Process and Pharmaceutical Development

Formulation & Drug Design

Holistic Chemical and Pharmaceutical R&D

We provide

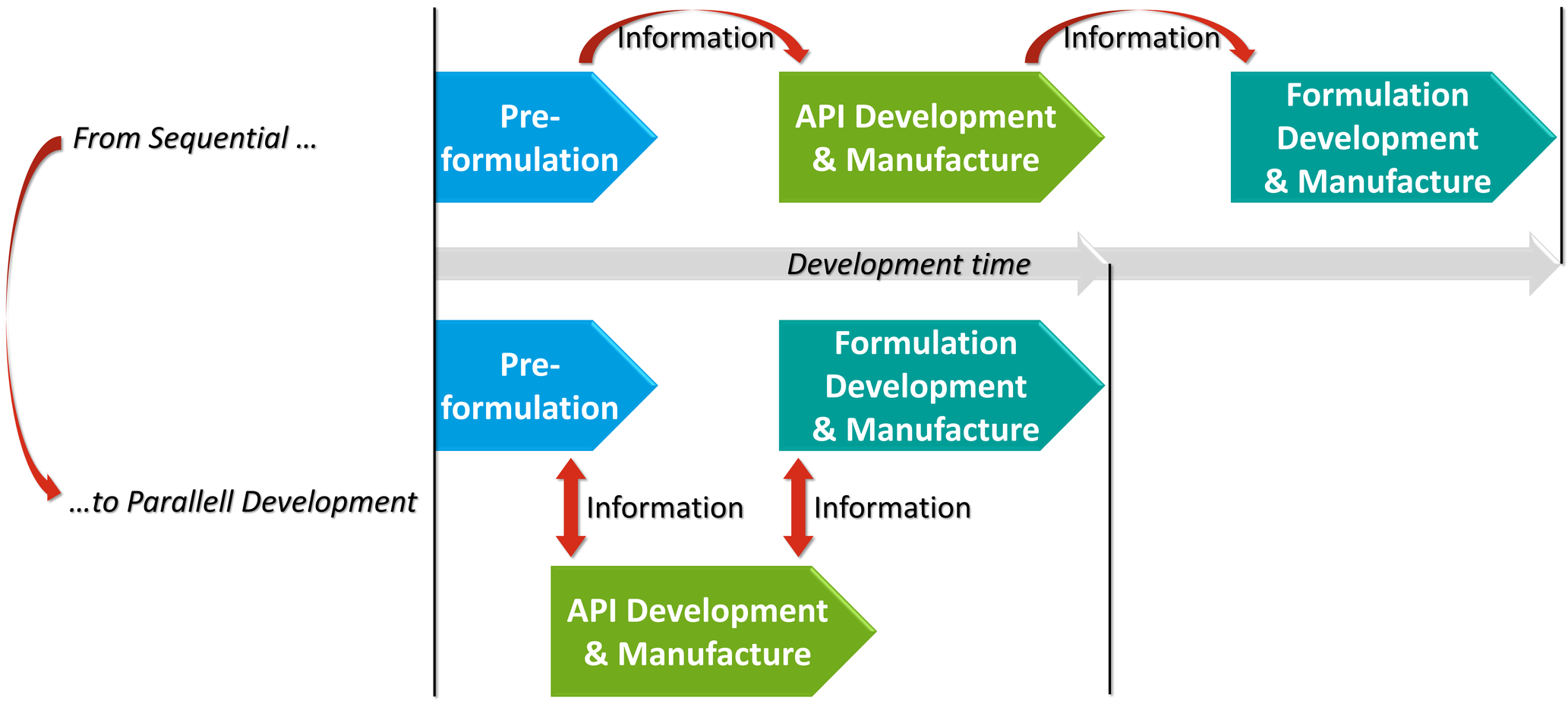
- **Pharmaceutical R&D in preclinical and early clinical development – for Drug Substance (DS/API) and Drug Product (DP/IMP).**
- **Identification of the best administration route, formulation and manufacturing process for the active compound.**

Formulation
- Drug delivery
- Solubility enhancement
- Fit-for-purpose drug product
- Formulation types: e.g. solutions, suspensions (nano/micro/from solution), emulsions, capsules, semi-solids, gels, drug in bottle
- GMP license to manufacture <5kg/5L of DP/IMP

Characteristics
- Physicochemical characterization
- Dissolution/permeation
- Physical and chemical stability (DS and DP according ICH guidelines)
- Degradation/impurities
- Bioequivalence
- Biopharmaceutical assessment
- Polymorph and salt screens and evaluations

Drug Substance
- Tactical or long term route design and process development
- PGI - Potential Genotoxic Impurity assessment, control and mitigation
- Scale-up to 100L
- Cost of goods
- GMP manufacture <5kg DS/API

Real Time Interdisciplinary Collaboration



- Saves time, lowers development cost and increases success rate in making Your Drug Substance into a cost effective pharmaceutical Drug Product.
- Informed strategies for manufacture of API and drug product throughout the clinical trial programme and commercialization.
- Minimizes risk for expensive delays later in the development and may enable otherwise impossible studies.
- Increases value at exit or other large investment milestones.

Single CMC Partner throughout the Project – Drug Substance and Product