

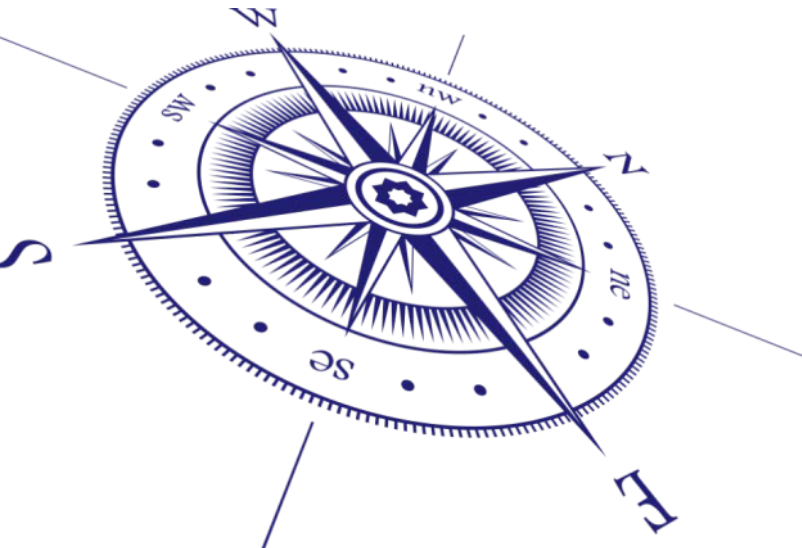
# Biological Development Support

Smarter data management increases efficiency,  
improves collaboration and shortens time to market

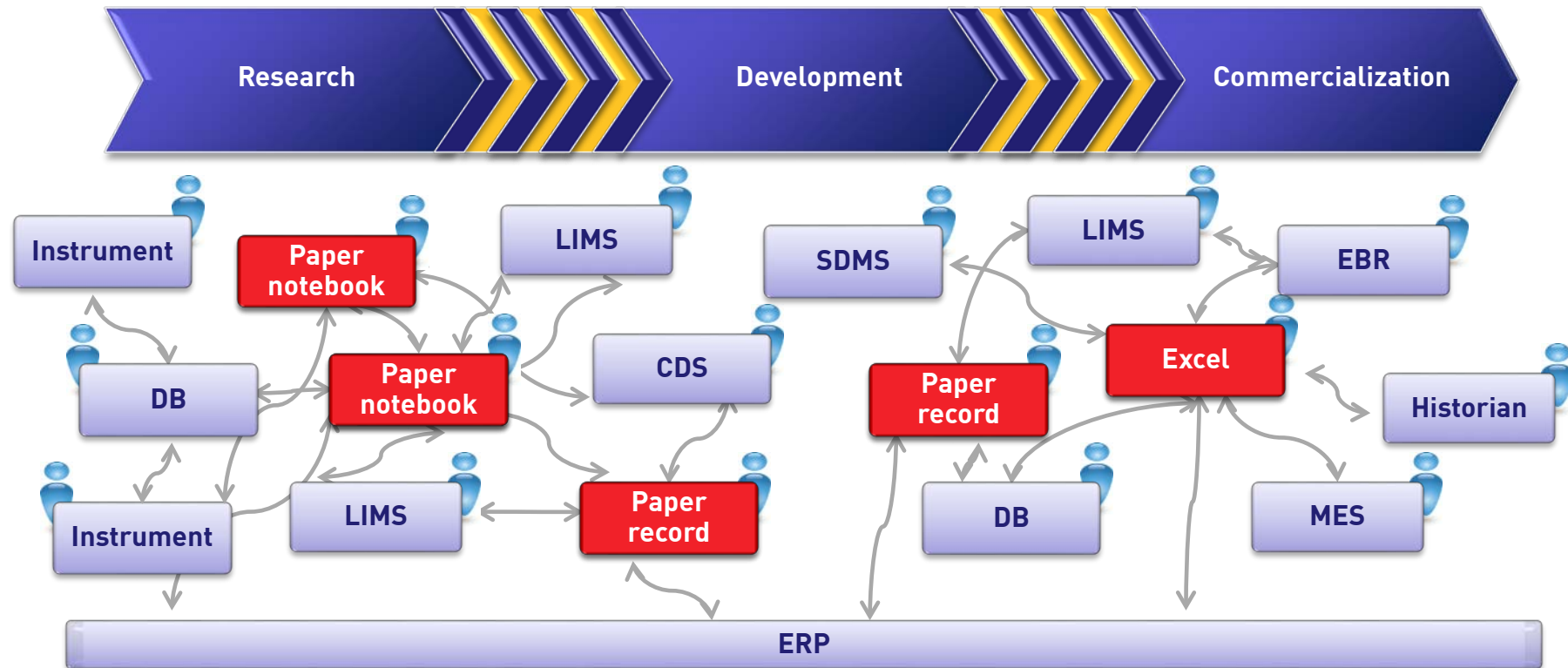
Dr Paul Denny-Gouldson CSO  
IDBS



# Where do you want to take your **R&D**?

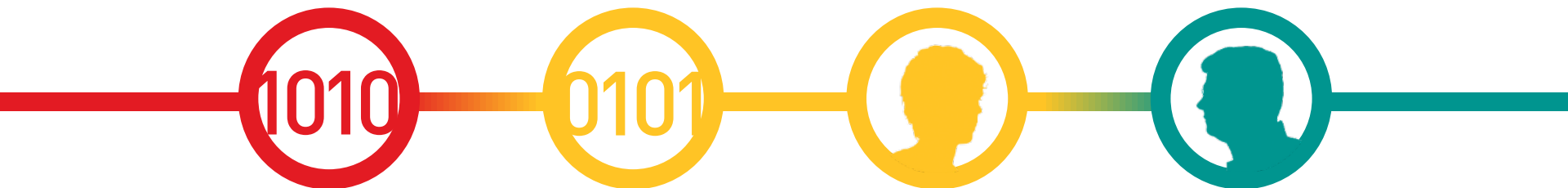


# Product and process lifecycle – current state



## Common actions will affect your drivers

- Link data to data
- Link data to people
- Link people to people



# Any major leap to upgrade your operation carries consequences





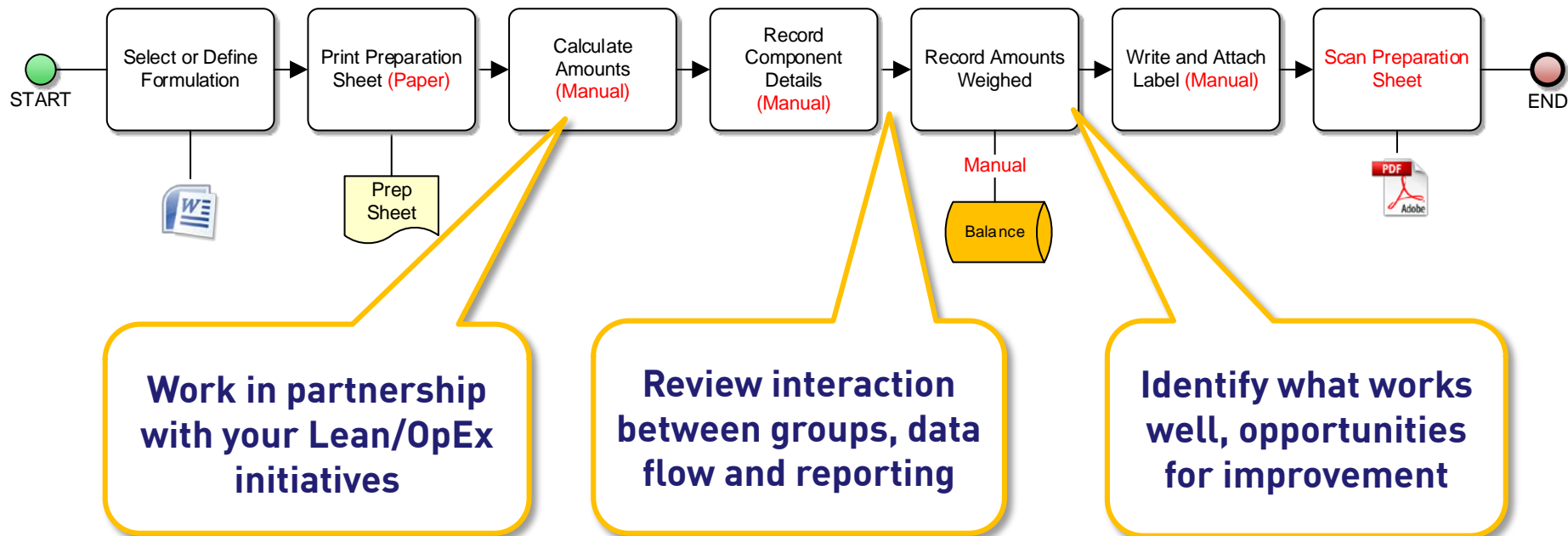
Where are you going to get the most value most quickly?

**Along the way there are common  
processes and science**

**Over 60% of what R&D companies do  
is fundamentally the same**

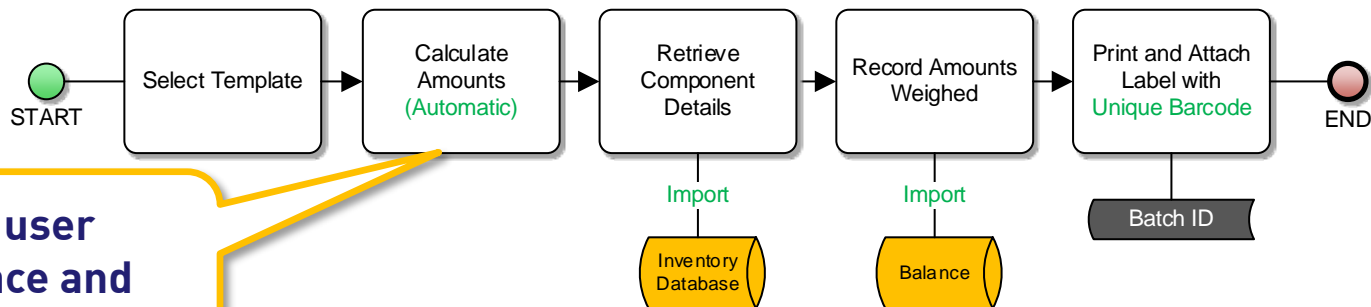
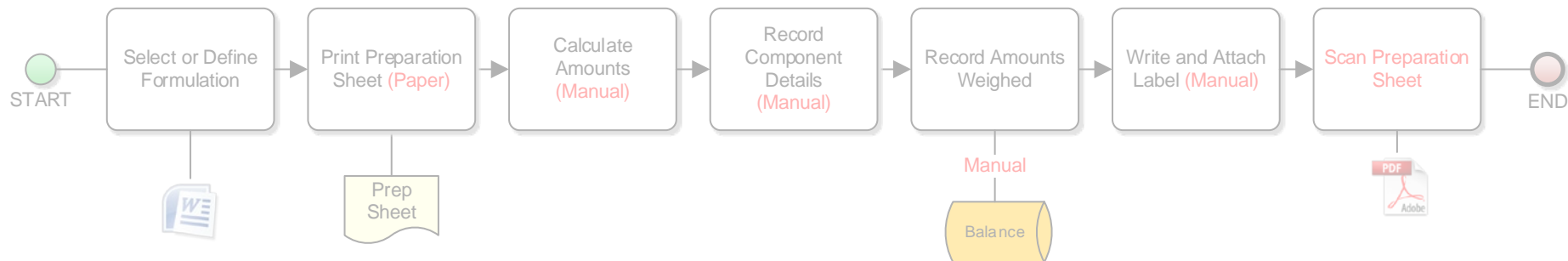


# Understand your business processes





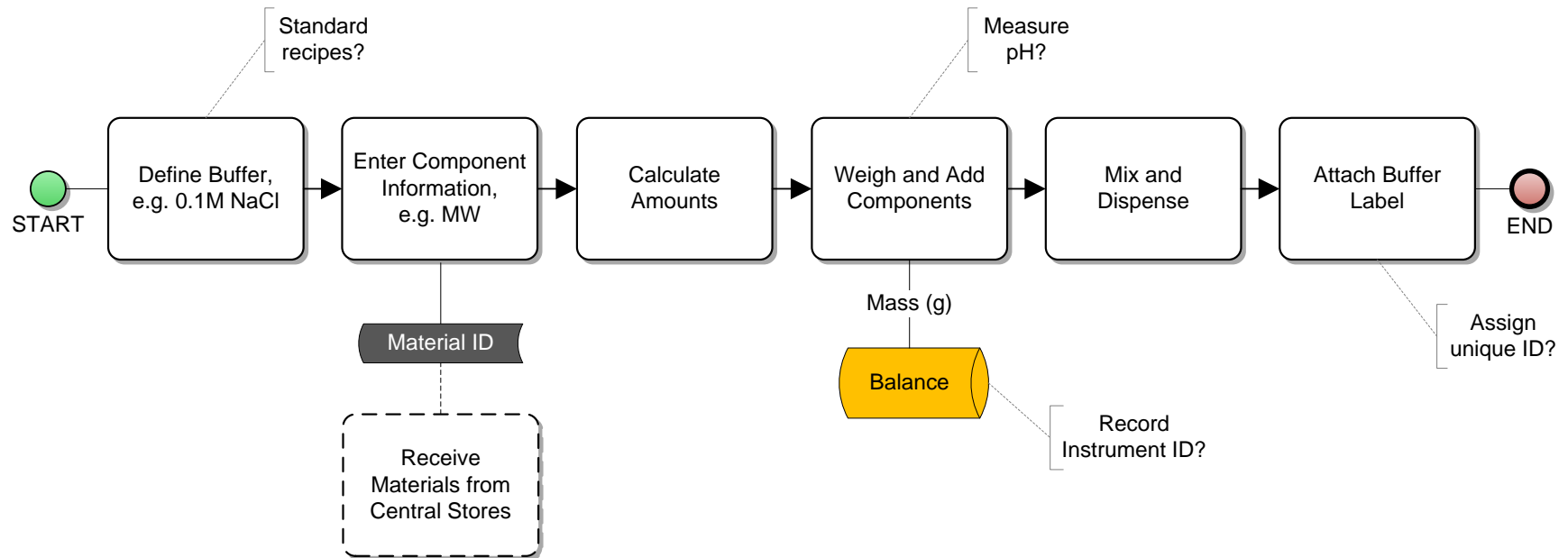
# Harmonize and optimize



**Better user experience and improved data flow**

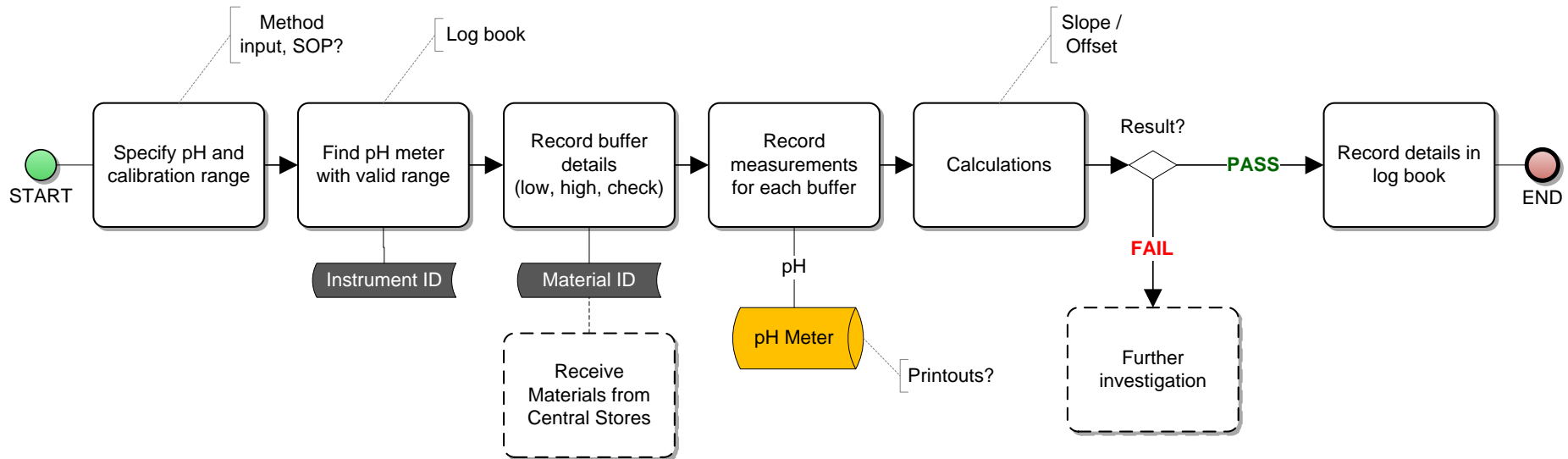
# Example: Scenario 1

## Prepare Dilution Buffer



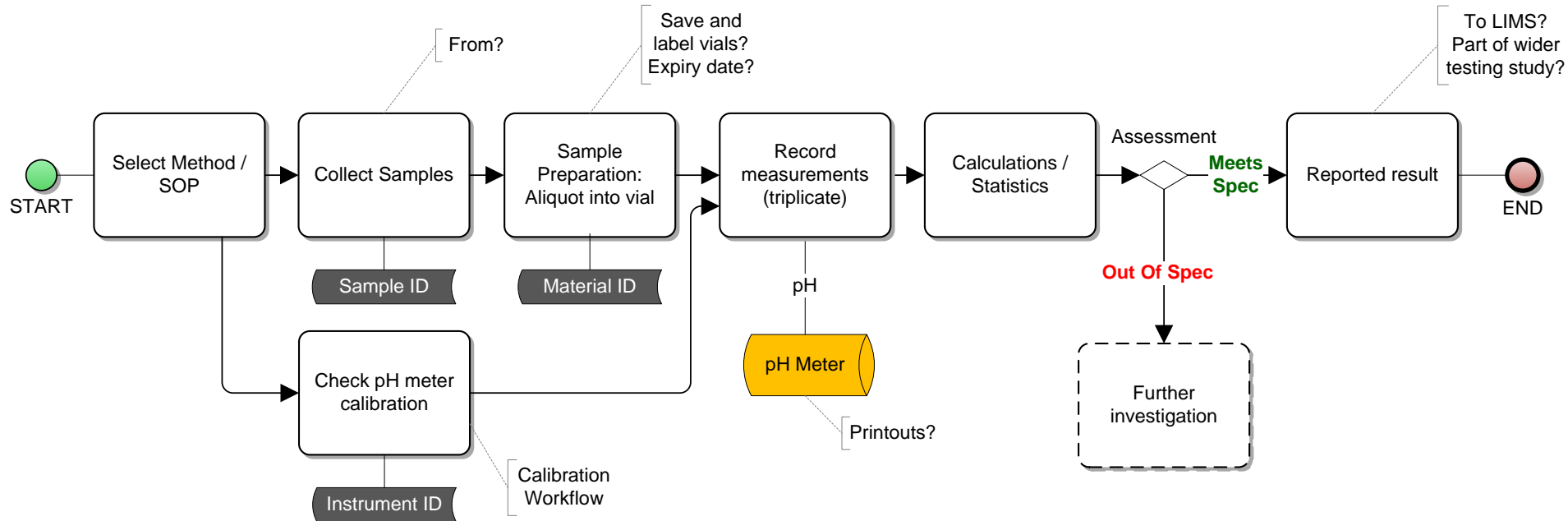
# Example: Scenario 2

## Calibrate pH meter

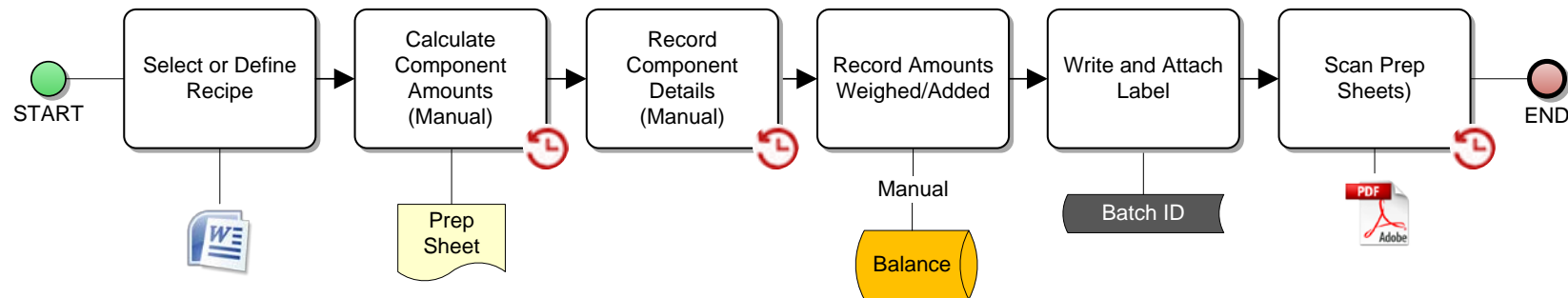





# Example: Scenario 3

## Measure pH of samples



# Example Workflow: As-Is

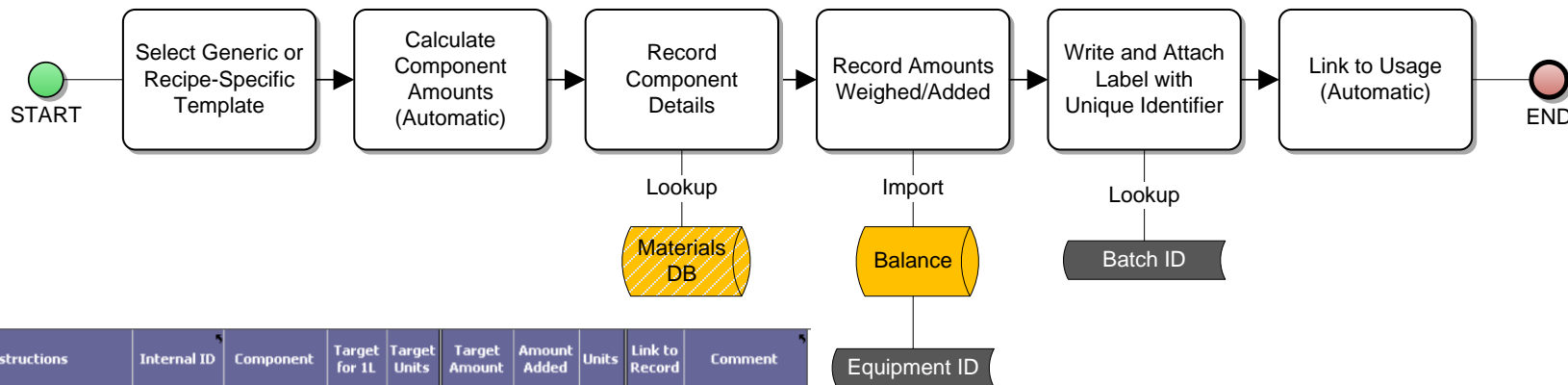


Order	Component	Supplier	Lot Number	Amt / L	Target Vol (L)	Amt Added	Initials	Date
1	Purified Water	WP 22	N/A	2.3 L	2.0	4.6L		10 Jan 13
2	Phytone	Funka	A 32 556	145.0 g		290 g		10 Jan 13
3	Sodium Phosphate	Sigma	<div>Q25102113 A 32 556</div>	18 g		36g		
4	Mix until dissolved							
5	Purified Water	WP 22	N/A	To total volume				
6	Mix until homogeneous							

Preparation Name:					
Total Volume:					
Component	Supplier	Lot Number	Expiry Date	Amount	Reference to Printouts
Prepared By & Date:			Location:		

Different forms, inefficient process, missing data

# Example Workflow: To-Be

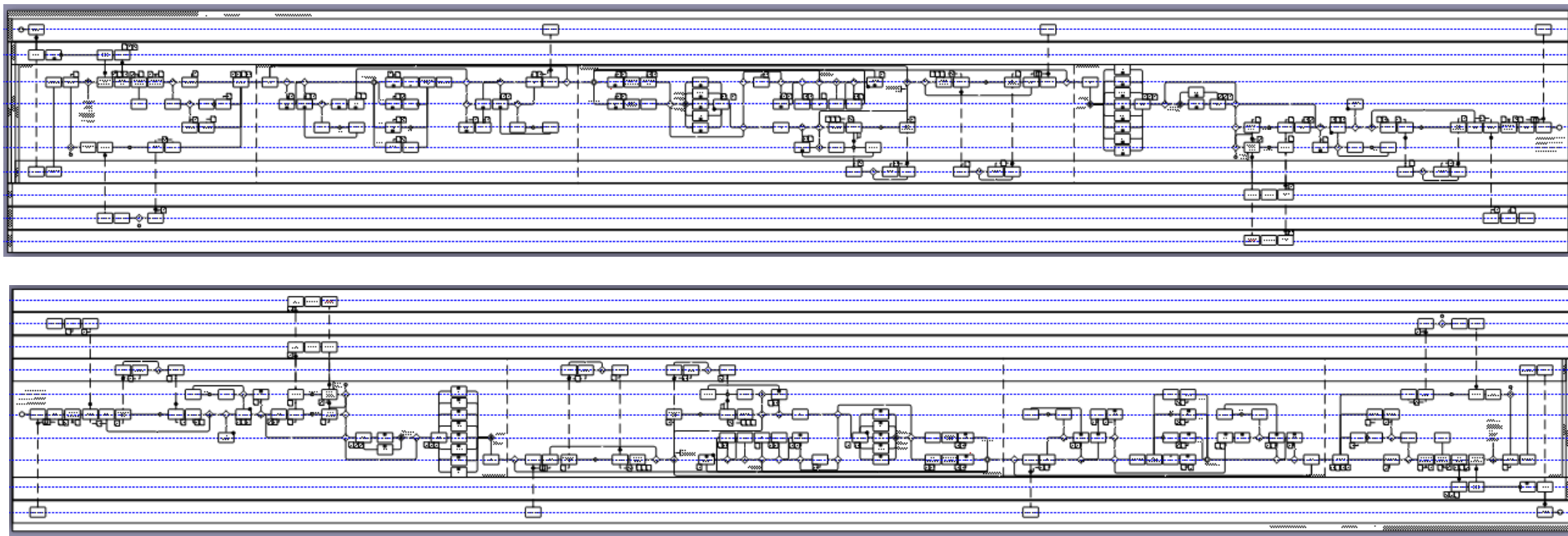


	Instructions	Internal ID	Component	Target for 1L	Target Units	Target Amount	Amount Added	Units	Link to Record	Comment
1	DI water	M000051	DI Water	0.8	L	0.8 L	0.80	L	<a href="#">OPEN</a>	
2	Calcium chloride.2 H2O	M000039	CaCl.2H2O	1.05	g	1.05 g	1.44	g	<a href="#">OPEN</a>	Adjusted Recipe
3	AlCl3.6H2O	M000045	AlCl36H2O	0.02	g	0.02 g	0.02	g	<a href="#">OPEN</a>	
4	ZnSO4.7H2O	M000046	ZnSO4.7H2O	0.08	g	0.08 g	0.08	g	<a href="#">OPEN</a>	
5	CoCl2.6H2O	M000047	CoCl2.6H2O	0.12	g	0.12 g	0.12	g	<a href="#">OPEN</a>	
6	Mix components until fully dissolved	M000048	CuSO4.5H2O						<a href="#">OPEN</a>	
7	HCl (35%)	M000053								
8	DI Water	M000126	HCl (35%)	1	L	1 L		L		
9	Mix solution thoroughly, until homogenous.									

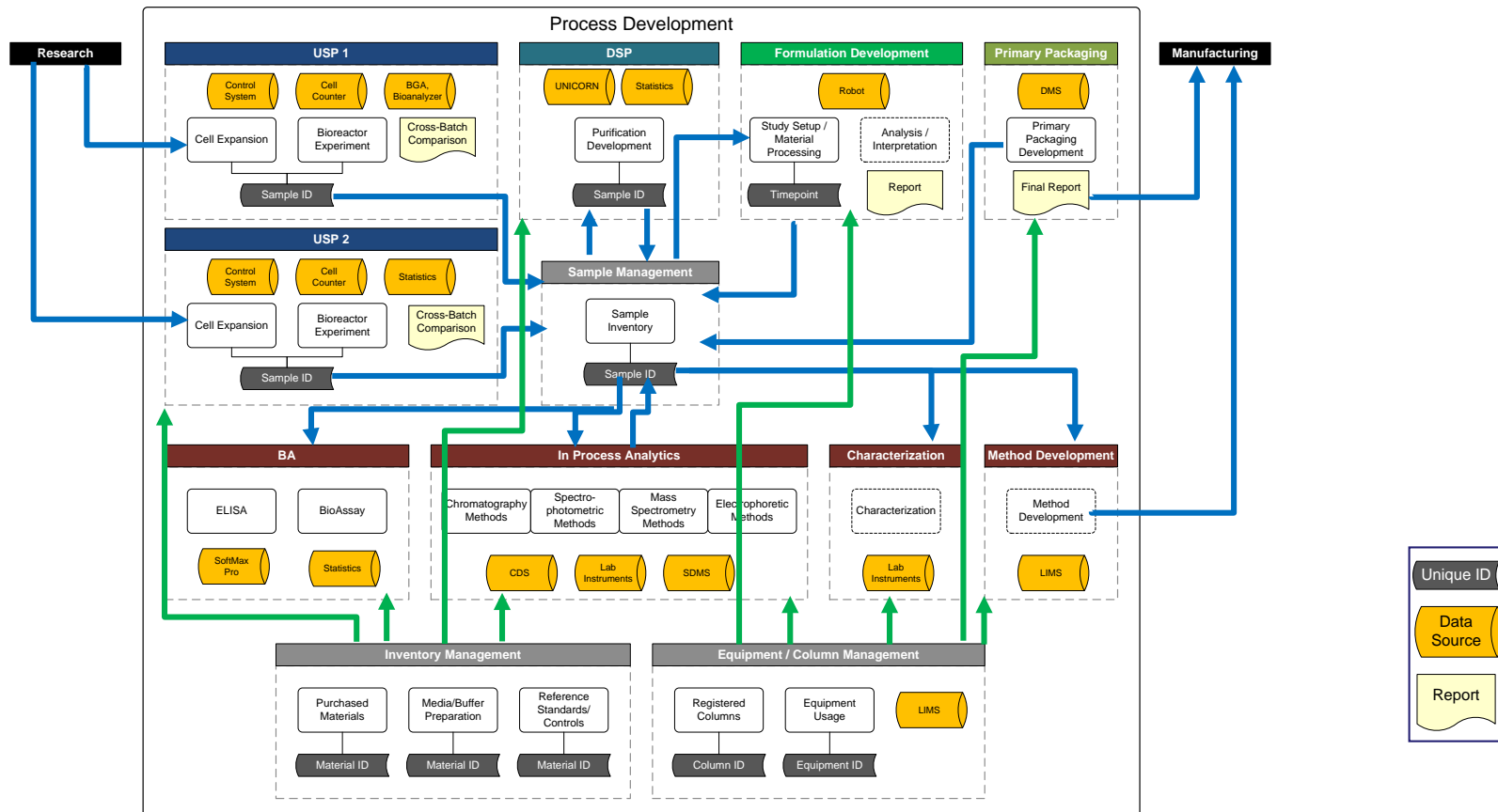


Make it easy to trace materials and expiry dates

# Think outside the swim lane

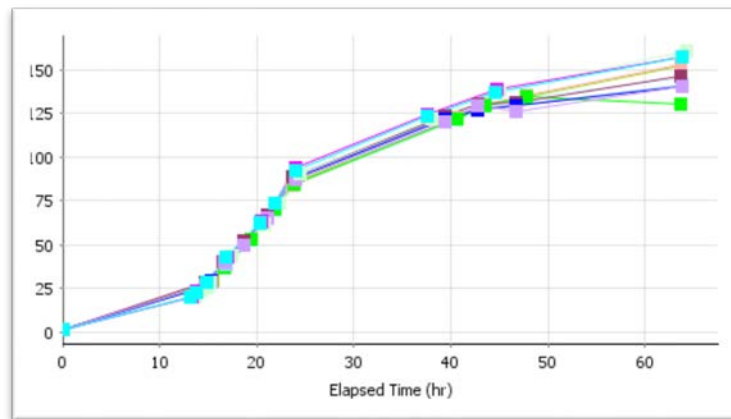
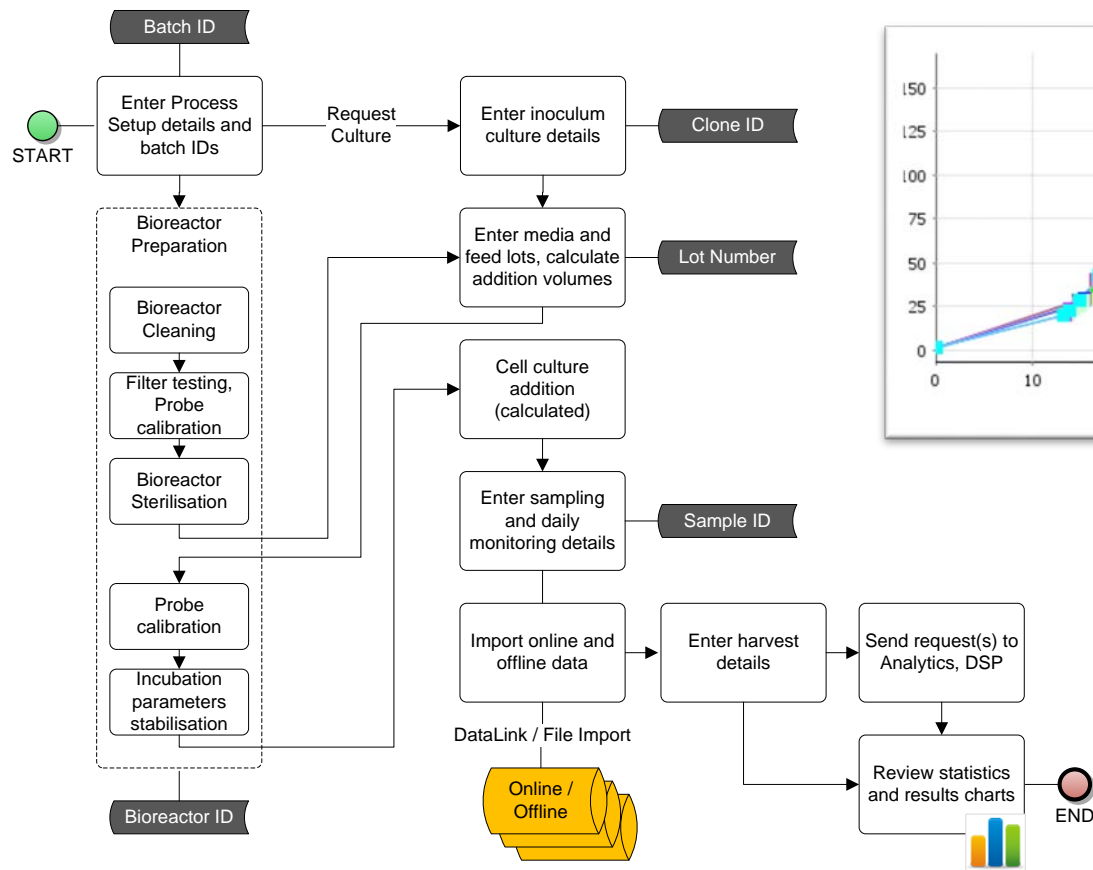


# Across Departments / Groups

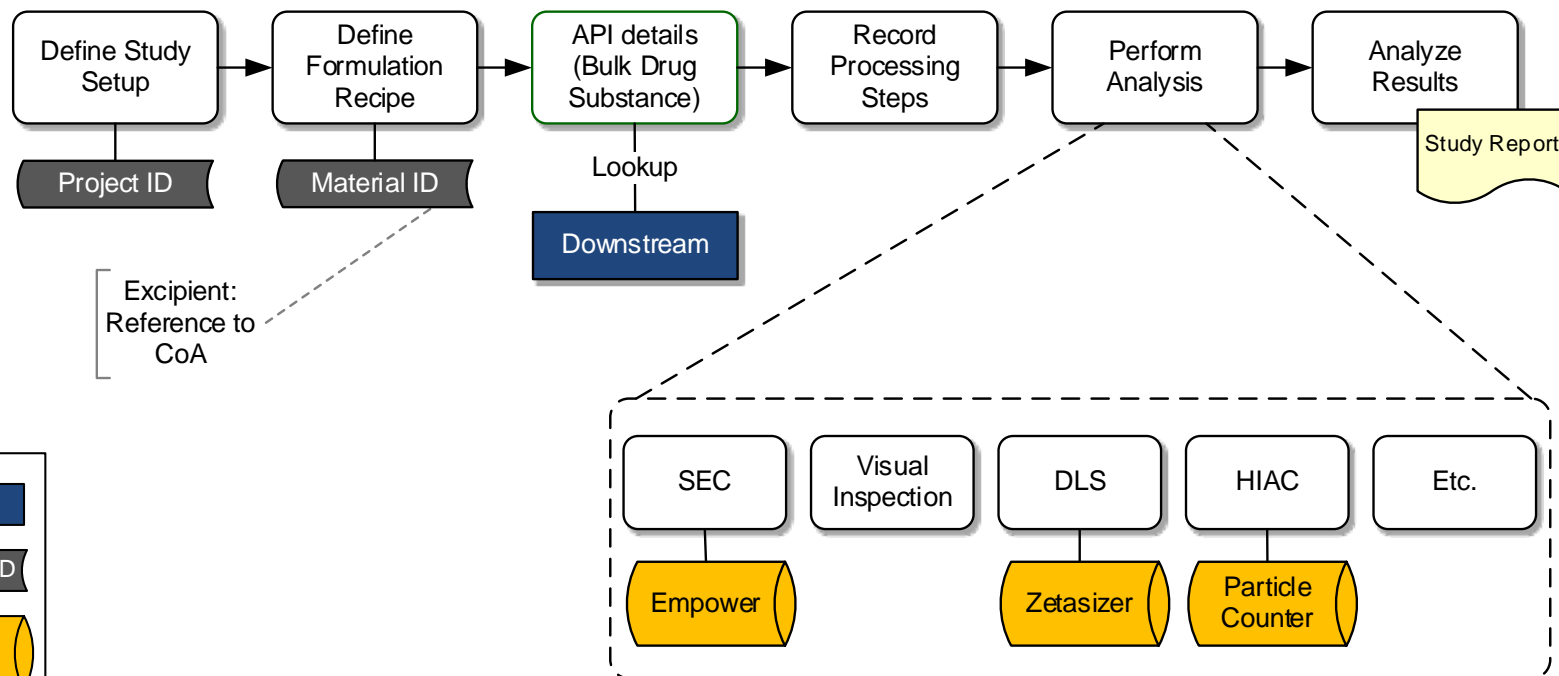




# Process at Workflow Level



# Large Molecule Formulations



Group

Unique ID

Data Source

Report

# Bioprocess Customer Case studies



# Case Study

## Company Overview

- One of the world's largest Contract Development and Manufacturing Organizations (CDMO)
- ~300 users in Slough, UK

## Business Challenge

Lonza had several key drivers to improve its business – increasing both quality and efficiency and reducing overheads. Going paperless offered Lonza an ideal opportunity to address these challenges.

## Areas Covered

- Mammalian Process Development
- Fermentation (cell culture)
- Purification
- Protein and Cell Line Analytics

# Case Study

## Fermentation (Cell Culture)

- Documenting media preparation, which now happens much faster than on paper
- Capturing at-line and offline measurements from a variety of cell culture scales, and combining these with summary online measurements

## Purification

- Capturing data across a wide range of unit operations, including Chromatography and Filtration
- Used to summarize data generated by Akta's and the Unicorn system

## Cell Line and Protein Analytics

- Replacing paper forms to capture assays to determine product quality and quantity, including ELISA, HPLC and Gel-Based analyses
- The project gave Lonza the opportunity to consolidate a large number of overlapping/redundant SOPs

# Case Study

## Company Overview

- The world's 2<sup>nd</sup> largest Pharmaceutical company
- Rollout to >400 users in Basel (Switzerland) and Cambridge (East Coast, US) in Process Development
- Novartis Research (NIBR) have also adopted E-WorkBook as their data management platform, with thousands of users worldwide

## Business Challenge

Novartis were finding it difficult to get a comprehensive understanding of their product and process data because of a heavy reliance on silos of information, such as Excel and paper notebooks

## Areas Covered

- Mammalian and Microbial Process Development
- Cell Line Development and Fermentation (cell culture)
- Purification
- Protein and Cell Line Analytics

# Case Study

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# Case Study

## Cell Line Development & Fermentation

- Capturing the details and results of all experiments involved in the development and optimization of a new cell line in a single platform
- Encapsulates the process from Molecular Biology and Transfection, through to small scale production
- Currently being augmented with AssetHub, to provide genealogy throughout the process
- Complements an in-house system that captures online data

## Purification

- Capturing data across a wide range of unit operations, including Chromatography and Filtration
- Supporting the exchange of samples and their results with Analytical groups

## Cell Line and Protein Analytics

- Capturing the results from a comprehensive range of assays to determine product quality and quantity, including ELISA, HPLC and Gel-Based analyses
- Adding valuable context to sample information



# Case Study

## Key Benefits

- Capturing context-rich development data (including details of reagents, equipment and instruments used) and making it more meaningful, searchable and reusable.
- Improved collaboration and sharing of information between cell culture, purification and analytical labs as well as between Research and Development
- Reduction in data entry errors
- Process genealogy



# Case Study

## Company Overview

- Roche are the world's 3<sup>rd</sup> largest Pharmaceutical company
- Both Roche Penzberg (Germany) and Genentech (West Coast US) use the IDBS platform for process development data management

## Business Challenge

Roche were finding it difficult to get a comprehensive understanding of their product and process data because of a heavy reliance on silos of information. Roche consider one of the primary outputs of their work to be DATA

## Areas Covered

- Mammalian Process Development
- Fermentation (cell culture) – (note that Genentech currently use a home built system for Fermentation )
- Purification
- Protein and Cell Line Analytics

# Case Study

## Fermentation (Roche)

- Captures Media preparation and enables referencing/traceability when media is used in a cell culture experiment
- Captures at-line (e.g. cell count) and offline (sample) data from fermentation runs at a range of scales
- Captures summary online data by integration with OSI-PI Historian

## Purification (Roche & Genentech)

- Capturing data across a wide range of unit operations, including Chromatography and Filtration
- Supporting the exchange of samples and their results with Analytical groups

## Cell Line and Protein Analytics (Roche & Genentech)

- Capturing the results from a comprehensive range of assays to determine product quality and quantity, including ELISA, HPLC and Gel-Based analyses
- Integrated with Roche's LIMS and Instrument Integration Layer

## Quotes

*In their own words:*

<http://www.idbs.com/en/videos/2014/09/connect-2014-case-study-damas-markus-braunreuther,-roche/>

## Key Benefits

- IDBS provides an integral part of a 'one stop shop' for all Roche's documentation and data analysis needs
- Improved linkage between groups in the development process
- Greater product and process insight

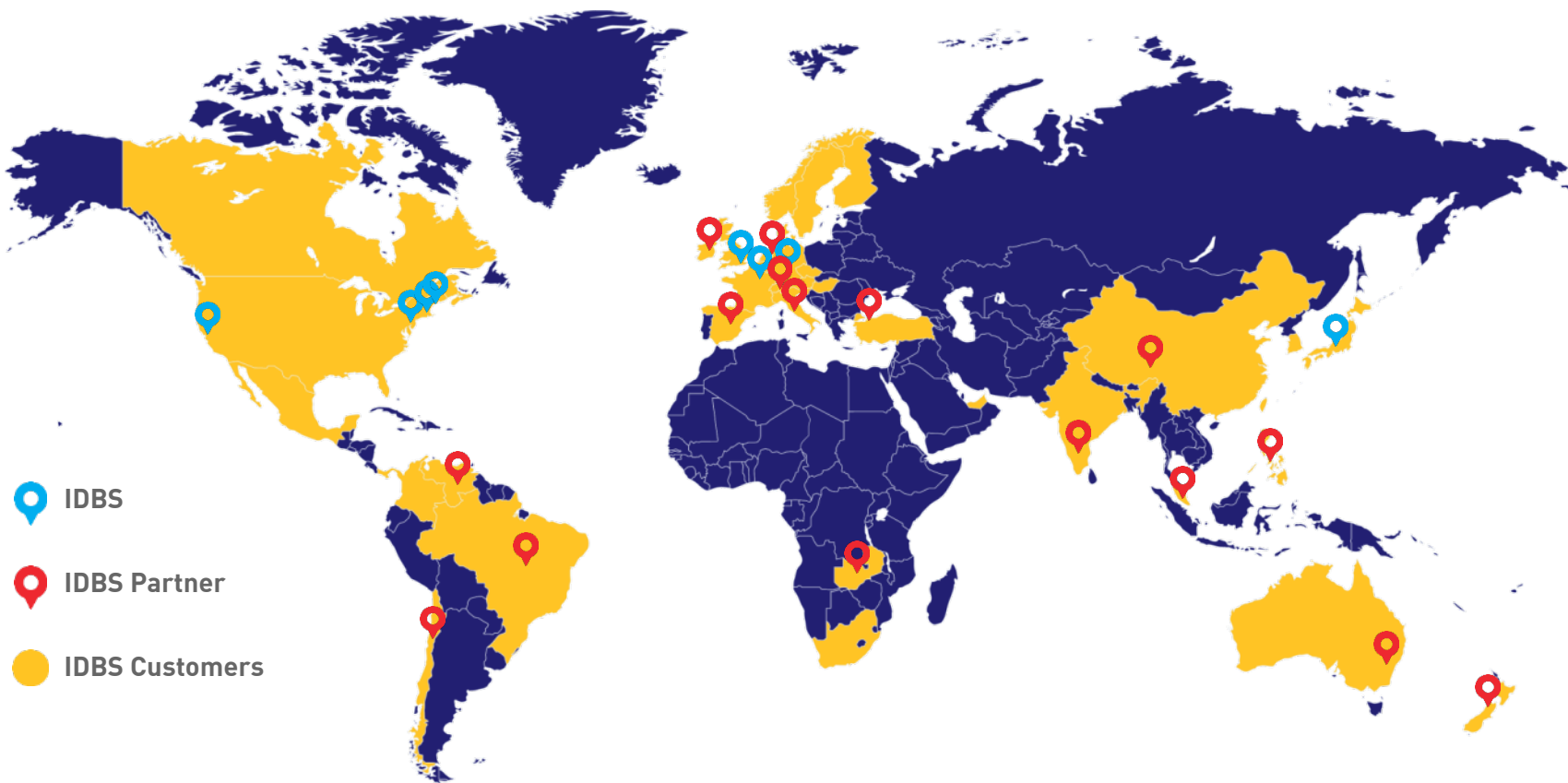
# Customer testimony

“....adopting IDBS' Bioprocess Execution System as our data management solution will help us **improve our processes** and **enhance the quality of the services we provide** to customers.

After due consideration the IDBS software and service offering was our preferred solution. **The knowledge and expertise of IDBS staff in the bioscience arena was a key factor in our decision.**”

Dr. Steve Flatman, Lonza Head of Mammalian Development Services

# IDBS Global

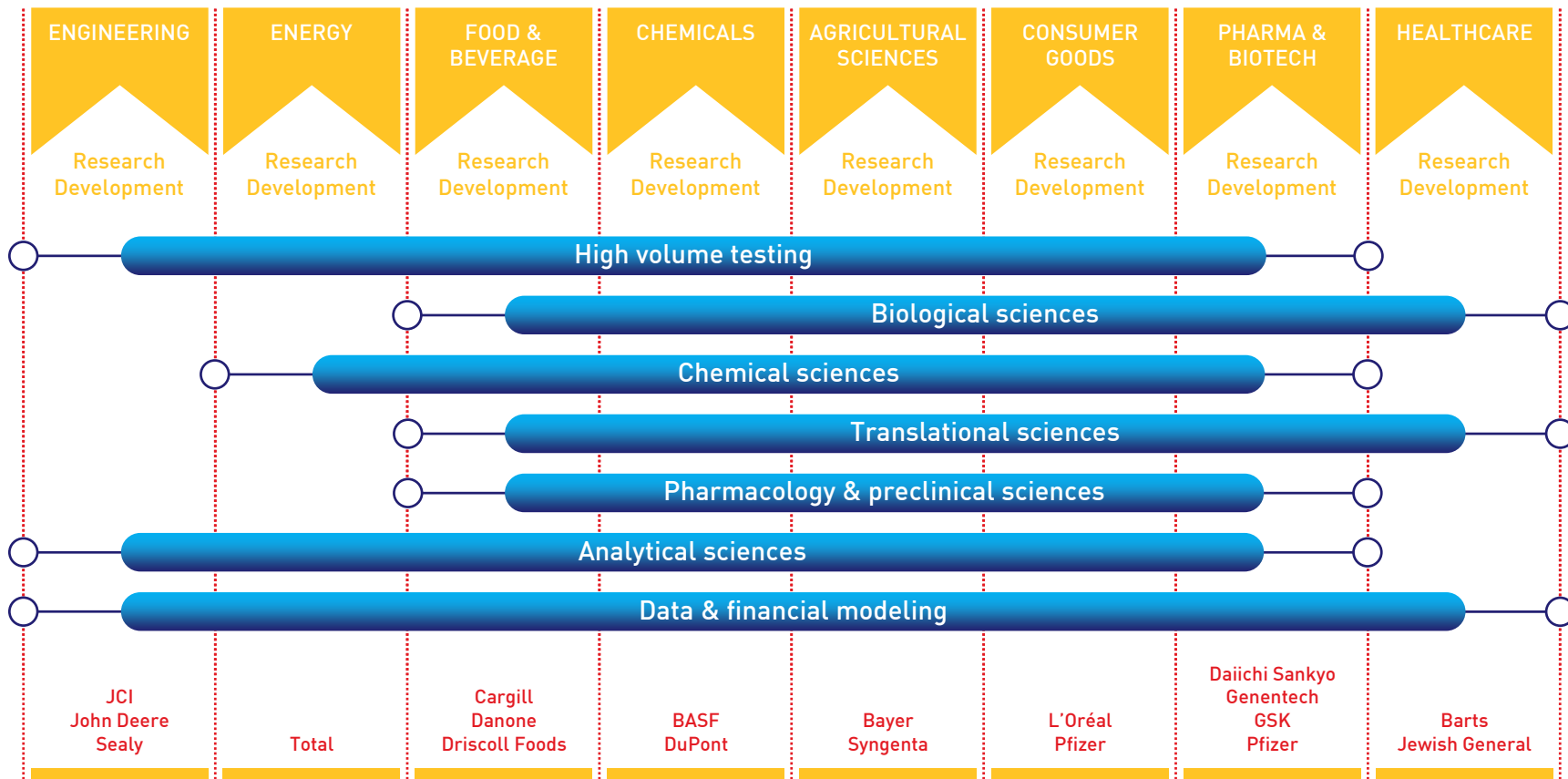


# Different verticals

ENGINEERING	ENERGY	FOOD & BEVERAGE	CHEMICALS	AGRICULTURAL SCIENCES	CONSUMER GOODS	PHARMA & BIOTECH	HEALTHCARE
Research Development	Research Development	Research Development	Research Development	Research Development	Research Development	Research Development	Research Development
   	  	   	    	   	    	       	   

Or in R&D – new product **vs** new material, new medicine **vs** new drug,  
new supplement **vs** new nutraceutical, IC50 **vs** IC<sub>50</sub>

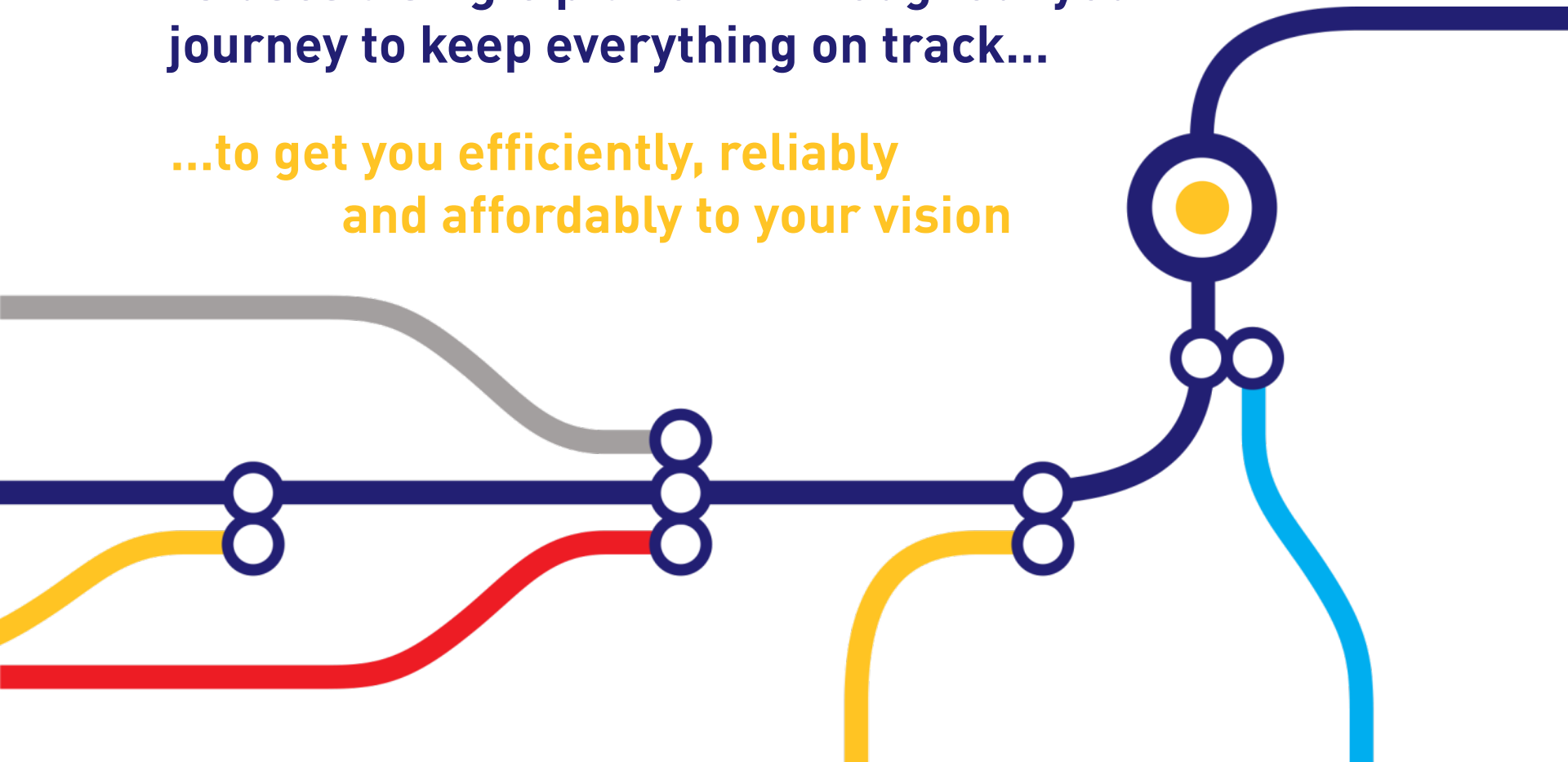
# Different verticals – similar science





# IDBS uses a single platform throughout your journey to keep everything on track...

...to get you efficiently, reliably  
and affordably to your vision



# Thank you for your time



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