

The Process Design Recipe

Process design is the foundation for information flow across the organization and should form the basis for technology architecture as well. Unfortunately, it is often underappreciated as a critical step in driving increased value, compliance and innovation.

Many growing biopharma companies see process as simply bureaucracy and structure, limiting creativity, but it actually helps people worry less on the steps they need to follow and focus more on the science and the creative aspects of getting life-saving therapies to patients.



A few years ago, I had the pleasure of attending a team-building exercise where our team was invited to prepare a meal at a commercial kitchen. While many of us did not have much cooking experience, the entire event followed a very precise process, which made it a very enjoyable event. Because the entire process was clear and explained in advance, the recipes we later followed were easier to execute and we were able to focus more on the results.

Today, biopharma companies spend a great deal of time and money on new technologies that use workflows and other mechanisms to



provide automation, without first defining and documenting their processes and information flows across the organization. This is

like introducing new recipes without considering the layout of the kitchen, the ingredients needed, the outcome of the recipe or the staff needed to cook the meal.

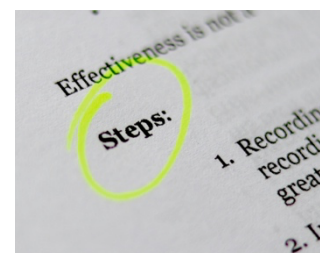
Taking a step back and spending some extra time on your process "recipe" will pay dividends in added value to the organization in terms of less churn, increased compliance and more time to focus on innovative solutions to complex issues that may arise around trial design or cross-functional interactions.

1. Processes define the most optimized path

A common design principle for a kitchen is called the kitchen work triangle. This design represents traffic flow in a kitchen by creating a rotational movement between different tasks that must be completed. These tasks include cooking (stove), chopping/peeling (sink), and storage (refrigerator).

A process flow, when properly designed, does the exact same thing for orchestrating business activities. A process must clearly define and represent **Who** does **What**, and **When**. Most companies rely on compliance documents such as SOPs to convey these important concepts, but many employees have a difficult time translating these documents into a repeatable, practical process steps. This knowledge gap results in new hires starting slowly and potential process variations and inefficiencies across the group.

Well-defined processes, and a little training, allows newcomers to get up to speed quickly and learn their responsibilities and role within the organization. This is especially helpful when we are forced to work remotely, often with teams and external vendors that are dispersed globally.



2. Defining roles and responsibilities make processes work

When you see professional kitchens in action it looks like a type of ballet. Each person is aware of their role and what part of the process they control. Without defining these responsibilities, we run risk of confusion and ruining the dinner!

In process modeling, defining the RACI (Responsible, Accountable, Contributes, Informed) is important to keep roles and responsibilities clearly defined. A great deal of optimization is a result of the RACI by eliminating redundancy, unnecessary work, and wasted efforts. Given the increasing reliance on outside organizations such as CROs, it is even more important to clearly define roles and responsibilities to obtain the greatest benefit and keep projects and trials on track. Some workflows can do this as well, but they typically help at a granular level, when a broader view is required. Defined processes and RACI are essential for a well-run and optimized workplace.



3. Processes can have multiple paths to manage risk and compliance needs

When prepping for a meal, you may have to change the recipe if you are serving 300 instead of 3. If you fail to consider scale as part of your process development, you run a risk of losing opportunities to save time and efficiencies.

While we want to avoid shortcuts that may introduce unnecessary risk, you should consider opportunities to save effort when possible. When designing processes for large, global studies, for example, there are opportunities to take advantage of innovative methods and technology. Some of these opportunities include solutions such as risk-based monitoring, patient centric technologies, or decentralized trials.

Processes should include flexibility to allow for economies of scale, risk management, alternative paths and informed decisions. Utilizing decision-based paths in our process design allows for multiple routes to achieve results. This flexibility allows clinical teams to maneuver as needed, while maintaining momentum. Linking process to information flows also helps improve the use of technology and decisions for investments to improve information flow, storage and reuse across the organization.



4. Processes all have a start and an end

Just like recipes have both ingredients and final products, business processes must have triggers and outcomes. It is important that we identify process triggers early to ensure we have the necessary information and data before beginning work. Of course, a decision can be made to start early and “work at risk” but this becomes an informed decision; processes should be designed to recognize and plan for these opportunities. For example, you can trigger site qualification using a protocol synopsis, but reevaluate based on protocol changes available. Optimized processes should continue to update the user when new information is available. Informed, risk-based decisions allow you to save time and money for critical path processes.

Restaurants can buy expensive equipment and purchase the finest ingredients but that does not guarantee a remarkable product. The same can be said for your clinical organization. Partnering with an organization that can help you define optimized processes can add significant value to the organization and help you get therapies to patients faster. Pretty soon you will be boasting about your own Michelin star!

– **Mike Hagan, Process Optimization Expert**

For more information, e-mail info@triradial.com or call 1-866-TRI-RADL