

**STREAMLINING PHARMA PRODUCT
DEVELOPMENT THROUGH **DIGITAL
CONSULTING****

Zifo.



Background

Our customer is a leading pharmaceutical company with several drugs in the market and pipeline for eye disease, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, infectious diseases, pain and rare diseases.

Problem Statement

The customer's organization has a large functional group responsible for the research and development of drug formulations, comprising of approximately 60 scientists and lab technologists. Their functions included performing experiments spanning several years to support stability studies, large-scale formulations manufacturing to support these more comprehensive studies, and shorter exploratory studies with small-scale formulations manufacturing in the pre-clinical stage.

In large, interconnected laboratories such as the ones at the customer's site, an Electronic Laboratory Notebook (ELN) system is an essential tool for documenting lab processes and experiments to ensure data management and regulatory compliance.

The formulations group used a single generic ELN template for a myriad of experiments with no pre-defined automated workflows or calculation capabilities.

This led to redundancy in data entry and made navigating multiple-step experiments, verification and searching of content time-consuming and challenging.

There was also dependency on other tools such as MS Excel to perform basic calculations and analysis.

Furthermore, the product vendor of the ELN platform had discontinued the creation and support of new templates in the thick-client environment used by the customer. This prompted the customer to consider adopting the newer web-based ELN platform and transitioning from a single generic template to a collection of 8-10 pre-defined templates specific to key experiments in order to improve their efficiency, data entry practices and user experience.

How Zifo Came into the Picture

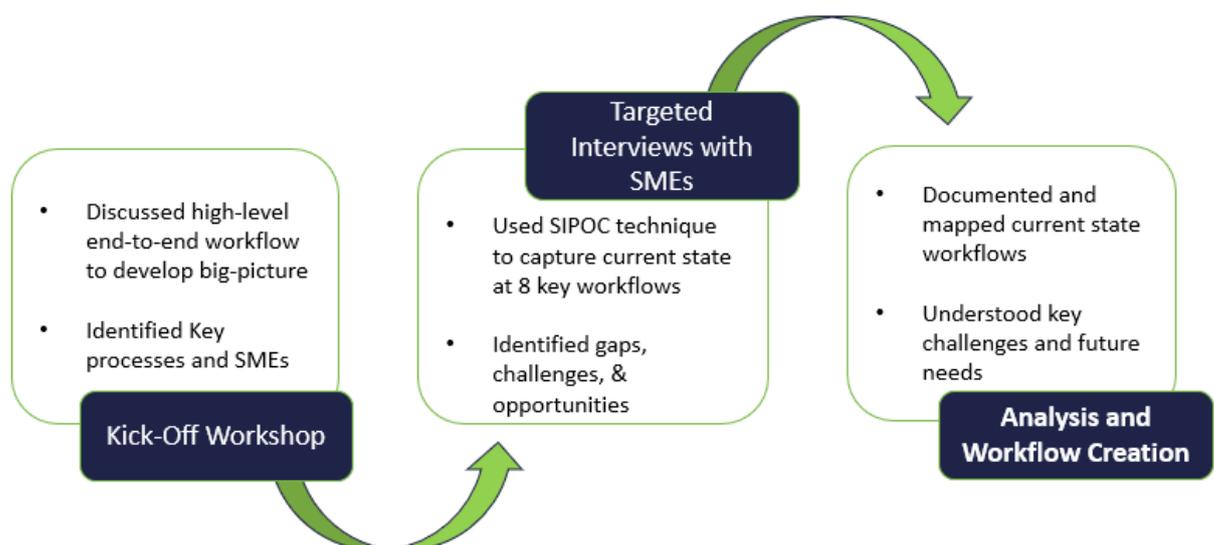
Zifo had been engaged with this customer for supporting some of their key scientific informatics applications. For this engagement, the customer reached out to Zifo to help streamline the transition to web-based ELN templates.

To hit the ground running on this endeavour, prior to beginning the development of the templates, Zifo proposed conducting a consulting engagement with the formulation group in order to map how these individual workflows fit together in the overall end-to-end lab process to identify inter-dependencies, validate the identified templates and identify the key capabilities that would be required for specific templates and workflows.

Plan of Action

Zifo's Scientific Informatics Consultants adopted a three-step plan of action for the consulting engagement with the formulations group (called Phase 0), comprising of:

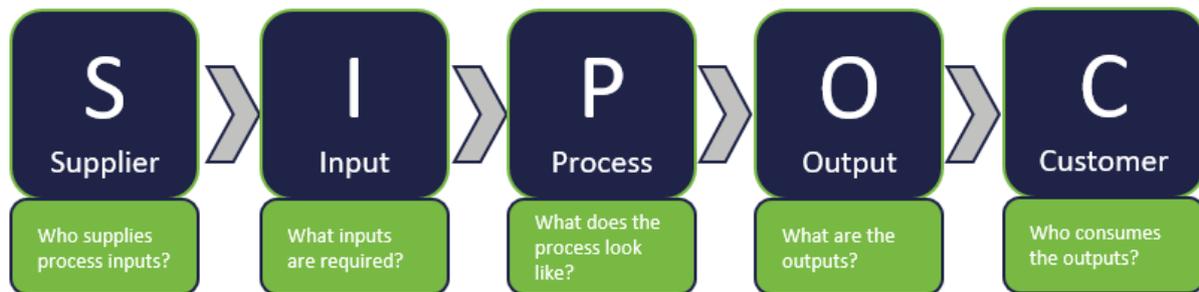
- Kick-Off Workshop with Stakeholders
- Series of Targeted Interviews with SMEs
- Workflow Mapping and Analysis



Before the kick-off workshop, Zifo Consultants studied various samples of experiments and calculations received from the formulations group to understand the variety and complexity of experiments and the complexity.

After the workshop, Zifo Consultants analyzed the findings and developed a plan for the Targeted Interviews with SMEs.

For targeted interviews, Zifo Consultants adopted the SIPOC methodology to strategically map the end-to-end process.



SIPOC is an easy and effective method to visually map any process and identifying dependencies between individual groups and processes.

During workflow mapping and analysis, Zifo Consultants strategically analyzed the information collected during the Kick-Off Workshop and Targeted SME Interviews and accomplished the following:

- Prepared Current-State Workflow Maps
- Identified Gaps and Challenges within the Current-State Workflows
- Identified Capabilities and Opportunities to Improve Current-State Workflows
- Prepared Future-State Workflow Map
- Ranked Capabilities per Workflow
- Categorized Workflows based on Business Value and Complexity of Template Development
- Prepared Implementation Plan for Template Development
- Prepared Recommendations for Next-Steps



Zifo's Solution

From the information gathered, Zifo Consultants prepared a collection of process maps of the current-state workflows:

- High-Level End-to-end Overall Process Map
- As-Is Process Maps of the 8 Workflows

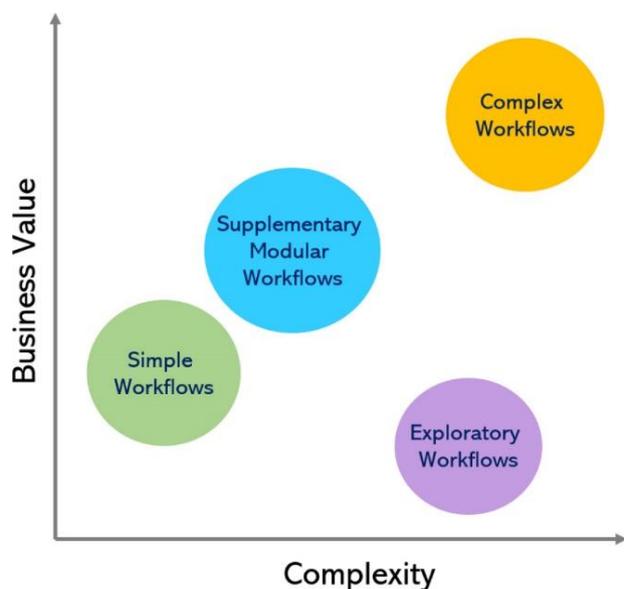
These process maps helped visualize complexity of a workflow and interdependencies between workflows with the inclusion of supplementary information regarding software systems/tools used for documentation, scheduling and data analysis to highlight integration or automation opportunities with the ELN platform.

Additionally, through thorough analysis of the current-state workflow maps, gaps and interdependencies within these workflows, the Consulting team identified key capabilities and opportunities to streamline the workflows and developed:

- Future State End-to-end Overall Process Map
- Prioritized Capability Matrix

The Prioritized Capability Matrix served dual purposes - firstly, it ranked each key capability on a High-Medium-Low scale for every workflow based on the functional need to support the workflow. And secondly, it grouped the workflows into:

- Complex Workflows with extensive interdependences and variability (e.g. Stability studies, compatibility studies)
- Supplemental Modular Workflows that enable other workflows (e.g. Compounding, Sample Analysis)
- Simple Workflows that are self-contained (e.g. Spray drying, Lyophilization, PEGylation)
- Exploratory Workflow that are not well-defined and needs flexibility (e.g. R&D studies)
- The complexity of custom template development
- Potential value-added to Business stakeholders



By grouping the workflows into the following categories Zifo Consultants built a roadmap for template development.

The Simple workflows gave moderate to low value to Business but are largely well-defined and had little interdependencies, hence were quick hits in terms of template development. These included Spray-drying, Lyophilization and PEGylation experiments.

The Complex workflows used for long-term Study design experiments provided the greatest value to Business but had the most interdependencies.

An important observation was that an ELN solution is not suitable to support some of the foundational capabilities, such as inventory management needed to enable these complex workflows; therefore, it was determined that a different informatics solution might be better suited for this purpose.

The Supplemental Modular workflows used for base functions like Compounding and Sample Analysis were relatively simpler, generic workflows that provided moderate to high value to Business.



Finally, the Exploratory workflows used for R&D, by nature were the least well-defined since these require large amount of flexibility, and hence template development would be relatively complex.

Zifo Consultants prepared a three-wave implementation plan for template development along with crucial recommendations to support this roadmap.





About the author



Mehnaz is a Business System Analyst at ZIFO RnD Solutions and is based out of USA. Her focus is around Scientific Informatics Solutions for process improvement and optimization. She has experience with Next Generation Sequencing and Clinical Drug Development processes.

She has helped our customers with:

- Driving operational improvement through Scientific Consultation related to Research Informatics, Clinical Biometrics & Genome Informatics.
- Requirement gathering and analysis related to multiple Laboratory Applications including LIMS, ELN and Electronic Batch Records.
- Mapping Current and Future state Business Process Workflows and Dataflows to identify gaps and improvement opportunities.

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