WEBINAIRE

Bioproduction : enjeux stratégiques, réglementaires et logistiques

Mercredi 8 avril à 17h

BIOTHÉRAPIE INNOVATION OCCITANIE

AD'OCC Agence de Développement Économique

EUROBIOMED

L'EUROPE S'ENGAGE L'OCCITANIE AGIT

Cofinancé par l'Union européenne

La Région Occitanie Pyrénées · Méditerranée

BIOTHÉRAPIE INNOVATION OCCITANIE

www.agence-adocc.com/biotherapy-innovation-occitanie

Contact:
biotherapie@agence-adocc.com

Biotherapy & bioproduction in Occitanie: an integrated offer across the value chain

BIOTHÉRAPIE INNOVATION OCCITANIE

Bio'Occ · France 2030 · Université de Toulouse · Université de Montpellier · INSA Toulouse · IMT · GIP FCIP Académie de Toulouse · Inserm · olon France · Just Evotec Biologics · EUROBIOMED · SANAO

Leading academic stakeholders aligned to innovate and train

CeBBOc Cell Based Biotherapies Occitanie

Fundamental and translational research

Dedicated interfaces

France 2030

E Cell France For Regenerative Medicine · TIBH Toulouse Industrial Biotechnology for Health · OBBI · ENVT École nationale vétérinaire Toulouse

Integrators / Pre-clinical testing

Economic stakeholders gathered in BIOTHÉRAPIE INNOVATION OCCITANIE

LFB Biomanufacturing · cell easy · INITS SMO · olon France

CRO / CDMO / Industrials

Clinical partners

IHU HealthAge Geroscience & Prevention · Immun4Cure · SIRIC Montpellier Cancer · ICM Institut régional du Cancer Montpellier · Institut universitaire du cancer de Toulouse · CHU Toulouse · CHU Nîmes

Hospitals

TRL1 | TRL2 | TRL3 | TRL4 | TRL5 | TRL6 | TRL7 | TRL8 | TRL9

Research → Development → Manufacturing / Deployment → Patients

Additional Partners: La Région Occitanie Pyrénées · Méditerranée · toulouse métropole · Montpellier méditerranée Métropole · cnrs · cea · INRAE · EFS Établissement Français du Sang

Labelling / national visibility France 2030

Ambitions de la filière Biothérapie Innovation Occitanie

1 - Accompagner / Soutenir le développement éco des entreprises régionales
Favoriser les collaborations
Favoriser l'émergence de projets de grande envergure

2 - Soutenir la formation, Former, Attirer et Retenir les talents

3 - Soutenir la recherche, le transfert de technologies, la mutualisation et synergie des moyens entre académiques et industriels

4 - Créer une communauté, communiquer, faire rayonner la filière régionale au niveau international

Site web, page LK, veille AAP, newsletter
Annuaire des acteurs
Journée filière
Participation à des congrès nationaux de la filière
Accompagnements des entreprises

BIOTHÉRAPIE INNOVATION OCCITANIE

Actions de la filière Biothérapie Innovation Occitanie

Plus de 53 M€ d'aides régionales et nationales obtenues par les entreprises

Lancement de la filière BIO

CeBBOc
Cell Based Biotherapies Occitanie

Bio'Occ

OBBI
Occitanie Bioproduction Biotherapy Integrator

Immun4Cure

GT Organoide

biocat

BIOWIN
Driving health innovation

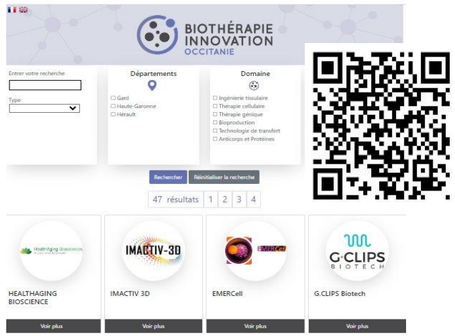
2019 2020 2021 2022 2023 2024 2025 2026 2027

Séminaire SRI

Cartographie Benchmark

Journée Filière

Page Web Annuaire



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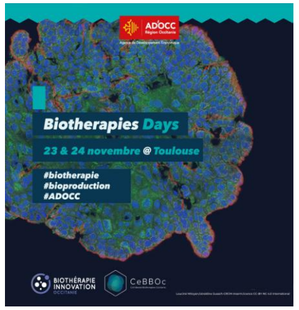

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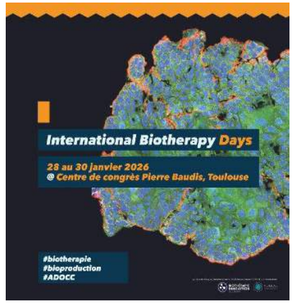
International BD



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Speakers of the day

Christelle ROCHON

Head of strategic partnerships & BD

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20 years of experience in pharmaceutical drug development
CMC Leader for Biotechs - Cell Bioproduction manager – Regulatory support – facility design
INITS

Fabian GROSS

Operational & Project Manager

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30 years of experience in Cell and Gene Therapy
Operational Manager of CIC BT and Project Manager in Biotherapy in CHU Toulouse
Clinical Center of Investigation in Biotherapy (CIC BT) of Toulouse/ CHU Toulouse

Christine DUTHOIT, PhD

CEO – CSO

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11 years research experience in immunology in France and the U.S. + 17 years in the biotech industry.
Project Manager in immunology and lentiviral vectors applications (in vitro / in vivo). Cell & gene biotherapy.
RNAlead

Agenda

BIOTHÉRAPIE INNOVATION OCCITANIE

Global roadmap

Pre-clinic

Clinic

Pharmaceutical development

Clinical trial application

Global Roadmap

Global Roadmap

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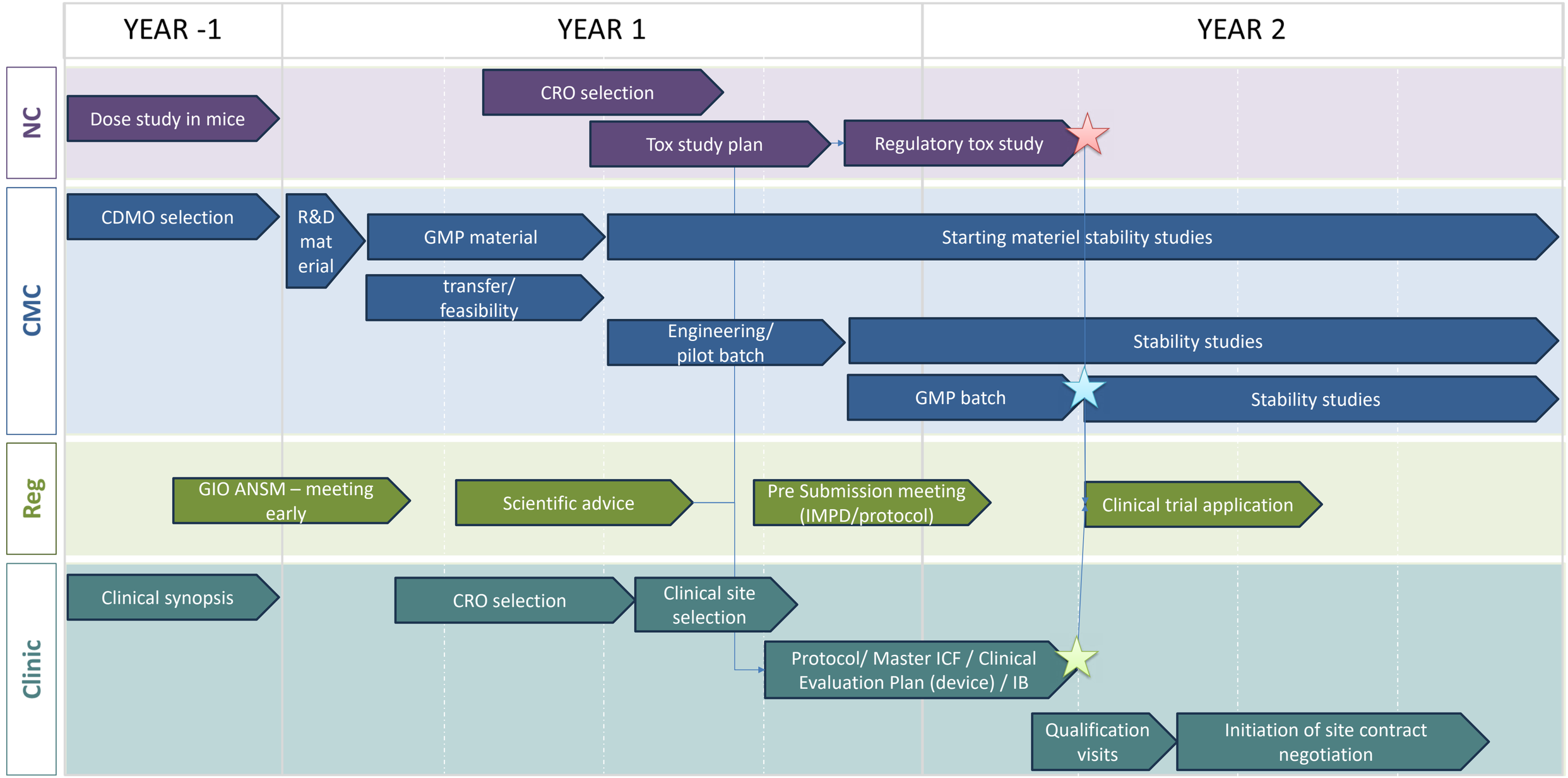

Quality Target Product Profile (QTPP) Building

QTPP: A prospective summary of the quality characteristics of the drug product that ideally will be achieved to ensure desired quality, safety, and efficacy.

Key Questions

- What is the intended indication and patient population?
- What is the optimal route of administration (IV, SC, oral)?
- What dosage form best supports safety, efficacy, and compliance?
- What are your purity, stability, and shelf-life targets?
- What is the required dosing frequency for efficacy and convenience?
- What is the safety profile you need to support regulatory approval?

Common Options

- Route: IV, SC, or oral
- Dosage Form: solution, lyophilized powder, capsule
- Strength: weight-based (mg/kg) or fixed dosing
- Frequency: weekly, bi-weekly, monthly, single administration
- Population: naive, relapsed/refractory, biomarker-selected
- Endpoints: ORR, PFS, OS, PD/safety biomarkers

One product – one QTPP

Attribute	Target A – (Biologic, IV, cancer)	Target B – (Small Molecule Oral, Migraine)
Indication	Advanced/metastatic endometrial cancer	Acute treatment of migraine in adults
Dosage Form	Sterile injectable solution	Oral tablet or capsule
Route of Administration	Intravenous (IV)	Oral
Dosing Frequency	Every 2 weeks (Q2W)	Single dose or BID during episodes
Strength / Concentration	14 mg/kg and 20 mg/kg	50 mg, 100 mg fixed doses
Purity	≥ 95% by HPLC	≥ 98% chemical purity
Sterility / Pyrogenicity	Sterile, endotoxin-free	N/A (oral solid form)
Stability / Shelf-life	≥ 12 months at 2–8°C	≥ 24 months at room temperature
Target Population	Adults post-standard therapy failure	Adults with episodic migraine
Safety Profile	No DLTs; manageable AE profile	Mild AEs (e.g. nausea, dizziness)
Efficacy Expectations	Disease stabilization or partial response (≥ PR per RECIST)	Relief within 2 hours

Strategic positioning - Product Designation

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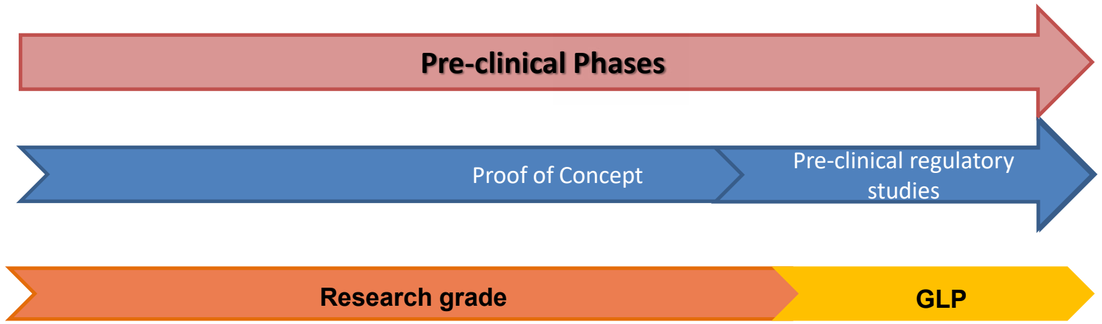
Designation	Region	Purpose	Key Benefits
Orphan Drug Designation (ODD)	US, EU	For rare diseases (US: <200,000 patients; EU: <5 in 10,000)	Fee waivers, protocol assistance, tax credits (US), 7 years (US) / 10 years (EU) market exclusivity
Compassionate Use / Expanded Access	US, EU	Allows early access to investigational products for patients in need	May provide access outside of clinical trials under strict conditions
Pediatric Rare Disease Designation	US	Subset of ODD for rare pediatric diseases	Priority Review Voucher (PRV), market incentives
Fast Track	US	Speeds development of drugs for serious conditions with unmet needs	Rolling review, frequent FDA meetings, potential eligibility for Accelerated Approval
Breakthrough Therapy	US	For drugs showing substantial improvement over existing therapies	Intensive FDA guidance, senior managers involved, rolling review, eligibility for Priority Review
Regenerative Medicine Advanced Therapy (RMAT)	US	For regenerative therapies addressing serious diseases	Similar to Breakthrough Therapy designation; includes early interactions and guidance from FDA
Accelerated Approval	US	Based on surrogate/intermediate clinical endpoints	Early approval with post-marketing confirmatory trials required
Priority Review	US	For drugs offering significant advances in treatment or public health	FDA review goal reduced from 10 to 6 months
Conditional Marketing Authorization (CMA)	EU	Early access to medicines that fulfill unmet needs, based on less complete data	One-year renewable authorization, must submit full data post-approval
PRIME (PRIority MEdicines)	EU	For promising medicines with major therapeutic advantage	Early and proactive EMA support, accelerated assessment
Pediatric Designation / PIP	EU	Ensures medicines are appropriately studied in children	Mandatory Pediatric Investigation Plan (PIP); up to 6 months additional patent/ Supplementary Protection Certificate (SPC) protection & 1 year market protection
Accelerated Assessment	EU	Shortens EMA evaluation for innovative medicines	EMA review time reduced from 210 to 150 days

Pre Clinic

Pre Clinic



TRL = Technology Readiness Level – TRL appliquées au domaine pharmaceutique								
1	2	3	4	5	6	7	8	9
Basic principles observed	Technology concept formulated	Experimental proof of concept	Technology validated in lab	Technology validated in relevant environment	Technology demonstrated in relevant environment	System prototype demonstration in operational environment	System complete and qualified	Actual system proven in operational environment
Basic Research	Research ideas and protocols	Initial proof of concept (in vitro & in vivo models)	PoC and safety	Preclinical studies (GLP) + toxicity	Clinical Phase 1	Clinical Phase 2	Clinical Phase 3	Post Market Studies and Surveillance
RESEARCH			DEVELOPMENT			DEPLOYMENT		

From POC to pre clinical studies

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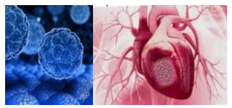
Questions to ask as soon as possible



Status of the Investigational Medicinal Product (IMP):

- **Cell or Tissue therapy:**
  - Stem or somatic cell
  - Autologous or allogenic
- **Gene Therapy:**
  - in vivo or ex vivo
  - Control of transgene expression
- **Combined :** activity of the Medical device

Development of an ATMP

- Integrated approach
- Early planning
- Process and quality control
- Appropriate scientific, medical and regulatory strategy

Mechanism of action (MoA) ➔ Potency assay

Active dose ➔ first in Human (FIH)

Production for Human use ➔ scale up, research grade to GMP

Administration to the patient ➔ route of administration, unique, repeated

Study **population** ➔ Eligibility criteria

Standard of care ➔ Control group

Concomitant and associate medications, pre medication ➔ impact on the IMP

Regulatory preclinical studies in animals

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2 animal models (small and large, rodent and non-rodent) if possible

Primary or organ toxicity in animals (mice in general):

- Systemic injection in increasing doses to determine systemic organ toxicity (♂ and ♀)
- Calculation of the first dose to be injected in humans (FIH)

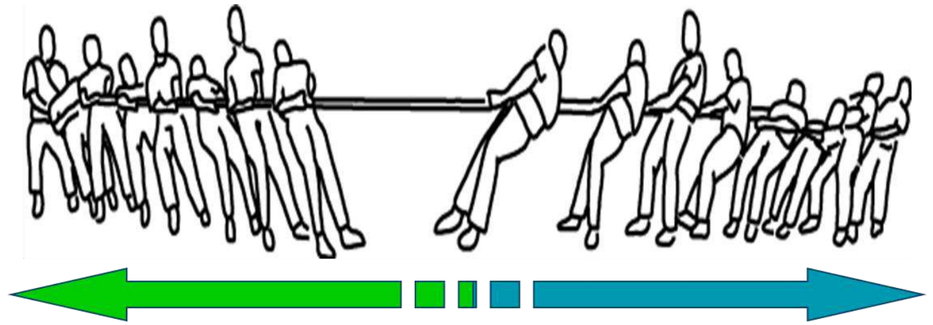
Toxicity and Biodistribution (♂ and ♀)

Injection according to the route of administration (IV, IT, SC, ID, etc.)

Expected frequency in humans (single or repeated),

Animal model of human pathology

- Acute (short term) (D2 to D7)
- Persistence or long term (D30 to D120)



No Observed Adverse Effect Level (NOAEL) ou seuil de toxicité≈ seuil de tolérance

Minimal Anticipated Biological Effect Level (MABEL) ≈ seuil d'efficacité

Tumorigenicity to assess the tumorigenic potential of the injected finished product

Immunogenicity to assess the immune response to the product or induced factors, particularly in the case of repeated injections

Non clinical development
For ATMPs significantly different from other products

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Define the effective dose, identify potential toxicity, determine biodistribution and evaluate pharmacokinetics

Choice of the Animal model: disease similar to human pathophysiology and condition of the patient

- Same animal in toxicology and pharmacokinetic studies, both gender
- Disease models ➔ clinically meaningful safety data, eligibility criteria, follow up and monitoring of patients
- Small Animal models useful but extrapolation to human becomes challenging ➔ large animal models
- One animal species if strong predictive model

Toxicity objective: Generate clinically meaningful and relevant data to support safe of the product in the clinical indication and patient population.

- Single-dose toxicity studies and post-dose observation period, Repeated dose toxicity
- Concomitant medications could have an impact on MoA or drug product
- In silico, in vitro and/or ex vivo data: substitute or supplement animal data
- Non-clinical safety in GLP but possible to conduct biodistribution studies in not full conformity ➔ justification

Cell and Tissue Engineering product: Immune response against Human cells

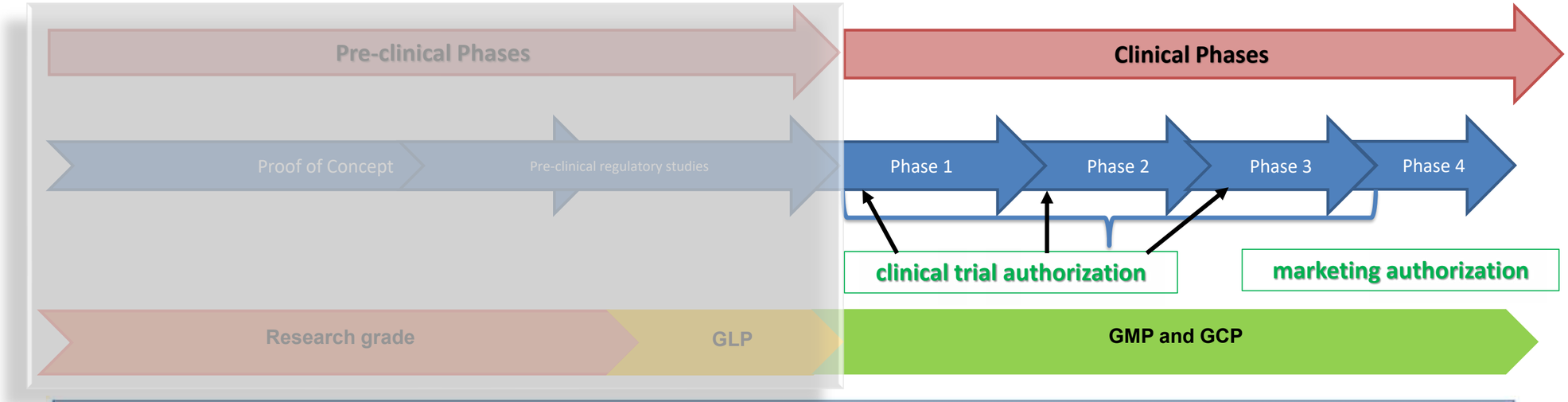
Gene Therapy Viral vector:

- Host and cell tropism
- Integrative vector
- Risk of competent replication vector/virus
- Human gene expression product

Immunodeficient animal model or Humanized animal models

Clinic

Clinic



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European Regulation

General regulatory framework

- Directive 2001/83/EC relating to medicinal products for human use, amending by the directive 2004/27/EC
- Regulation 1394/2007: specific to Advance Therapy Medicinal Products (ATMPs), introduces enhanced requirements for manufacturing, traceability and pharmacovigilance.
- Regulation 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use
- Regulations 2017/745 for Medical Device and 2017/746 for In Vitro Diagnosis medical devices.

Clinical Trials of Drugs	Clinical Investigations of Medical Devices
European Regulation n° 536/2014	European Regulation n° 2017/745

3 main objectives:

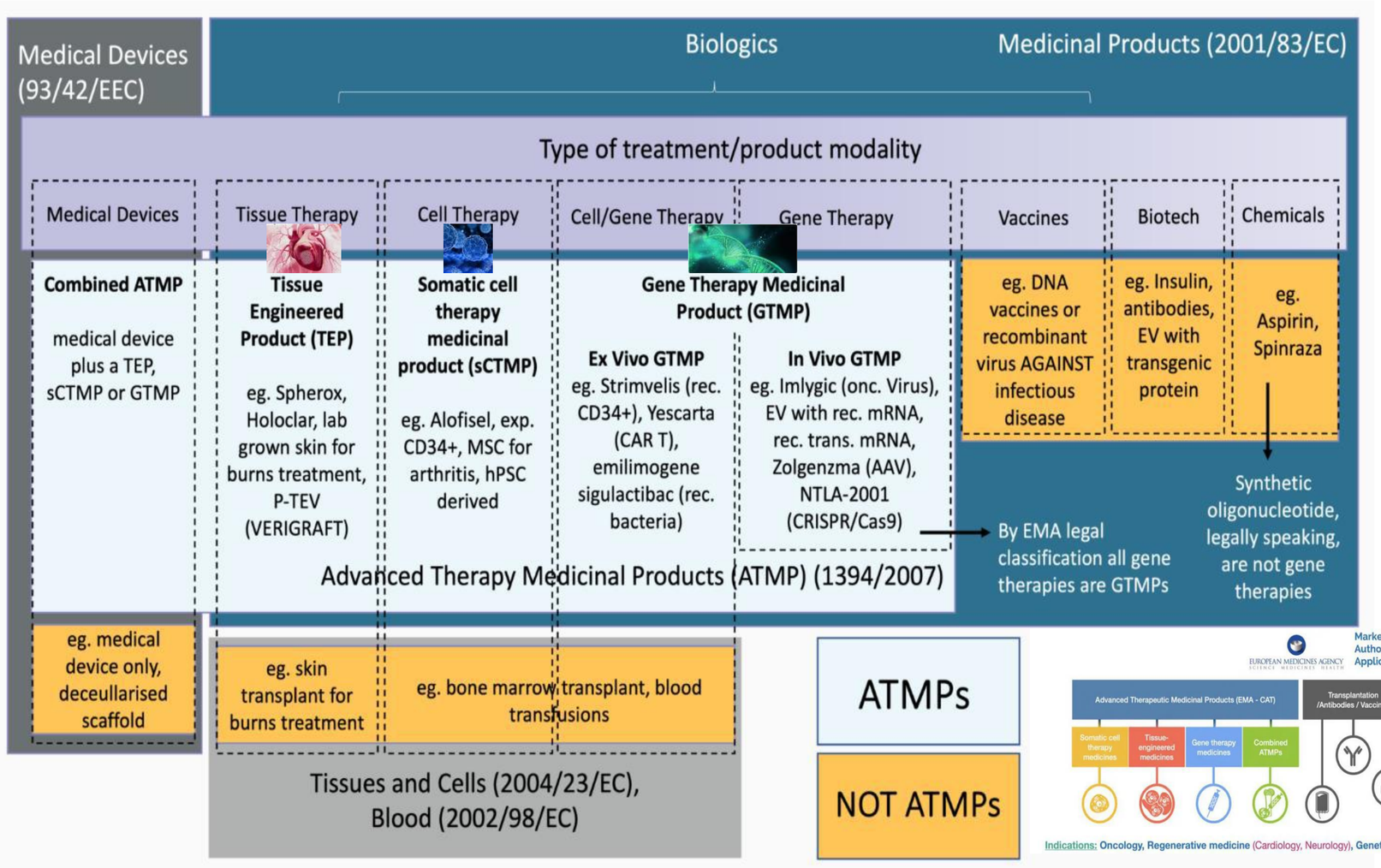
- Facilitate patient access to new treatments
- Strengthen the attractiveness of Europe for clinical trials
- Increase transparency and access to data

Harmonise and simplify clinical trials:

Processes of submission, Evaluation and monitoring of the patients

- Single dossier, Single submission
- Single evaluation 128 days (+10 days revue for each competent authority of each country participated)
- Review by each relevant Ethics Committee for each country

Advanced Therapy Medicinal Product (ATPM)



European Regulation of ATMPs EC 1394/2007 of the 13 November 2007

- Creation of the Committee for Advanced Therapies (CAT), confirms the innovative nature of Cell and Gene Therapies: assessment of ATMPs
  - Quality, Safety and Efficacy
  - Classify products

- Establishes a legal definition of tissue engineering products and combined ATMPs:
  - Develops and improve the quality and safety
  - Introducing safety and efficacy monitoring requirements
  - Following scientific developments in the field

- **Facilitates** and **stimulates** research on ATMPs and ensures market access for all European Union Member States

Regulatory approach: a dual regime, a dual responsability

Opinion of the Ethics Committee

Relevance of the research
Protection of participants
Assessment of the benefit/risk balance
Information and consent of participants

Authorisation by the Drug Safety Agency

Safety and quality of products used on persons undergoing research
Quality and conditions of production and use of experimental drugs
Medical acts performed, methods used and monitoring of participants

Principal Investigator

Qualified person trained in Good Clinical Practice (GCP)
Directs and supervises the clinical trial at the investigation center
Scientific and ethical quality responsibility
Recruitment and monitoring of enrolled participants
Has a team and the equipment necessary for the running of the study.
Ensures the safety of volunteers in accordance with ethics and the law

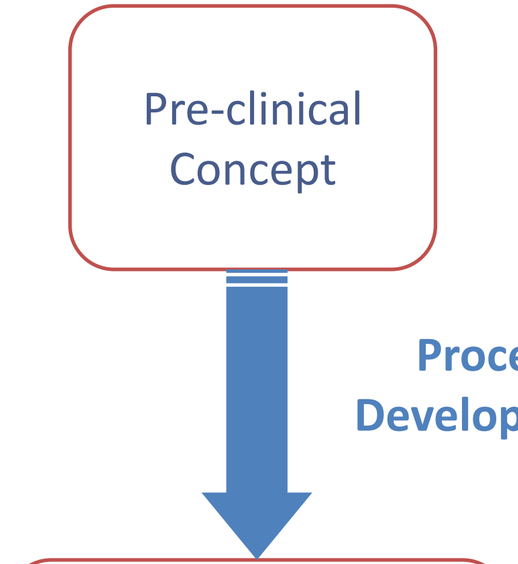
Sponsor

Natural or legal person
Assumes responsibility for setting up a study
Manages and finances
Authorisation from the competent authorities
Selects investigators and clinical centers
Ensures the quality of the data collected Informs the CAs of any new developments concerning investigational medicinal products

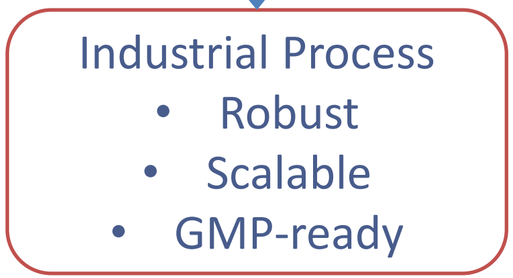
Pharmaceutical development

Process development

Process development enables the transition from a preclinical concept to an industrial process.



Process Development



- Compliancy with regulatory
- Optimisation of production yields
- Garanty target quality defined in the QTTP
- Cost-effective

- **Importance of Quality controls**
  Product charactireization ; impurities ; activity…
- **Key role of iPCs**
  Yields, Process understanding, Product safety…
- **Using DoE**
  Increased yields and predictability during scaling

Process development

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« Start with the end in mind »

- Integrate GMP culture starting at the early stages
5P Principles : People ; Products ; Processes ; Procedures ; Premises

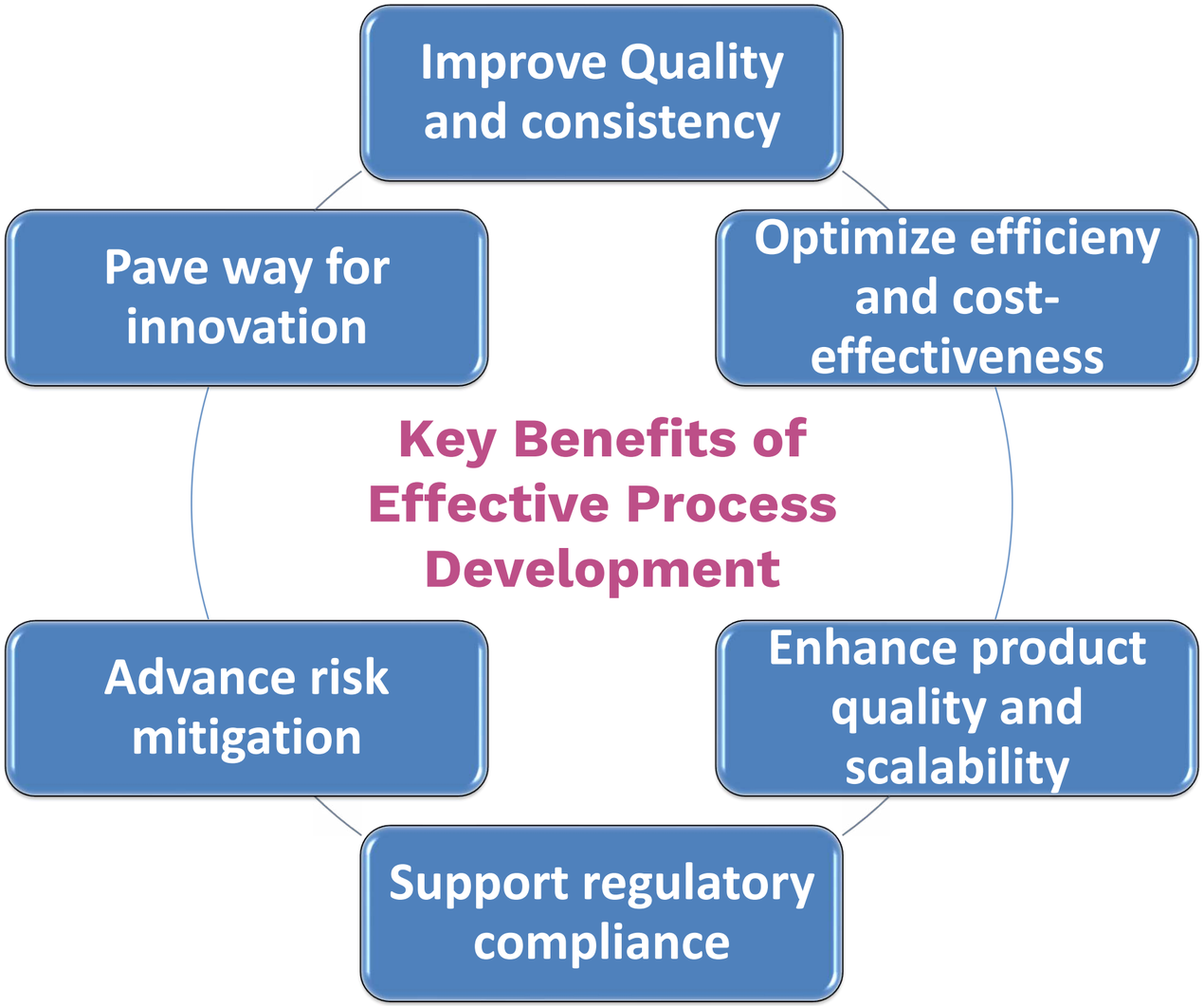
- Define **Critical Process Parameters (CPP)** and **Criticals Quality Attributes (CQA)**
(in anticipation of the validation, verification, and documentation of these steps)

- Build a process « **scalable** & **transferable »** to a CDMO
Selection of equipment and critical supplies/consumables (GMP-compliant supplier)
Description of the process : process map ; Technology Transfer Package

- Incorporate **Regulatory Considerations**(IND/IMPD readiness)

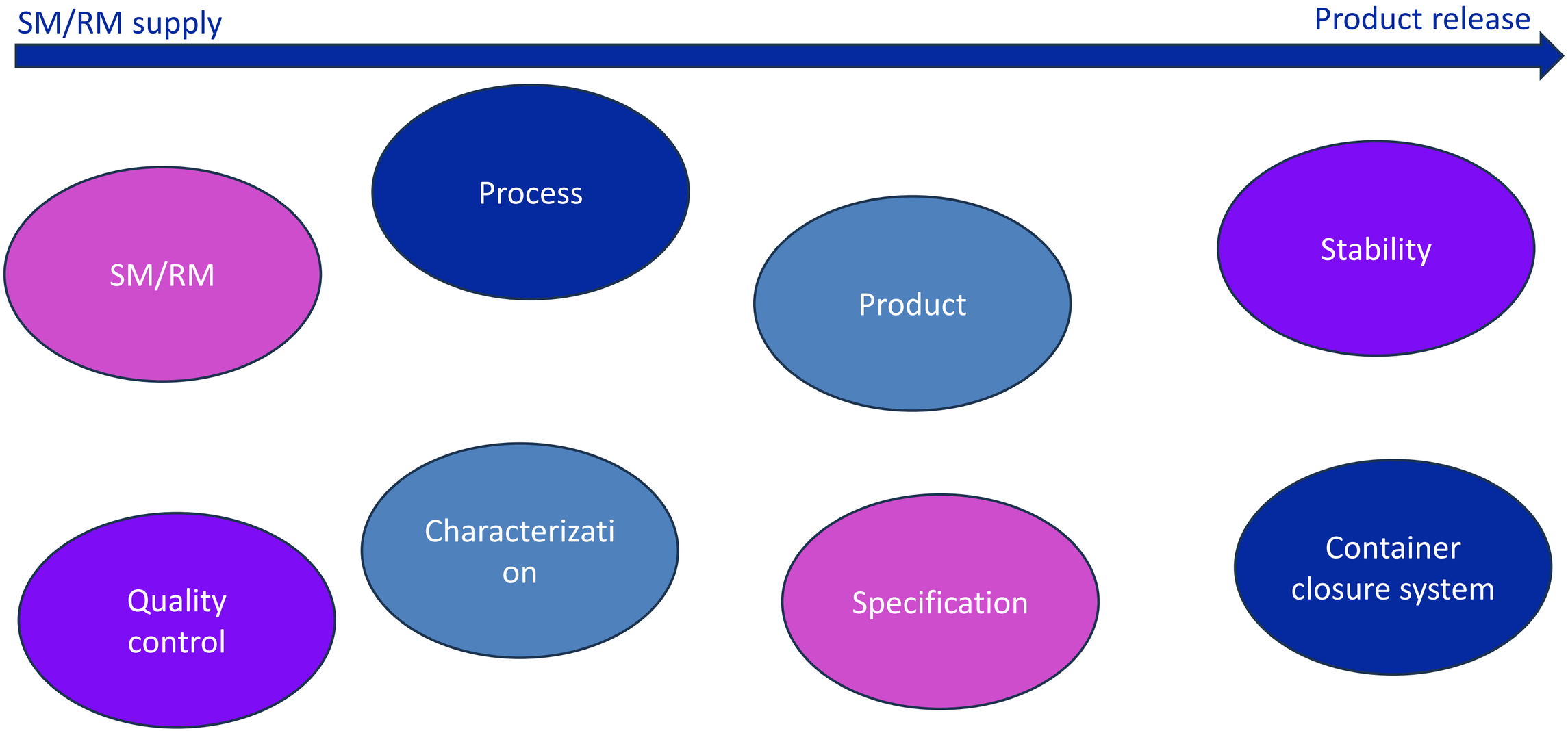
Develop a robust process that achieves the desired yields
But keep in mind: easy to operate, easy to document, easy to transfer

Process development



CMC

CMC: Chemistery, Manufacturing and Control : Scope



Prerequisite for clinical batch production

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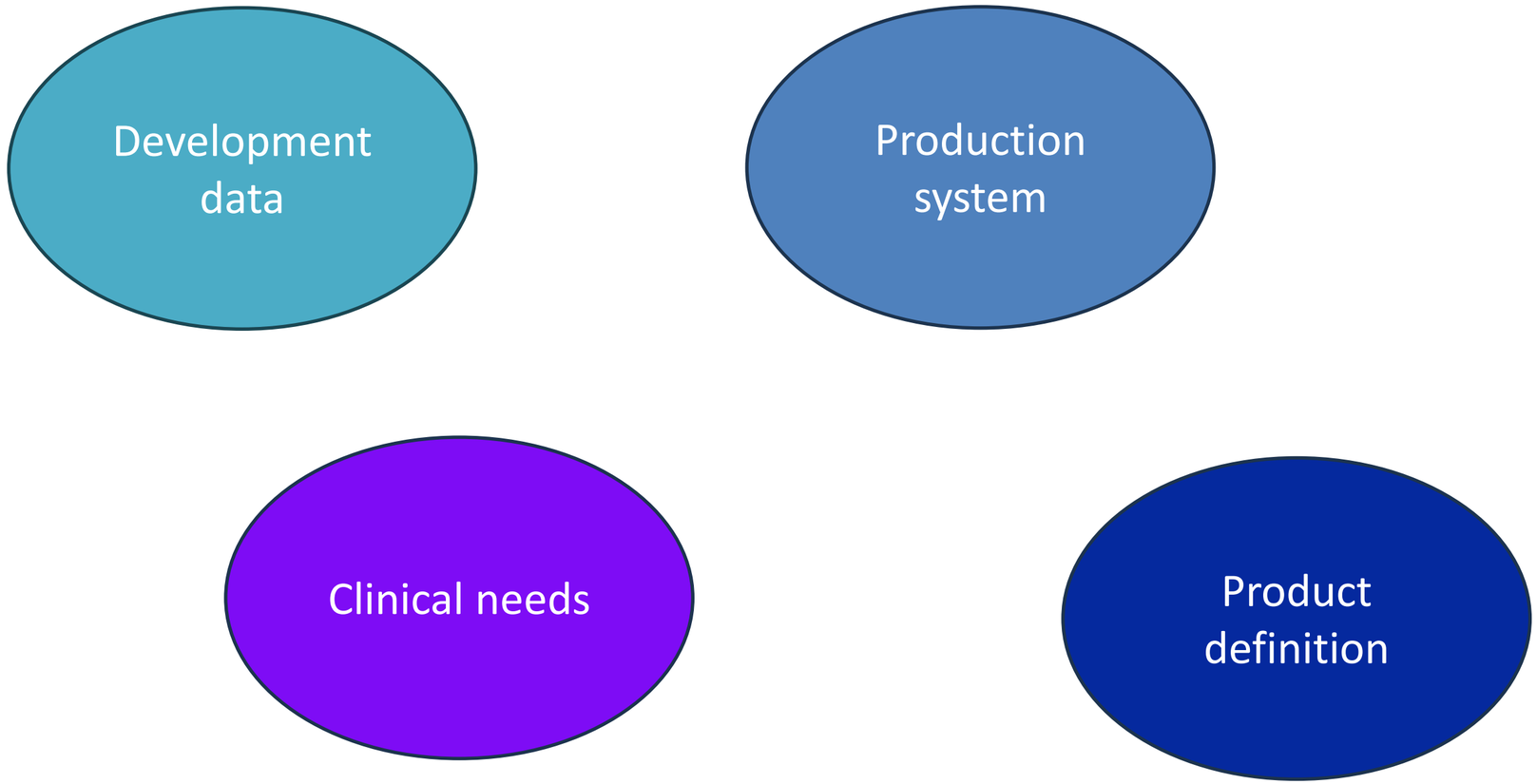
At least:

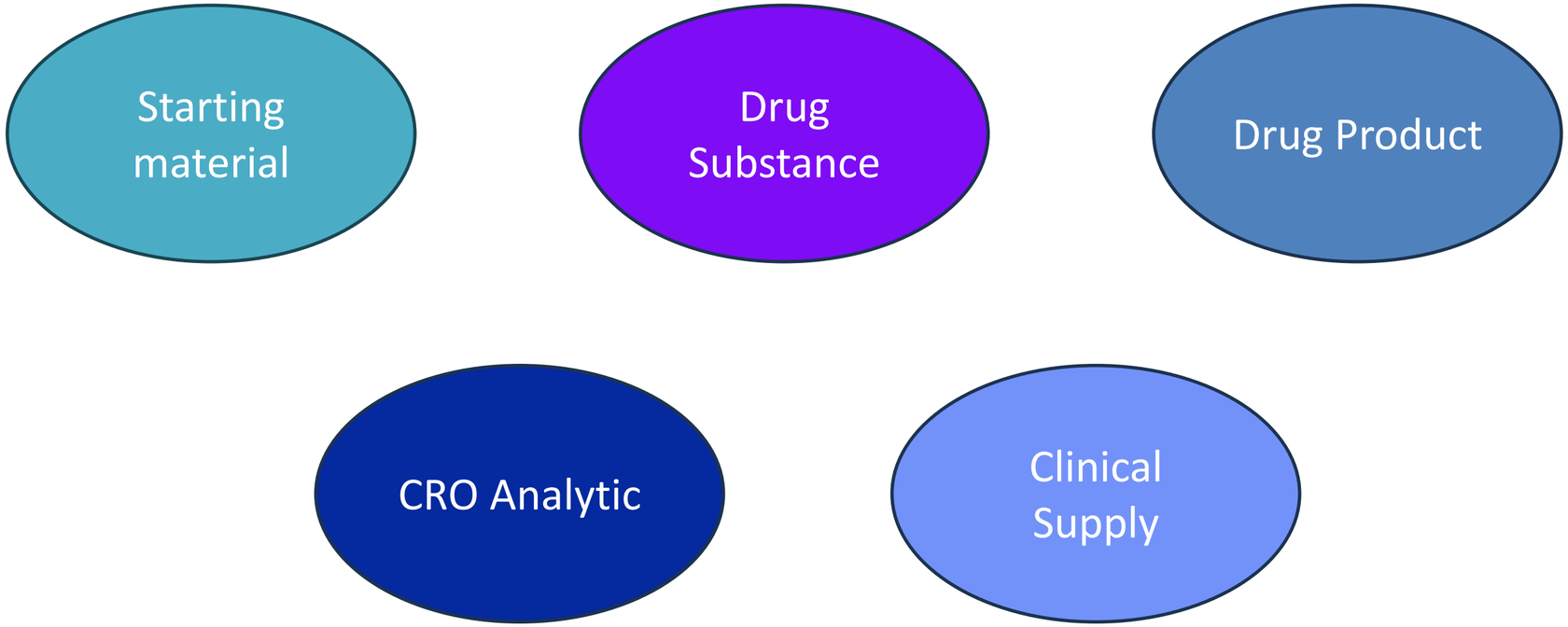


CDMO selection

Manufacturing options

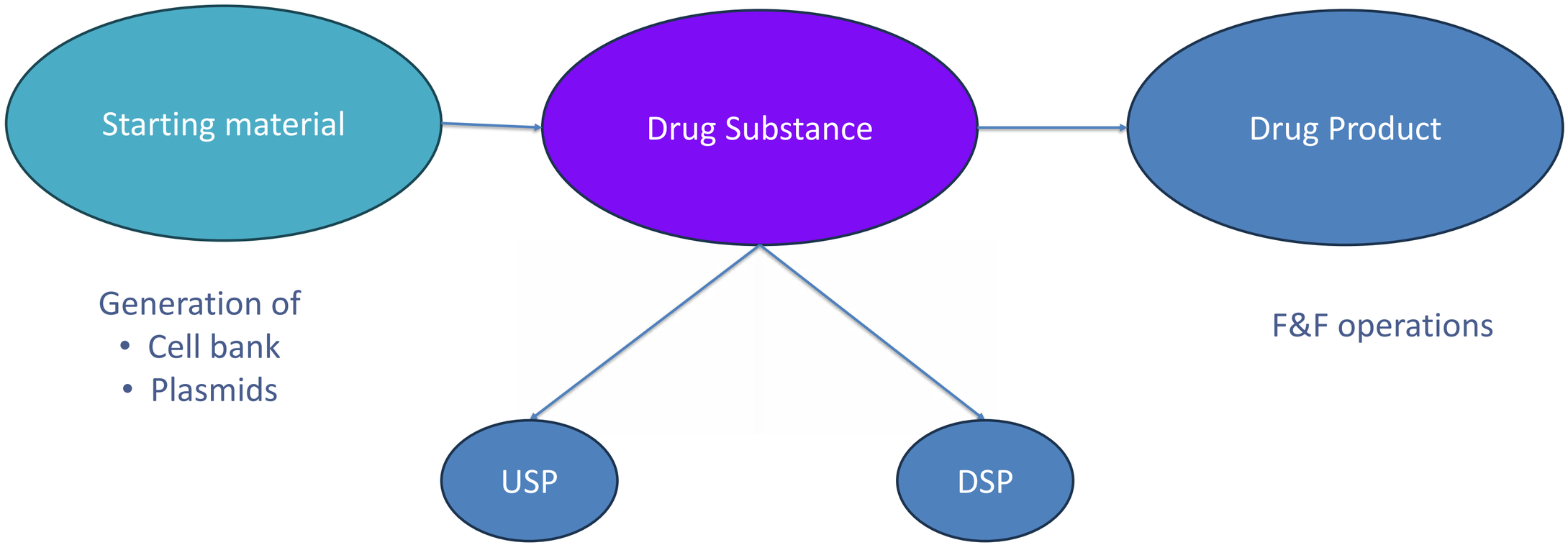
In house	CDMO	SMO
• Full control over process and IP • Flexibility • Risky, expensive • Lack of expertise and *"GMP culture"*	• Access to Expertise • Scalability • Process platform • Know-how risks • Less flexible	• Full control over process and IP • Flexibility • Costless • Sponsor should have process dev team
Sponsor with high & secure fundings Multiple products Process Dev team	Sponsor with classic product (AAV/mAb..) No development resources	Sponsor with non classic product Process Dev team Specific know how

One or more CDMOs ?



Be careful to limit the number of subcontractors !

Production steps



Generation of
- Cell bank
- Plasmids

F&F operations

Upstream process
Production of the product

Downstream process
Product purification and formulation

Starting material quality grade

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Cell bank

⇒Phase I/II: GMP MCB sufficient – WCB not required at this step

⇒MCB should be done from RCB/ cell for which you are able to file the cell line history

Plasmids (Gene Therapy)

⇒GMP MCB

⇒Phase I/II: High quality grade plasmids sufficient

Other raw materials

⇒As much as possible : animal origin RM to be avoid, if not: ensure product safety (TSE/BSE certificate, CoO, irradiation status….)

⇒GMP or high-quality grade

Product production

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Process transfer : transfer run

- To ensure reproducibility of you process in the CDMO in non-GMP
- To generate material for method implementation and reference standard
- For tox studies

Pilot/Engineering run

- To ensure reliability of the process in GMP environment
- To generate data for production specification
- To generate stability data to define product shelf life
- For tox studies

GMP clinical batch

- To file CTA application
- To generate data for specification/ stability studies

Analytical transfer, development and qualification

- Method ready in GMP QC for batch analysis
- Only safety method should be fully validated
- Other method should be qualified
- Activity often underestimated

ICH Q2(R2)

Stabilities studies

- To define product shelf life
- To be done on at least on the 3 first batches

ICH Q1A

Control Strategy Cell Bank - Biologics

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Safety

Sterility

Endotoxin

Mycoplasma

Test of specific viruses

In vitro cell culture infectivity assays

Adventitious agent detection

Endogenous retroviruses

Karyotype*

Tumorigenicity*

* On diploid cells

Identity/ Purity

Genotypic assay

Phenotypic assay

Quality

Cell viability

Cell recovery

Potency**

Functionality

Impurities

Process related impurities

Product related impurities **

** For cell therapy products

Up to 4 months for a full MCB characterization!

Example of control Strategy DS & DP

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Release testing

DS

- **Safety** — Bioburden, Endotoxin, Mycoplasma, Adventitious agent (harvest)
- **Identity** — Product dependent
- **Purity** — Product dependent: process and product related impurities

DP

- **Safety** — Sterility, Endotoxins, Any relevant safety assays, CCIT
- **Identity** — Product dependent
- **Purity** — Product dependent
- **Strenght** — Product dosage
- **General** — pH, Osmolality, Appearance, Extractable volume
- **Potency** — Product dependent

IPC/ Characterization assays

All relevant assays to monitor the process and/or to product knowledge

ICH Q6B

Stability studies

Starting material

On plasmid and cell banks: to be anticipated but for phase I/II can be covered during their use for production

Drug substance

To cover holding step

Drug product

- Long-term stability studies => to cover product shelf life
- Accelerated stability studies => to cover product shelf life and temperature excursion
- In use stability => to cover product stability when product delivered to the patient
- Freeze/thaw stability study => to save material for stability study or QC testing

For tox batch : product stability might be required by CRO

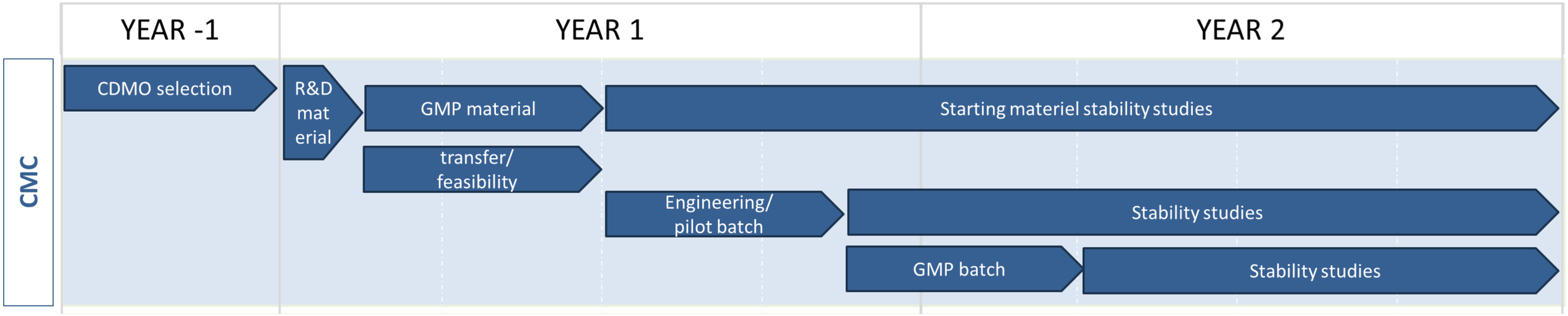
Quality

Sponsor has the final responsibility of the oversight of the regulated activities (under GMP/GCP/GLP => GxP)

Need to set up a **Q**uality **M**anagement **S**ystem to:

- Manage Subcontractors
- Audit
- Quality event management (Deviation, Change control…)
- GxP training
- Documentation management and operational procedure
- Regulatory vigilance
- Set up of QA with CDMO

CMC summary



CMC take home messages

⇒ Traceability of development data – Key of success

⇒ CDMO selection is a critical step

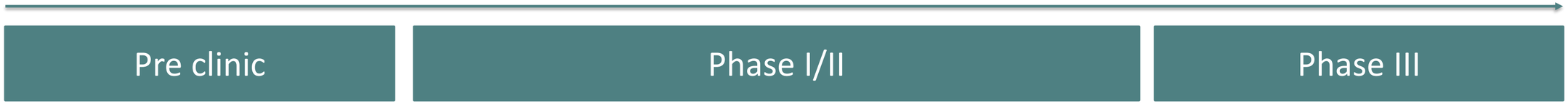
⇒ Analytics to be anticipated

⇒ Choice of batches for preclinical regulatory studies

Regulatory

Scientific advice

Pharmaceutical development



Agency meetings – EMA, FDA or national competent authorities

Scientific advice early stage to secure the CMC strategy

Scientific advice Lifecycle (*i.e.* CMC changes/challenges)

Scientific advice to prepare MAA

- Voluntary but highly recommended
- To clarify **regulatory expectations** early in development

Clinical Phases

BIOTHÉRAPIE INNOVATION OCCITANIE

Phase I	Phase II	Phase III	Phase IV
Sécurité Dose maximale tolérée, pharmacocinétique	Immunogénicité Sécurité Relation dose/effet	Efficacité Sécurité	Pharmaco-épidémiologie
1ere administration chez l'homme	Définition de dose	Études « pivot » pour le dossier d'enregistrement	Etudes Post-AMM
N = dizaines	N = centaines	N = milliers	N > 10 000

Exploratory phase : FIH clinical Trial

BIOTHÉRAPIE INNOVATION OCCITANIE

Primary Objective : Safety and Tolerability

The identified risks must be taken into account when selecting the target population and monitoring patients enrolled in clinical trials.

Safety

Adverse events (expected and unexpected)

- Frequency, duration and severity
- Possible persistence of the product or immunogenicity
- Potential malignant transformation, genotoxicity
- Risk of virus shedding and germ transmission
- The need for long term efficacy and safety follow up
- Administration procedures/delivery
- Shipment and handling requirements

Tolerability

Key concepts of dose finding/escalation

- Dose for FIH studies based on Non-Clinical data
- Dose finding starts with FIH study, dose escalation
- Evaluation of the correlation between exposure and effect
- Absence of dose finding should be thoroughly justified in the trial protocol
- Repeated injections : choice of the waiting period between the staggered administrations (time course, nature, subacute toxicities)

Clinical Trial Authorisation

BIOTHÉRAPIE INNOVATION OCCITANIE

Setting up an ATMP clinical trial ➔ rigorous process, scientific, ethical and regulatory requirements

Investigator and sponsor

Clinical protocol

- Identification of medical need
- Definition of objectives (primary and secondaries) and evaluation criteria
- Analysis of scientific and clinical context
- Definition of patient eligibility criteria
- Follow-up and monitoring
- Pharmaceutical circuit
- DSMB
- Adverse events

Manufacturer and sponsor

IMPD (Innovative Medicinal Product Dossier)

- Part 1 and 2: Process and Quality
  - Raw and starting materials
  - Drug substance and drug product process,
  - Quality control
  - Stability
- Part 3: Preclinical studies
  - Toxicity, biodistribution, tumorogenicity, genotoxicity
- Part 4: Clinical studies
  - Product
  - Pathology

IND Module 3/IMPD

DS

3.2.S.1. General Information
3.2.S.2. Manufacture
3.2.S.3. Characterization
3.2.S.4. Control of Drug Substance
3.2.S.5. Reference Standards or Material
3.2.S.6. Container Closure System
3.2.S.7. Stability

DP

3.2.P.1. Description and Composition
3.2.P.2. Pharmaceutical Development
3.2.P.3. Manufacture
3.2.P.4. Control of excipients
3.2.P.5. Control of DP
3.2.P.6 Reference Standards or Material
3.2.P.7 Container Closure System
3.2.P.8. Stabilty

A

3.2.A.1. Facilities and Equipment
3.2.A.2. Adventitious agents safety evaluation
3.2.A.3. Excipient
3.2.A.4 Solvent for reconstitution and diluents

R

Regional information

>50 subsections
> 500 pages

www.agence-adocc.com/biotherapy-innovation-occitanie

WEBINAIRE

Bioproduction : enjeux stratégiques, réglementaires et logistiques

Mercredi 8 avril à 17h

BIOTHÉRAPIE INNOVATION OCCITANIE

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