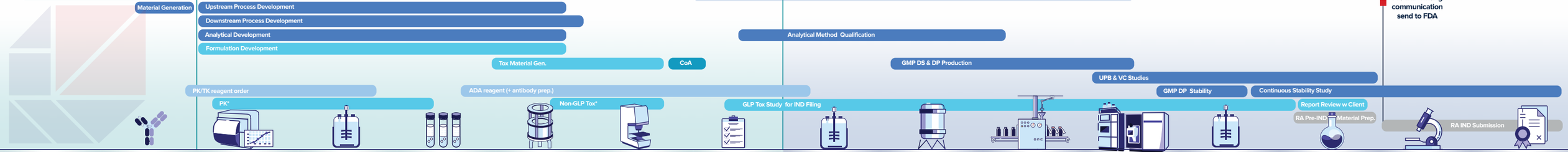
DEVELOPMENT

MANUFACTURING AND TESTING

3 MONTHS

12 MONTHS

Transient Production
Molecule Assessment
Material Generation
Cell Line Development (Including Cell line Stability)
Upstream Process Development
Downstream Process Development
Analytical Development
Formulation Development
MCB Creation & Release Test
Tox Material Gen.
CoA
Analytical Method Qualification
GMP DS & DP Production
UPB & VC Studies
GMP DP Stability
Continuous Stability Study
Pre-IND writing communication send to FDA
PK/TK reagent order
ADA reagent (+ antibody prep.)
PK*
Non-GLP Tox*
GLP Tox Study for IND Filing
Report Review w Client
RA Pre-IND Material Prep.
RA IND Submission



Information Transfer

- Data Package Exchange
- Material and Sample Handoff
- Process Documentation Review

*Non-GLP tox studies can be performed earlier by leveraging MA generated material

**cGMP manufacturing available if required. We can also perform non-GLP manufacturing if preferred

Developability and Molecule Assessment

- Transient production
- Molecule assessment
- Material Generation

Cell Line Development

- Plasmid construction
- Pool Screening
- Top 3 clone selection
- PCB Banking/Testing
- Stability Study and Final clone selection
- Available Cell Lines: ATCC CHO-K1, CHOZN CHO-K1/GS Knockout, E. coli (UK)

Material Generation Pre-Tox Run

- Non-GMP 200L manufacturing
- Upstream Process Development
- Downstream Process Development
- Formulation & Filling Process
- Material for PK and tox study
- Reference Standard

Cell Banking

- Research cell bank
- Research cell bank testing
- cGMP master cell bank
- cGMP working cell bank
- cGMP master and Working cell testing
- Secure cell bank storage

Process Development

- Upstream Process Development
- Downstream Process Development

Formulation Development

- Evaluation of pH and buffer systems
- Screening excipients and surfactants
- Viscosity optimization
- Long term (4 week) accelerated study
- Container compatibility assessment
- Final formulation

Analytical Method Development

- Appearance
- PH
- Osmolarity
- Size-Related Variants
- Primary and HOS
- Charge variants
- Potency
- Residue Analyses
- Glycan Profiling
- Endotoxin
- Bioburden
- Host-cell DNA
- Host-cell protein
- Sub-visible particles
- Extractable volume
- Sterility
- Container closure integrity
- Polysorbate concentration

Tox Batch Manufacturing

- Drug substance Tox batch Production
- Drug product Tox batch Production
- Tox batch testing
- Reference Standard
- Fill or Finish

First at Scale Manufacturing

- First at scale cGMP Drug Substance Batch Production
- First at scale cGMP Drug Substance Batch Testing
- Fill or Finish

Manufacturing Drug Product

- Phase I Clinical Trial Material Production
- Viral clearance study
- Phase I Clinical Trial Material (CTM) batch Testing
- Fill or Finish

Characterization Study

- Size-Related Variants
- Primary and HOS Characterization
- Charge-related Variants
- Potency
- Extinction Coefficient

*Methods will be added based on client request

Manufacturing CTM placebo batch

- cGMP DP placebo manufacturing
- QC release testing
- Placebo batch disposition and certification

Stability Study

- Reference standard (TOX batch)
- Non-GMP Drug substance
- Non-GMP Drug product
- GMP Drug substance
- GMP Drug product
- Reference Standard

In Use Studies

- Toxicology in-use
- Clinical In-use

Regulatory Filing Service

- Regulatory CMC
  - 3.2.S+3.2.P + 2.3.S+ 2.3.P
  - Non-clinical: 2.4+2.6

* Pharmaron can also support eCTD publishing as well as complete IND package preparation and submission, including pre-IND and IND.

REGULATORY SUPPORT

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