Customer success story: streamlined cell line development

This success story demonstrates how an IDBS customer was able to reduce the time to create cell line development reports by 50%. The IDBS platform supports hundreds of users globally at a multinational biotechnology company focusing on biologic therapeutics.

The challenge

Six to eight weeks to generate a cell line development report

The cell line development group was struggling to generate reports. A hybrid paper, ELN and Excel-driven landscape hindered the creation of reports to release cell line cultures. IDBS worked with the Customer to understand the current challenges and bottlenecks. Given the hybrid paper/digital operating environment, it was estimated that more than 32,000 resource hours per year were spent manually connecting processes, data, materials, equipment and people, together. It took six to eight weeks to generate a final cell line development report.

The solution

The Customer accepted IDBS' recommendation to conduct a series of workshops to map out their cell line development processes, business rules and desired flexibility. The graphic below is a generic output of the developed process map. Each line represents a flow of structured data and information that can be easily modified and extended in a GxP-compliant manner.

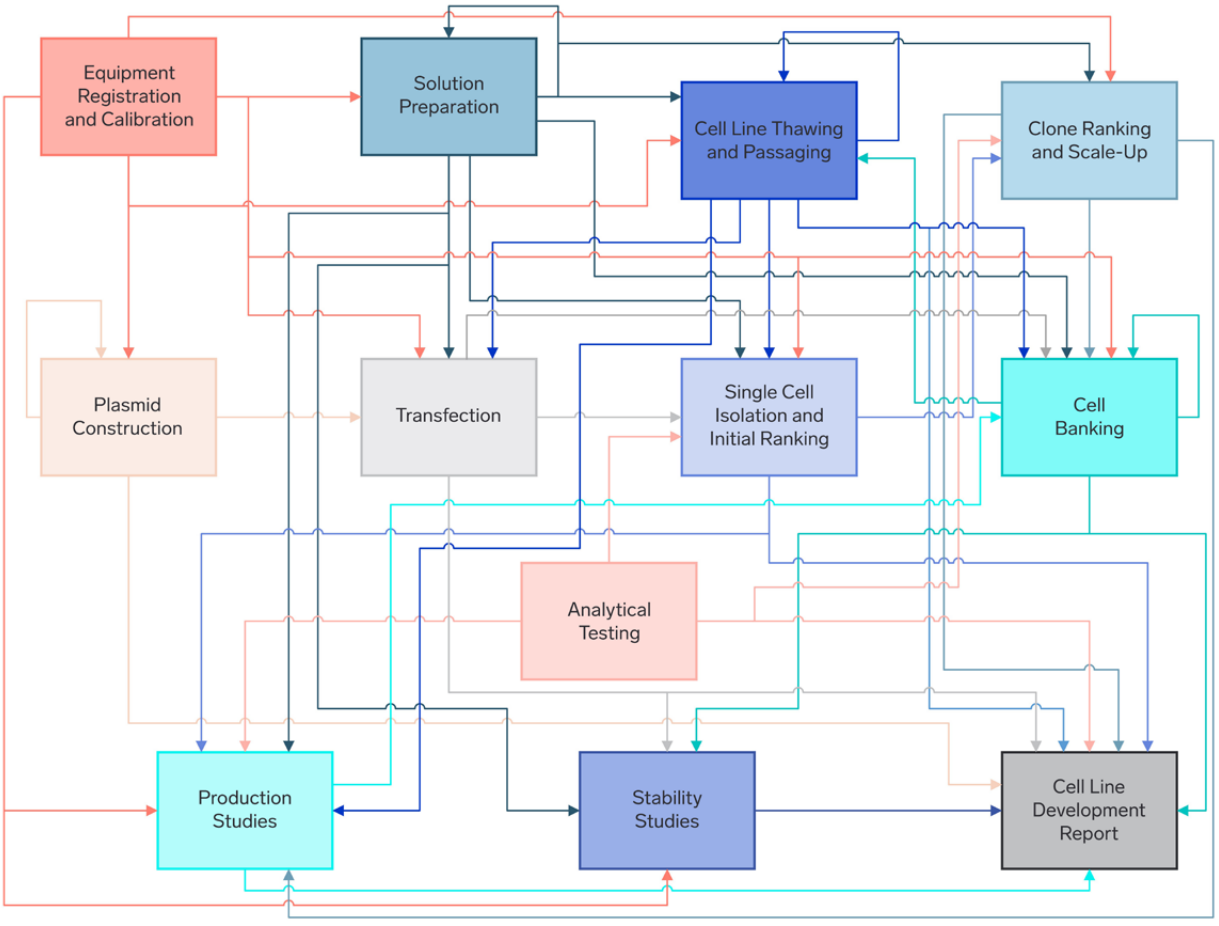

Fig. 1. Information and data flow throughout cell line development

The results

IDBS worked with the Customer to estimate the current time spent on core activities and expected time savings. After implementing IDBS' digital workflows for structured data capture, the Customer calculated actual time savings of over 14,000 resource hours per year (Fig. 2). The time to generate a final cell line development report was calculated to be two to three weeks, which is a 50% reduction.

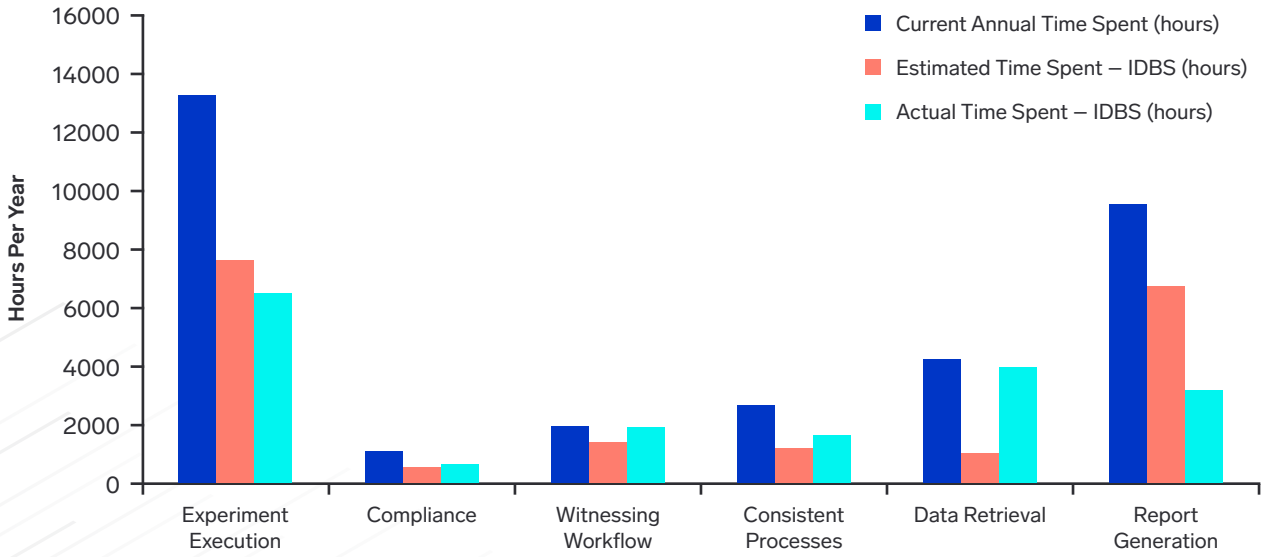

Fig. 2. Estimated vs. actual time savings by activity

Additionally, the Customer's own success team reported:

50% reduction in time to generate a cell line development report

- The ability to generate technical reports against searchable data enabling scientists to search for cell culture data directly
- Reduced error resolution times because alerts were added to flag data errors and inconsistencies in the clone selection process, which called immediate attention to issues
- As a result of the increased efficiency, there was a 25% increase in lab capacity to support additional projects.

Business rules to elevate a target to the next step can be applied or adjusted within each workflow to expand or contract the "hits" based upon specific acceptance criteria. The dataflow is preserved, and managers are presented with consistent, accurate and complete data associated with the generation of a master cell bank including product quality, clonality and plasmid construction.

IDBS' approach to bioprocess development digital workflows is:

- **Flexible** – Our platform accommodates both flexible non-GxP and controlled GxP workflows
- **Standardized** – Digital workflows ensure consistency and comparability
- **Structured** – Process data capture, storage and retrieval
- **Traceable** – Genealogy and material consumption is recorded across all process steps
- **Compliant** – Meets the FDA's 21 CFR Part 11 guidelines for GxP operations

The IDBS difference for biologics development

Biologic therapeutics process development is a complex, iterative and multi-disciplinary activity. Before electronic lab notebooks (ELNs) became widely available, this work was typically recorded in paper lab notebooks, which meant senior scientists had to spend hours printing, cutting and pasting Excel and instrument printouts. While ELNs eliminate paper, electronic "paper on glass" systems don't solve the more fundamental challenge of enabling scientists to easily find, compare and reuse information. Complex development reports spanning months of activity still take weeks of effort to prepare and data integrity issues uncovered at the eleventh hour can delay regulatory submissions by as much as six months.

Since 2008, IDBS has been implementing both large-scale and modular deployments of bioprocess development solutions designed to provide structured data capture through digital workflows with integrated instrument connectors. While biologics process development is challenging, IDBS believes that managing and integrating your workflows and data shouldn't be.

Find out how IDBS can help streamline your cell line development.

Talk to one of our experts today.

CONTACT US

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