ADVANCED DIGITAL DESIGN OF PHARMACEUTICAL THERAPEUTICS

Visualising Digital Design Workflows
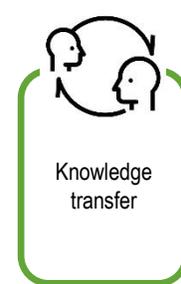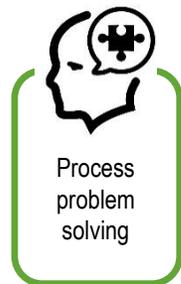
Charlie Gordon & Rob Peeling, Britest Ltd

Britest

Britest is a highly successful not-for-profit SME. Since its founding in 2001, the application of Britest tools has generated many €millions of productivity gains, driving enhanced business sustainability and competitiveness.

Britest's **expert technical facilitators** use a suite of proprietary tools to help organisations **define, structure, and translate knowledge into process understanding**.

This promotes **effective communication** of the underlying science across disciplines and functions, **enabling knowledge transfer** and allowing organisations to derive tangible **business value**.
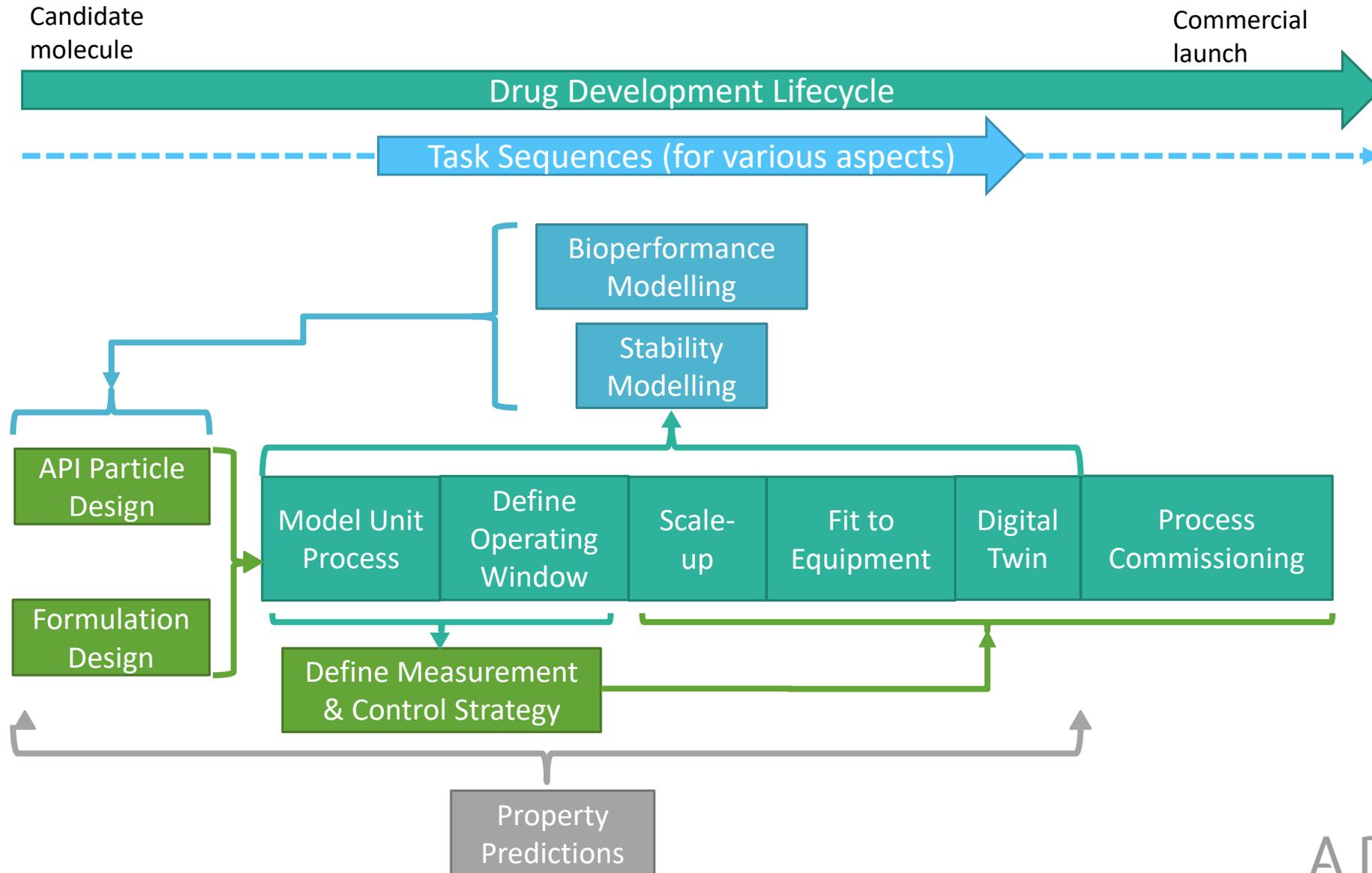
Process problem solving

Whole process design

Complex decision making support

Knowledge transfer

Expert technical facilitation

ADDOPT

ADDOPT DIGITAL DESIGN SHOWCASE, LONDON

ADDoPT information flows

Ensure that the opportunities offered by digital design can be clearly mapped onto industry's product and process development workflows.

Allow industrial end-users to understand the current and future state of models, including the data requirements and level of information fidelity needed.

Desired future state: The only experimental work required is a validation step to confirm the output of models.

ADD⦿PT

Benefits of a Digital Design Workflow

Reduce development time & cost without compromising patient safety

Reduce risk

Reduced/improved experimentation

Enable iterative design approach

Implement measurement and control from a very early stage

Carry out experimentation *in-silico*

Model manufacturing unit operations

Use experimentation to confirm models

Model bio-performance of drug products

Provide greater added value for experiments performed

Optimise process via closed-loop feedback control

Making innovation affordable

ADD**O**PT

Overview and starting point

- Introduction
  - What is ADDoPT?
  - What is Digital Design?
  - What is this Guide?
  - How do I use the Guide?
  - Training and Support
  - Glossary of Terms

Stability

Target performance attributes
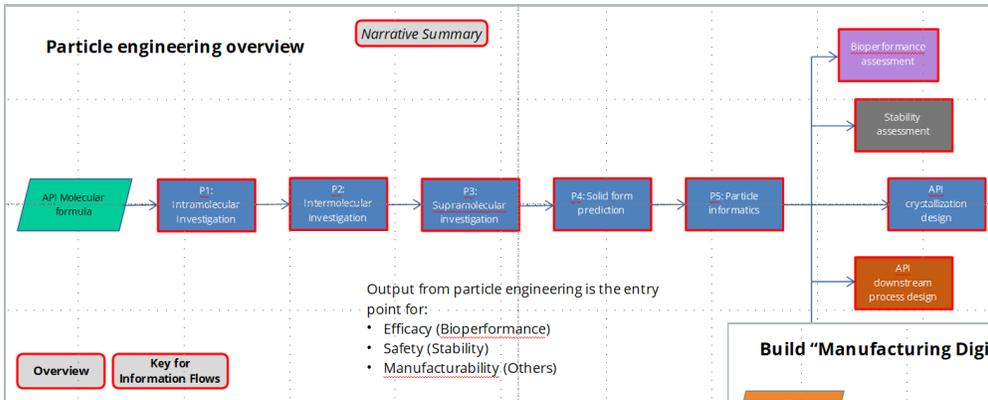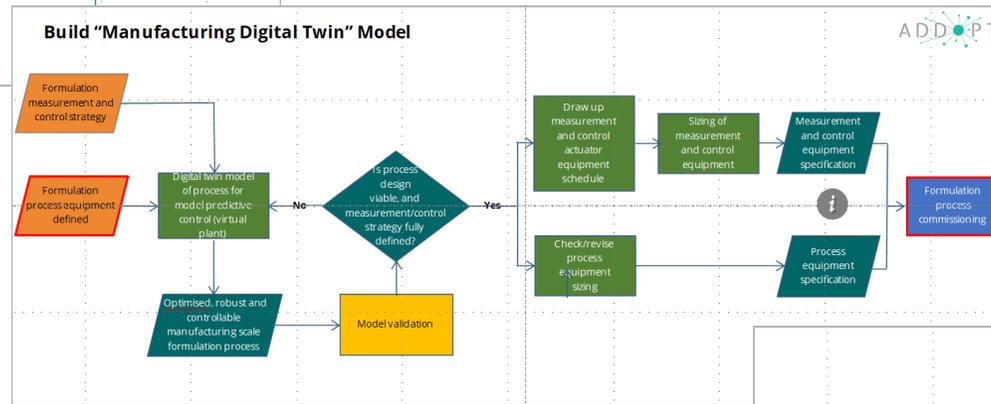
API particle informatics

Efficacy (Bioperformance)

Manufacturability

API crystallization design

API downstream process design

Formulation design

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High-level workflows…

Particle engineering overview

Narrative Summary

- API Molecular formula
- P1: Intramolecular Investigation
- P2: Intermolecular investigation
- P3: Supramolecular investigation
- P4: Solid form prediction
- P5: Particle informatics
- Bioperformance assessment
- Stability assessment
- API crystallization design
- API downstream process design

Output from particle engineering is the entry point for:
- Efficacy (Bioperformance)
- Safety (Stability)
- Manufacturability (Others)

Overview

Key for Information Flows

…drilling down to specific tasks…

Build "Manufacturing Digital Twin" Model

…with appropriate supporting information

Training and Support

In addition to links to support and training provided throughout the main information flow, it is possible to interrogate the full training / support database (the "Digital Design Training Cloud") directly to drill down to offerings matching a variety of use cases, application areas and general needs.

Digital Design Training Cloud

Overview

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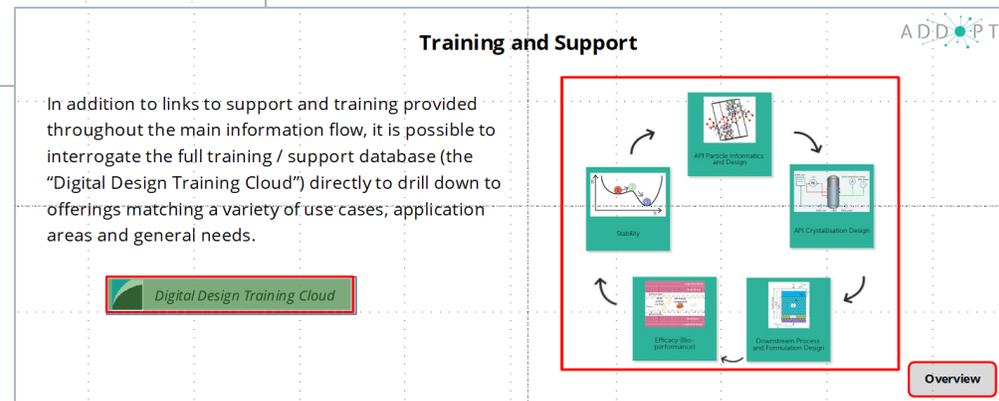
Accessible resource to support digital design

Relevant to different user requirements and interests

Customisable to different applications and industries

Britest can support development and implementation of a digital design workflow in your organisation

ADDOPT

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