



Improving Patient Health and Safety

Case Study: SOPs and Process Mapping

A rapidly growing biotech company did not have enough SOPs in place to achieve compliance, and lacked compliance within their existing, light-weight SOPs. In addition, the SOPs did not include process maps. As a result, the ProPharma project manager (consultant) recommended a process mapping exercise in order to increase compliance to SOPs, train employees and contractors on processes, and to map end to end processes so that the team members could better understand how processes and decisions fit together throughout the drug development process. To accomplish this, the consultant recommended the creation of retrospective process maps from Immunovant SOPs as well as the creation of an integrated process map from existing Immunovant SOPs.

The client was also starting a new Site Relationship Management group and required help in developing process maps, SOPs, and training on procedures to ensure compliance.

The consultant developed a project plan with workstreams and processes to divide the work into smaller groupings, and to outline the steps required to draft, review, and approve the deliverables. The expert consultant utilized their clinical and process experience to facilitate kick-off meetings with each department and to gain buy in with the drug development functions to complete the project on time. The consultant then facilitated a series of meetings with each function to draft and approve the process maps. The team of consultants then drafted the SOPs from the process maps and followed them through to approval. Once each SOP was approved, the team of consultants then drafted the end-to-end process map to provide a pictorial view of the tough points within and between functions throughout the development process.

Based on this work, the client was able to utilize a fully documented, mapped out, end-to-end process that served as the backbone for training and compliance. The client was able to utilize the SOPs for the new Site Relationship Management function, and this project helped the group define their remit and scope of responsibilities in relation to how it fit with the clinical function and its stakeholders.

