

Managing the Process of Biologics Registration

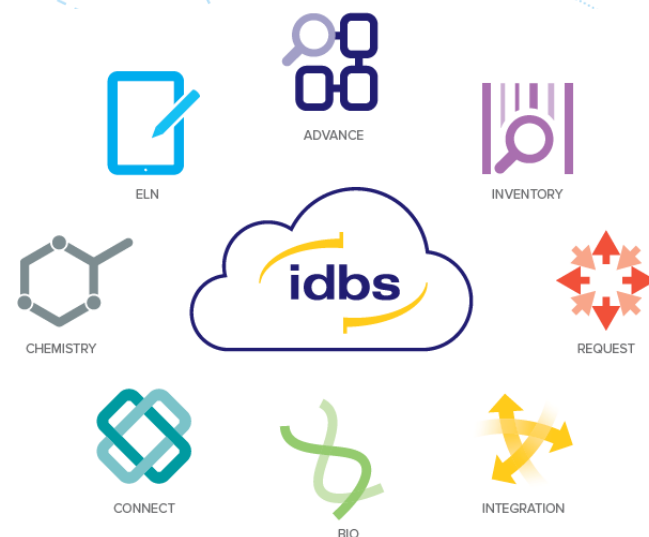
Jarrold Medeiros



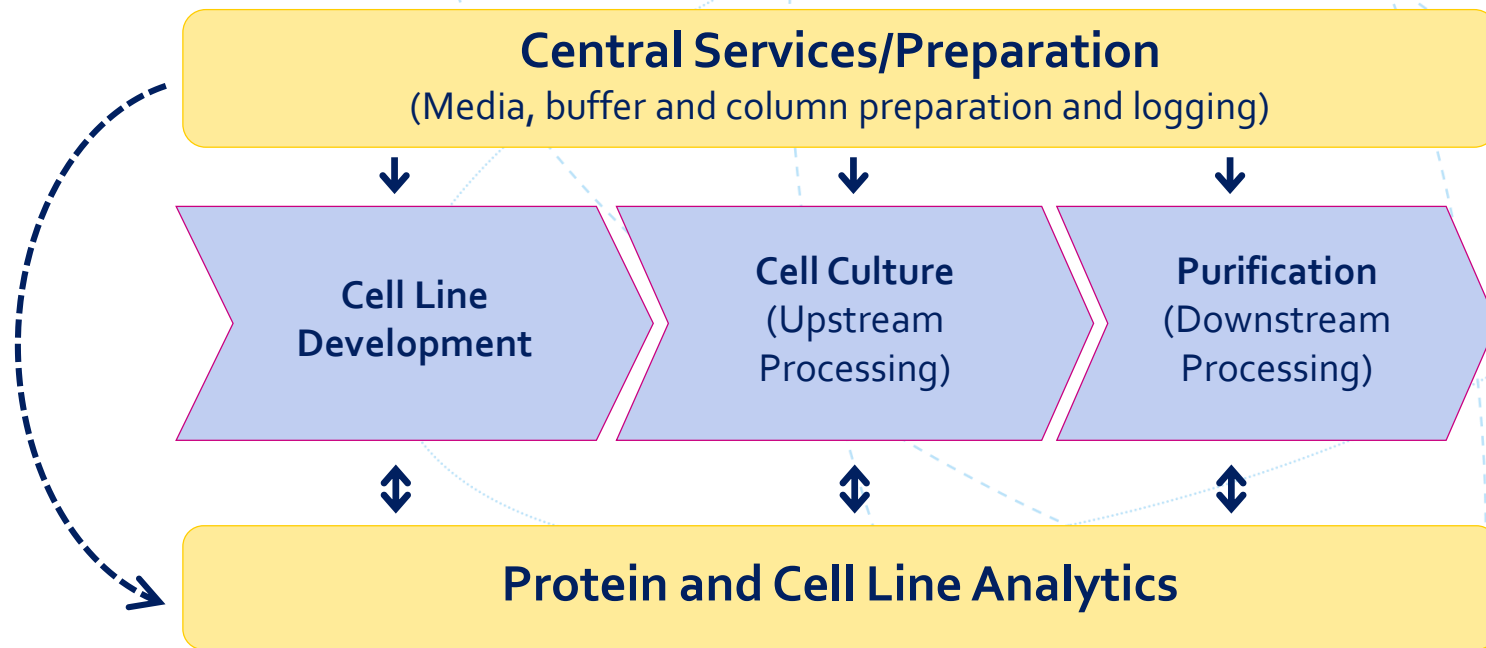
IDBS E-WorkBook

• Next-Gen Platform for Scientific R&D Informatics

- Plan and coordinate work
 - Manage samples & inventory
 - Capture content and results
 - Support external collaboration
 - Provide decision support and process insight
-
- Modules designed to work seamlessly together
 - Modern interface for intuitive user experience
 - Support for different devices and OS
 - Can be integrated with existing infrastructure
 - On-premise or SaaS deployment



E-WorkBook for BioProcess



Biologics Landscape

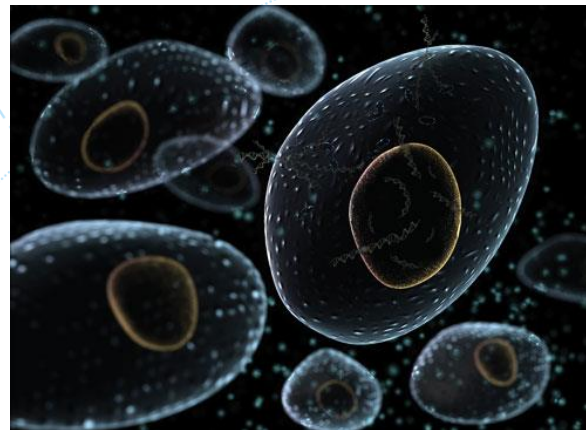
Materials



Nucleotides

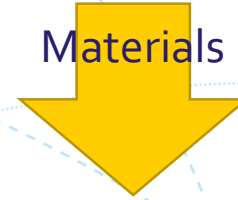


Materials



Expression Systems

Materials



Peptides



Samples



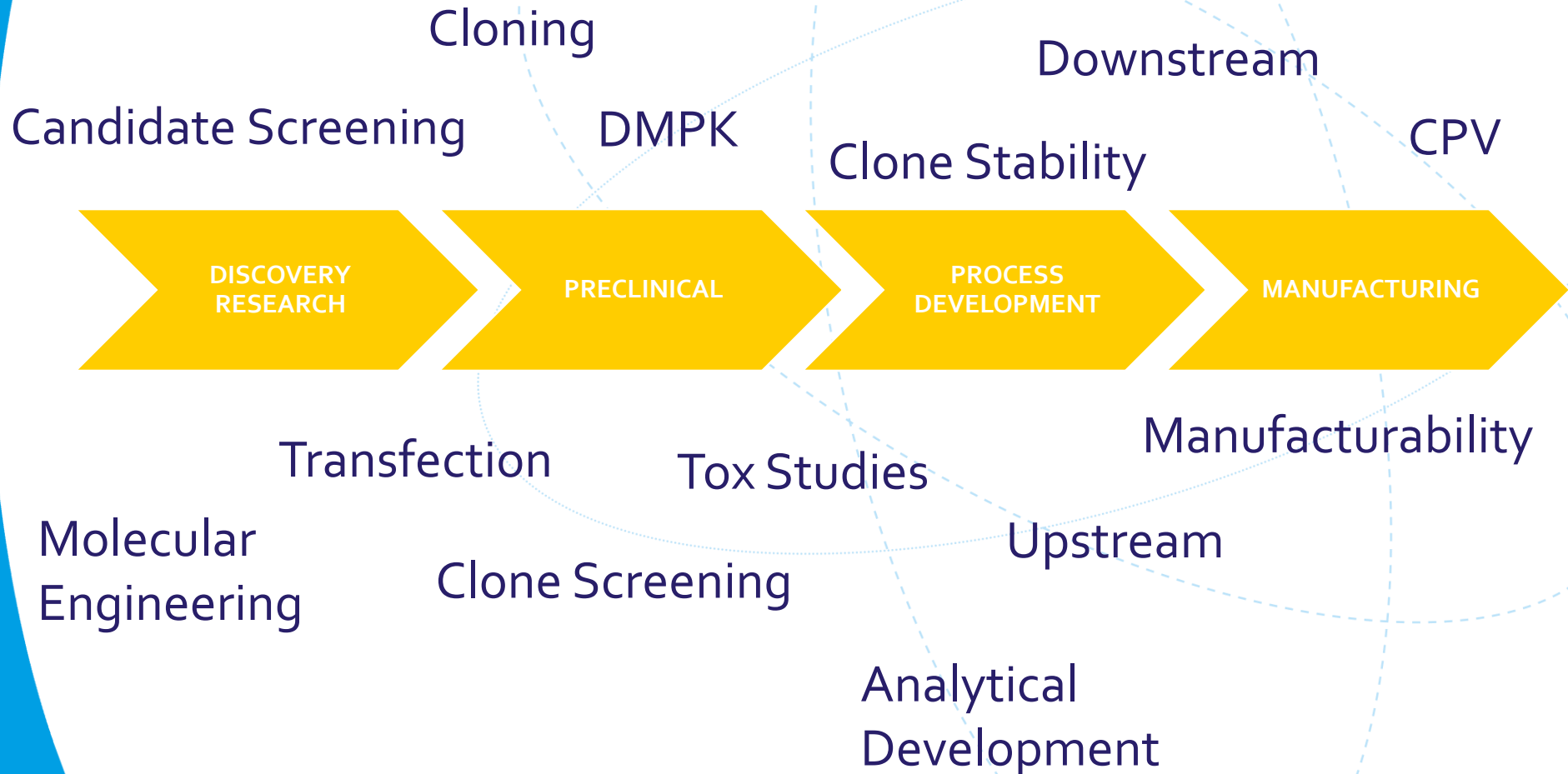
Samples



Samples



Process Impact Along the Way



What do we mean by BioReg?

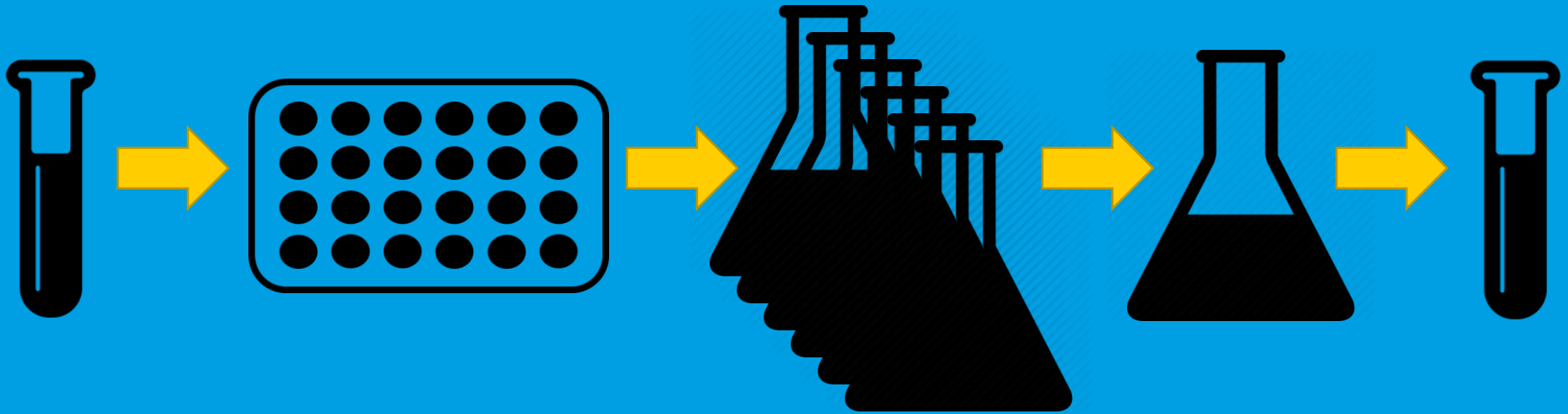
PHYSICAL

- Example: a vial of primer
- May or may not be linked to registered entities
- Genealogy – parent:child relationships of physical materials and samples

VIRTUAL

- Example: a primer sequence
- Typically linked to batches in inventory
- Genealogy – relationships between entities
- Uniqueness checking and business rules for registration

Example Scenario



E-WorkBook Biomolecule Hide title ? Options

This is my experiment title
My Company / Group3 / Project1 / path / path

+ Sequence **Circular** < > ≡ > Tools

E-WorkBook Biomolecule Show title ?

+ ↶ ↷

↕ [] []

Library X <

Search

Peptide CHEM Nucleic acid **BLOB**

mAb

idbs E-WorkBook Administrator User ?

Navigator My Tasks My Workflows Activity Save As Review & Sign

biomol Root / Administrators / Jarrod / biomol

Title: biomol Version Type: CACHE

(v1) Biomolecule: Biomolecule 0 0 i ≡

(v1) Procedure: Edit 0 0 i ≡

Peptide Synthesis

1. The peptide synthesizer is switched on.
2. The amount of waste and solvent is checked.
3. To ensure nitrogen is circulating and there is no leak in the system the flowmeter is checked. Flowmeter is placed in the top right corner of the instrument.
4. Using the program interface of the instrument, the reagent bottles are pressurized and primed.
5. The amino acid vials are prepared with appropriate amount of amino acid along with commensurate activating agent (HCTU/HBTU) based on the chosen scale and excess. Excess sheet is used to determine the values of amino acids and activators to be used.
6. The amino acid vials are loaded backward according to the desired sequence.
7. Appropriate amount of resin is measured into one of the reaction vessels.

E_i INVENTORY

- ADD NEW...
- BROWSE LOCATIONS
- SEARCH INVENTORY
- SETTINGS
- HELP

icbs

Jarro Medeiros

CHO-S Host Cells
 Registered: 10 Apr 2017 23:16:05 by JMedeiros | Last edit: 10 Apr 2017 23:16:05 by JMedeiros

DETAILS USAGE LOG ATTACHMENTS OPTION E-

System ID: MA00000647
 Name: CHO-S Host Cells

test
 Root / User Notebooks / Jarro Medeiros / Demo / Jarros Transfection Experiment

Title: Jarros Transfection Experiment Experiment ID: EXP-11-Apr-2017-052
 Version Type: CACHE

(v1) Inventory: Edit

Inventory	Type	2 Items
CHO-S Host Cells	Non-Vendor Material	Expiry Date
MA00000647	BPES - Cell Line	Expiry Date
Test Plasmid 1	Non-Vendor Material	Expiry Date

Transfection

Transfection Parameters

Study Name	Cell Line Development
Date of Transfection	February 10, 2016
Type of Transfection	Stable
Number of Transfection	1
Maximum Number of Plasmids Per Transfection	1
Pools Per Transfection	2
Electroporation (kV)	0.3
Electroporation (uF)	1000
Resuspension Media Batch	IDBS111
Resuspension Media	CHO Media A with 0.5mg/L Insulin
Expiry Date of Media	Oct 31, 2016
Link to Media Preparation	/Root/Central Services/Media Preparations/Media Batch (v3)
Cuvette Supplier	Eppendorf
Plate Type (Wells)	1
Planned Days Until First Media Change	3

Host Cell Line

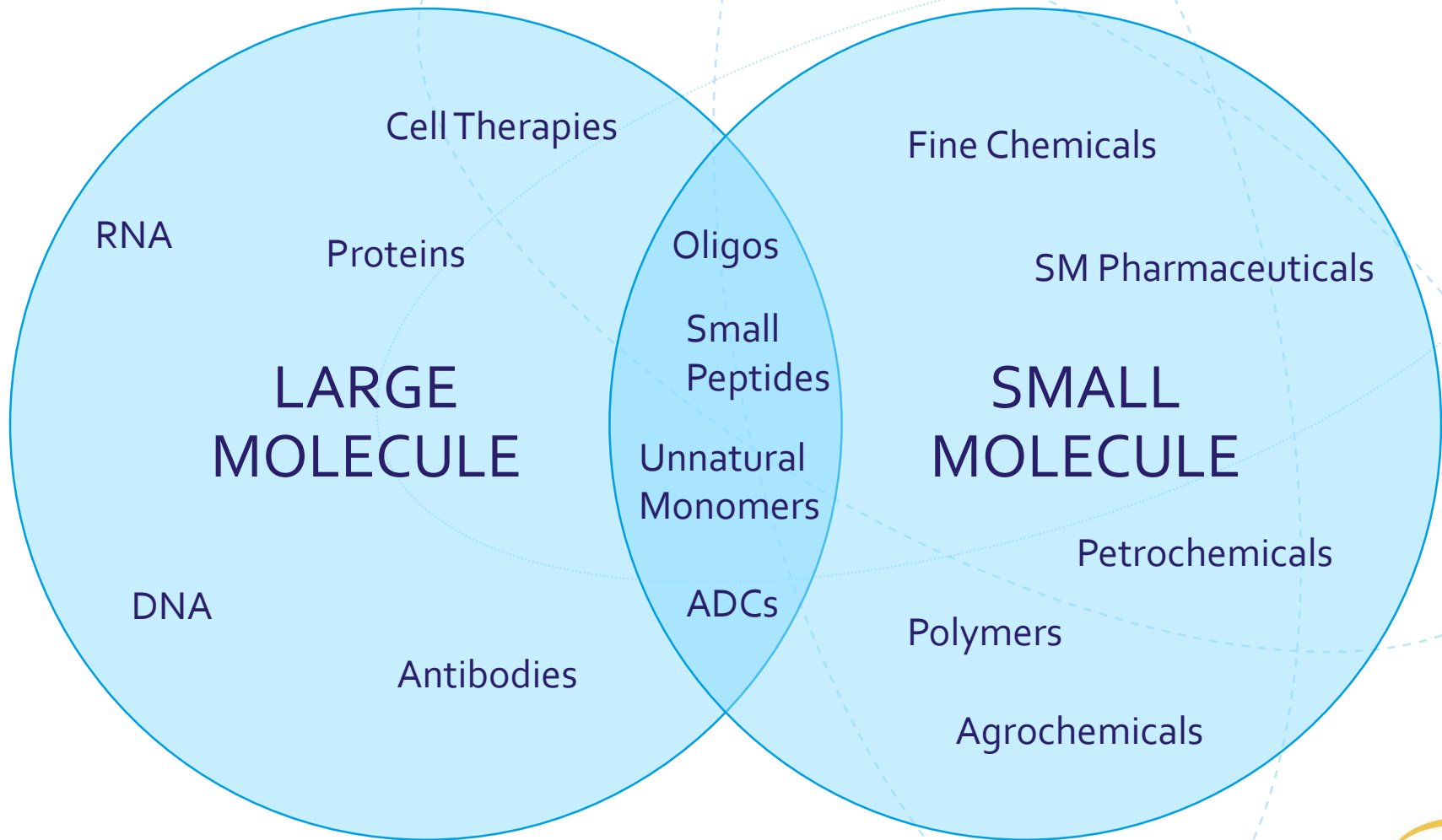
Mixture	Host Cell Line Type	Host Cell Line
Mixture 1	CHO	CHOK1

Passage Details

	ID of Plasmid	Amount of Plasmid to Transfect (ug)	Name of Plasmid	Gene Target	Protein Product	Link to Plasmid Preparation	
Mixture 1	Plasmid 1	P-02817	10	pcDNA-habc1	hABC1	Human Abc1	/Root/DEMO/Research/Cell Line Development/P002-00002/01 Plasmid Prep (v4)

- Instructions Data Format
- Record Transfection Parameters.
 - Enter details of your Host Cell Line(s).
 - Enter details of your Plasmid(s).
 - Run Media and Plasmid Search. ★
 - Review Passage and Transfection pool details.

Chem, Bio and Everything In Between



**THANK
YOU**

