MEDICAL DEVICES

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Discovering the Opportunity

Motive Power has engaged in the creation and implementation of a globally standardized clinical research study management process (SMP) and harmonized standard operating procedures (SOP) for multiple leading Medical Device companies.

These projects were driven by each companies' need to ensure compliance to regulatory requirements as well as drive consistency across their organizations. The objectives were to optimize operational efficiency and to increase data quality across its global clinical research organization. Each posed a major change from the current operations of the companies.

Building the Strategy

Motive Power's approach was built around involving stakeholders from each organization throughout the entire program. Motive Power developed a Change Strategy which engaged each organization globally in a comprehensive change management program, including focus groups, training design and facilitation, a multi-tiered communication strategy and a change agent program.

Motive Power developed a flexible Change Strategy that was adaptable to project complexity and size. The simplest of which involved less than 200 users whereas the most complex affected more than 2,000 users and spanned 18 business units.

Additionally, Motive Power developed a comprehensive communication plan that identified audience segments and tailored information for distribution within each organization on a measured timeline.

This ensured that all the clients' staff, in all locations, and all roles, were kept appraised of updates and upcoming milestones.

Motive Power created a Deployment Plan which would meet the determined goals of each organization. Each company posed different challenges relating to deployment with one being dispersed globally and the other having a limited budget. Therefore, Motive Power weighed each potential deployment method with metrics related to cost of process development, % of staff trained, cost of training comparing method, frequency, and travel, all weighed against pros and cons of each decision. Motive Power reviewed each plan with senior stakeholders, and for each organization could determine an approach that balanced the effectivity, cost, and schedule.

Leading the Team

Motive Power partnered extensively with the clients to develop the SMP, by engaging steering committee members and focus group members, representing the global organizations, in the creation of a process which could provide global guidance to each business unit, regional group and functional group.

To tackle this challenge, focus groups were established for each of the 18 global organizations. Each focus group was led by a Motive Power lead and a regional/functional client leader. This established client accountability and facilitated efficient client input and decision making.

Focus groups met bi-weekly for two hours at a time. This consistent meeting time also allowed strong relationships to develop organically between Motive Power and client organizational leaders.

Motive Power also identified Subject Matter Experts (SMEs) to review training materials and provide guidance and credibility in each training delivery.

Core Tenants of Change Management Practices:

1. **Global standardization**

2. **Conduct as-is asessment**

3. **Align project goals to stakeholders' objectives**

4. **Develop Gap Analysis**

5. **Develop and deploy change management strategy**

6. **Lead focus groups, workstreams, and workshops to develop deliverables**

7. **Developed and deployed training to 1,800 staff**

8. **Developed actionable adoption metrics**

Building the Tool

Motive Power also led the developer team, consisting of internal Motive Power developers as well as within the client's IT, to design and deploy a centralized, interactive one-stop-shop software application where clinical employees would access the process, SOPs and business efficiency tools to perform clinical research study management in the future state. Motive Power engaged the focus groups and stakeholders throughout the process of design of the user interfaces to ensure that all "user stories" were understood and that the final design solution would meet the expected user experience. Prior to deployment, Motive Power conducted workshops with a subset of the study teams to perform a "dry run" of a study using the new tools to verify user acceptability. The result was a tool that was simple to understand and navigate, and with minimal training, administrable by the clients own personnel.

Training for Deployment

Motive Power began the training deployment phase with pilot training sessions to tailor and begin iterative improvement of training content design. After final updates were made in coordination with client project leads, Motive Power deployed the training to the rest of the organizations. Each training was supported in person by two to five trainers, depending on the size of the training group, which ranged from 15-150 employees. The sessions were conducted per the organizations deployment plan, and were executed over 0.5 days to three days, and were conducted over a period of time that was up to six months for the larger client.

In addition to review of the project objective and background, Motive Power performed indepth instruction on all new material and tools. This included activies which Motive Power designed to keep the employees attention and inject energy into the training. This ensured employee engagement throughout the sessions resulting in a high level of knowledge assymalation.

Motive Power's training design and facilitation performance was measured by surveys distributed at the end of the training sessions. Motive Power partnered with the client to make iterative adjustments to the training

materials throughout deployment, which resulted in steadily improved scores and left the client happy and supportive of our work.

To ensure that 100% of the staff received the training, Motive Power conducted Webex sessions for any staff who were unable to attend in person. Finally, for staff who was hired after the training concluded, Motive Power created video training modules which consisted of a subset of the material, to ensure that all staff would continue to have access to the knowledge.

Tracking the Progress

Adoption support continued after training deployment with a program called Hypercare, which provided an elevated level of support throughout deployment through targeted topic webinars, an actively maintained support email address and open office hours. Motive Power also shifted stakeholder focus group engagement to clinical team engagement to minimize client resource demand and to position the organization to drive results through its existing quality control function.

Finally, Motive Power developed metrics based on each organizations roll-out of the new tools, based on quantitatively measured statistics on Clinical Study Document updates, and transition plans. These metrics were used to identify actionable risks, and allowed for proactively management of any that could affect the clients' regulatory determined transition completion date for the adoption activities to be completed by.

Reviewing the Project

Upon completion of the project activities, the metrics and surveys showed that each deployment was a great success. Training reached 100% of the staff, and that staff stated that the tools would greatly help each in their daily jobs. And finally, through active management of the risks identified in the Adoption Phase, all studies completed their transition activities by the required completion date. This resulted in each of our clients realizing each of their project goals, in schedule, and within stated budgets.

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