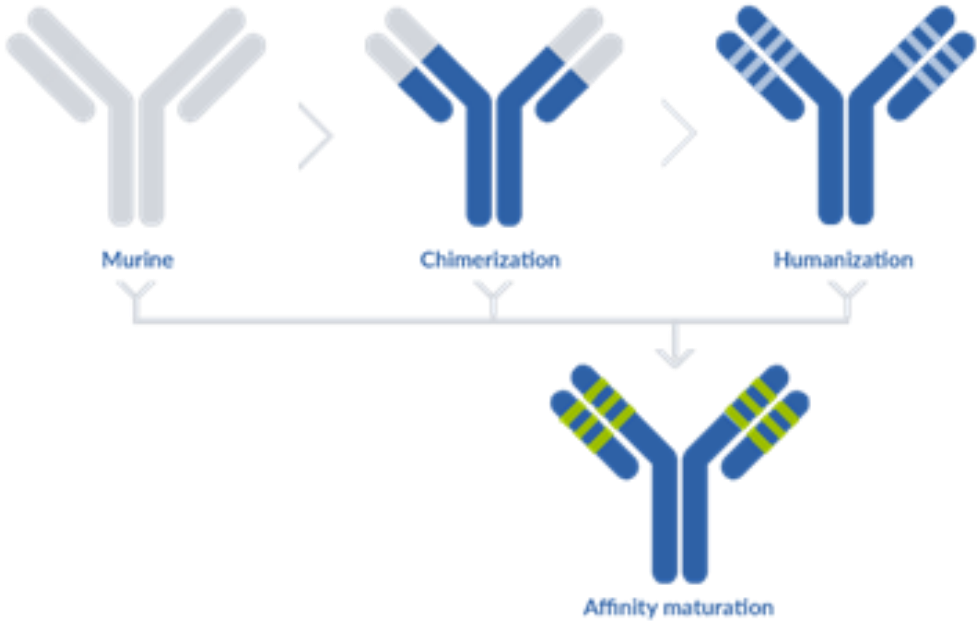
- Humanization
  - CDR grafting, reduce ADA
  - International experts
- Format development
- Stability improvements
  - 3D modeling





Affinity Maturation

- Random mutagenesis
  - Diversity up to 10^8 of new library
- Phage display



Hits characterization

- ELISA, WB, FACS
- Cross-reactivity to mouse and monkey targets
  - Generate surrogate antibodies
- Functionality analysis (*in vitro*)
- Aggregation
- Functionality in cell-based assay

Leads characterization

- Affinity determination
  - Biacore, OctetRed, SPRi
- Epitope mapping
- ADCC, CDC
- PK/PD analysis
- *In vivo* efficacy
- Toxicity studies

Stable cell line development

- Vector technology and transfection
- Choice of the cell line (CHO)
- IP conditions
- Selection marker (GS, DHFR)
- Productivity several g/L
- GMP transferable

Process development
Bioreactor production

- Medium optimization
  - Composition, anti-foam and shearing aspects
- Feeding strategies
- Process monitoring
  - pH, T°, gas streams, side components, product…
- Purification optimization
  - Increase recovery rate, quality and purity
- Fine-tuning

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Our services

- Protein production : 1 000+
  - 5 expression systems, stable cell line, fermentation, process development, High Throughput screening...
- pAbs production : 1 500+
- Peptide synthesis : 20 000+
- Gene synthesis : 5 000+
  - Starting 0,21€/bp, Gene optimization tool
- mAbs development : 200+
  - Hybridoma technology, Phage display, Antibody Engineering (Humanization, Bi-specific, ADC, ScFv, Fab, Fc-fused protein)

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  - increased success rate
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Thank You

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