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Review Article

Components of a Successful Training Model for Statistical Reporting in the Pharmaceutical Industry

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Abstract

In the current highly competitive and global market, organizations in the pharmaceutical and biotech business sectors are forced to either adapt to the current conditions or perish [1]. The pharmaceutical and biotech industries have an added stressor of necessary and ever changing regulatory oversight of their product line. Ateam of contract staffing organizations, Experis, Inc. and Intego Group (Clinical and IT staffing, respectively) responded to the current conditions with a well thought-out learning and placement model consisting of cooperation between industry and academia. The goal of this specialized training program was to have a viable client placement of the trainee at the end of program. This program is now completing its second year of implementation, with interns being placed in the summer of 2015. The training model implemented specific curriculum coupled with industry mentoring to prepare students for entering the research and development effort of clinical trial reporting using SAS programming for statistical analysis and reporting. The model will be explored with the purpose of reflectively understanding components which lead to success, one of which included a high retention rate and placement of each graduate in an entry level position in one of the partnering organizations. Theoretical models of leadership, team building, and organizational learning will be explored using the context of the practicing model. This understanding will offer insight into the root components leading to the successful implementation of this model, such as, commitment from the client for placement, relationship with the university, strategic and technical leadership, and built in incentives for the students. Future research directions will also be explored as a result of this working model.

Introduction

One joint business venture, consisting of two organizations that provide staffing to pharmaceutical and biotech organizations, responded to the current market conditions with a well thought-out learning and placement model consisting of cooperation between industry and academia. Experis is a niche Contract Research Organization (CRO) that specializes in contracting SAS programming experts to clients for the purposes of statistical analysis and reporting of clinical research study data. Intego Group is a global IT outsourcing provider for dedicated software development, with teams hosted in Ukraine. After describing and delineating essential components of this model, current research in organizational learning will be explored to propose, from a theoretical basis, how this model met with success. Research highlights in the areas of organizational learning, team learning, adult learning, and leadership will be perused, as they apply to the training model under consideration. Most organizational change efforts are motivated to enhance success in the organization, thus understanding components of this successful training program shouldbe useful in planning for other growth opportunities in the organization.

Why do we Care about Learning?

Noted that empirical research had moved past the question of whether the ability of the organization to learn led to improved performance [2]. They proposed that researchers focus on exactly how learning leads to an improved performance state for the orga-

nization. The organization's ability to respond quickly to market forces, to have leadership in place to promote change, and have viable learning tools and systems in place are critical to the developing processes in the organization and are necessary to the continued success of an organization. Current research has demonstrated a positive correlation between learning organizations [3,4] and sustainable competitive advantage [5] as well as business effectiveness [6].

When evaluating a current training model, it might be of interest to identify the components which contributed to its success and reflectively understand how each fits into the current theories in organizational learning research. More importantly, this understanding of critical components could then be applied to the planning stages of any proposed model to ensure building a successful model. For the present effort, the training model of interest will first be illustrated. This description will be followed by identifying the components which the formulating team declared contributed to its success. Success was measured by observing whether the outcomes met matched the goals of the project. Finally, current organizational learning research will be used to illustrate how the components of this training model aligned with successful outcomes as proposed in theoretical models.

Introduction of the Training Model

The training model began with a question at the strategic leadership level of the joint venture between two Contract Organizations, Experis, and Intego Group. This partnership relied on mutual trust, respective in-country knowledge (US and Ukraine, respectively), clinical expertise, and a shared goal to make a global footprint. The question was "How to meet client requests for lower-cost offshore clinical statistical programming to support the clinical research team globally?". Clinical statistical programming is a niche in the pharmaceutical/biotech industry which requires highly trained and motivated personnel with strong technical aptitude and expert problem solving ability. Additionally, SAS is the programming software system of choice for clinical trial work, because it provides the tools necessary to enable programmers to take raw data from collected clinical trial data and perform statistical analyses as well as create data summaries, tables, and graphs. The joint leadership team, consisting of members from both Experis and the Intego Group, had the goal that graduates from the program would be able to join a clinical project team and contribute immediately. From the organizational side, this plan provided a cost-effective alternative to on the job training, resulting in a highly skilled, very specific addition, to the organizational work force. The pool of experienced resources in this business arena is scarce and the industry need is increasing.

After exploring a number of possible sites, Kharkov, in Eastern Ukraine, was selected as the site for the training model. Ukraine was selected because it offers availability of students with a history and culture imbedded in scientific and mathematical emphases. The target of the training was to develop high quality Clinical SAS programmers to be resourced to programming and analysis divisions of world-wide organizations in the pharmaceutical, biotech, and clinical research sectors of business. Kharkov had an established Intego Group presence, with a pool of experienced clinical programmers, who could be used for mentoring during the education part of the program, for placement for internships, and possible placement at the end of the internship period.

The training model included university based training at Kharkov National University, also located in Kharkov, which could work in conjunction with the Ukraine based Intego Group. The university helped design curriculum in consultation with both Experis' and Intego Group's organizational staff as an adjunct to a currently operational master's degree program. The curriculum included a total of 30 weeks of instruction, 15 weeks overtwo semesters, with an emphasis on hands-on experience that would prepare the student for the work world. Courses included Base SAS, Clinical SAS Programming, and English for the pharmaceutical industry, Introduction to Databases, Clinical Data Interpretation, Advanced Statistics, and Introduction to Clinical trials. Both Experis and the Intego Group aided in administration, helped to cover expenses, and acted as a resource for curriculum design. All classes were held at the university and complemented the students' regular university curriculum schedules. To ensure complete and successful learning students were required to dedicate 15to18 hours a week in addition to the time spent in the regular curriculum.

Having the students in the training program in close proximity to experienced resources already in place in Eastern Ukraine, Kharkov, offered both mentoring capabilities during the classroom period and internship opportunities for graduating students. Eventually this would also have a potential opportunity of job placement. The planned curriculum for the program included a team-building activity each semester where the university students mingled with the operational team to build relationships and long term associations. In addition to the strong focus in Math and Statistics, this university was chosen because it has a variety of schools and departments in its structure. This enabled the students in the program to be engaged with professors and instructors from three schools in the university: School of Mathematics, School of Medicine and School of Foreign Languages.

Students were recruited at the university, using flyers, emails to graduate students in Mathematics, and social media announcements. The initial meeting on campus to recruit prospective students was in June, 2013 with the plan for a fall, 2013 program launch. A total of 38 graduate student applications were received, and 26 were selected by the university after taking entrance examinations which included competency testing in Statistics, Databases/Programming, and English.

From this set of selected students, 24 students were chosen for interviews based on their GPA, university records, and entrance examination results. Students in the final year of their Master's degree program in the School of Mechanics and Mathematics were

targeted for this training model. The university graduate program required the Clinical SAS courses to be taken in addition to their major curriculum (Applied Mathematics, Statistics, or Computer Science). Prospective students were interviewed by Intego Group, the Ukraine based IT organizational team leader, the Ukraine based organizational HR Manager, and a representative from the University Admissions Department.

Areas of assessment were:

- Students' records (GPA, attendance history)
- Interest in biostatistics
- Desire to learn something new
- Availability to study evenings
- Body language and behavioral assessment
- Communication skills

The top reasons given by the students for applying were: a strong desire to apply learned math skills; interest in serving a humanitarian effort (saving people's lives); and understanding of the possibility of obtaining a position in an internationally recognized company. Eighteen students were accepted into the program, 16 completed both semesters, and of those 12 were recommended to take the SAS Certification exam. 100% of these 12 successfully passed the SAS certification exam with 3 students reaching over 95%. Also, from these 12, 8 were selected for paid Summer Internships. Experis, Intego Group, and a supporting client supported the internship program financially.

The 8 students selected for internship were divided into 2 groups. The strong supporting client of both Experis and Intego Group committed to have 4 of the interns work with current organizational team members, shadowing their activities. The Intego Group organizational team lead provided both mentoring and general oversight to enable an intern to learn client systems and be evaluated for permanent hire. Several interns in this experience were contributing members of the team toward the end of the internship. The other 4 interns were paired with US-based senior SAS programmers who worked in the Experis organization, serving several clients. In this experience they were assigned project work that was contrived to give them real-world, study team, experience but were not introduced to actual client work. During the internship, mentors and interns met both as a group and each intern with his/her mentor about 2 times a week. The communication among the Ukraine based team members mimicked a real work experience of email, Skype, and internal communication logs. The second set of interns, with U.S. based mentors, had different challenges. In addition to the technical challenges, the interns needed to adjust to time-zone constraints, possible language and communication barriers, as well as the cultural differences in work style. The second set of interns had a truly global working experience.

The mentors from the Ukrainian team were not paid for this experience, it was voluntary. The mentors from the US team were paid some for their time although the amount they were paid and what they claimed as training varied widely. A comment made by the Intego Group management staff was that the mentoring helped mentors more than the interns. The mentorship encouraged senior staff to develop leadership skills as well as a generate loyalty to the company because of their involvement in this critical endeavor. The mentors took ownership of training of the interns to ensure the next generation of incoming SAS programmers were ready to contribute to an actual project team. The interns had an opportunity at the end of the experience to provide feedback to the organization. One of their favorite parts of the program was working with their mentors.

The class of interns from the first graduating class (June, 2014) are currently 100% engaged in employment with the Experis or Intego Group, supporting either European or U.S. clients. For the 2ndclass, which just graduated in June, 2015, 26 applied, 12 were accepted, and 11 completed the program and took the SAS Certification exam. Of these, 8 were selected for internships. Those internships began in the summer of 2015.

The Experis/Intego Group team updated the training program in the 2nd year of operation. The selection process was changed, with fewer students enrolled initially into the program, 12 instead of 18. Additionally, the curriculum in the second year was updated to include more hands-on programmer in the first semester and more focus on databases and statistics across the program.

Factors of Success

The joint Experis/Intego Group team that devised this plan has considered this training model a success [7]. They attributed that success to several factors, among which was, (a) a commitment from the pharmaceutical client, (b) an established relationship with the university, (c) technical leadership, and (d) incentives built into the program. Although not claimed as a factor of success by the authors, the structure of the training model included placement of leadership components which ensured the implementation of the plan. Strategic leadership provided the original vision of the training model as well as continued support as needed for the implementation of the plan. The training plan offered the leadership of the organizational staff from both organizations, who managed the day-to-day oversight for students, which included technical staff to troubleshoot issues during the two-semester training period and functional team leadership who provided mentoring and team support during the internship period.

A major pharmaceutical client of Experis/Intego Group also provided support throughout the training and internship which was crucial to the success of this training model. In addition to the support that was already mentioned as part of the leadership component in the program through the operational working teams in Kharkov

and in the U.S., the client committed to support a minimum number of interns and subsequent permanent hires. During the internship phase of the training, the organizations in both Kharkov and the US supported the mentoring and personal training of students. Further this client provided some instruction to supplement classroom curriculum and gave the students global exposure to both industry technology and professional interactions.

Another factor which contributed to the success of this training model is the university in Kharkov. The willingness of the university to partner across all aspects of the program enabled access to students and facilities. A SAS academic partnership was created with the university which enabled the training program to incorporate best-in-class software solutions to not just the students enrolled in the training model but all students in the university. This effort also required updates to its network, which was financed by Experis. The university partnered with both contract organizations as well as with SAS to fully integrate the SAS training program into the university.

The availability of technical leadership to the students from both of the established organizations of Experis and Intego Group during the training program was another factor which contributed to the success of this training model. This was the same access to training and materials that were available to staff programmers, which included regular interaction with senior team members who served as mentors. The organizational instructors were competent and engaged, an integral part of the technical leadership team, who fully supported the course curriculum goal to formulate successful Clinical SAS programmers.

A final component of success can be attributed to the incentives which were built into the training model for those who participated, and ensured retention from the investment standpoint. For the students the appeal of gainful employment was a large incentive. But, in addition to the opportunity to gain employment with a large internationally recognized organization, the key incentives were:

A 3 month paid internship sponsored by the client, Experis, and Intego Group The opportunity to learn from world-class professionals such as the Senior Clinical SAS programmers of Experis and Intego Group a unique hands-on approach to education which was not offered in the main curriculum at the university The opportunity to learn SAS software Engagement in actual clinical projects during both the education and internship phases of the program A SAS certification, an industry-recognized endorsement, ensured students of a better market value as a SAS programming candidate, regardless of placement within the formulating organizations as an intern.

Organizational Learning Research

We now turn to the question of this manuscript. How does current research in organizational learning retrospectively support the methods used by the joint effort of Experis and Intego Group to ensure the training plan whichwas devised would be successful? Some research context will help to contextualize the research parameters of organizational learning and explore how leadership plays a role in it. Additionally, within the context of organizational learning, what features associated to it may explain some of the success components of the exemplified training model? In particular, the features that will be considered are (a) the structure of the organizational team, (b) leadership, and (c) the contribution of the individuals. The associated research for each of these features will be considered briefly, that is, the learning organization, teams within the organization, adult learning, and finally leadership contributions to the learning effort in the organization. Within each of these research streams, a comparison will be made to the training model to exemplify how much the model contained features as theoretically prescribed in the research literature.

The group of students that were in the training program under consideration was outside of the organizations being considered. However, the training program was designed to join academia with the business sector for the purpose of training future candidates for the organization and the training model had its roots in the organization as a model of training. Thus, the training program fits within the parameters of discussion for organizational learning.

Learning Organization

Recently, [8] asked the question, "Is Yours a Learning Organization?" They asserted that the concept of a learning organization was not a new one but instead was first used by Senge in the 1990's [4] and was discussed much in academic literature [3] at that time. The definition has become well formulated, "A learning organization is a place where employees excel at creating, acquiring, and transferring knowledge [8]. A learning organization has three blocks: (a) a supportive learning environment, (b) concrete learning processes and practices, and c) leadership that rein forces learning. Imbedded in this model is the ability for the organization to modify its behavior to reflect new knowledge and insights [3].

A second model of the learning organization was proposed simultaneously to the above described model. Theorized a learning organization model integrating two interactive components within the organization which promote organizational learning [9], and that is, people and structure. This theory of organizational learning identified seven dimensions of a learning organization with factors at the individual, team, and organizational level: continuous learning, inquiry and dialogue, team learning, embedded system, empowerment, system connection, and strategic leadership [9,10].

Even though the two presented represent different characterizations ofa learning organization, there are common characteristics (a) the organization has the ability to learn, (b) the organization has systems in place that support learning, and (c) the leadership facilitates learning. In comparing the training model to theoretical models, we will examine these three common characteristics.

In addition to the above training models, there are theories about how an organization learns. Proposed that there were two types of learning, informative learning and transformative learning [11]. It is only through transformative learning that an organization becomes a learning organization, where assumptions and values of operation are challenged. In order to develop a learning organization, a climate needs to be created that rewards openness about ideas, examines data and assumptions, and helps people become more self-reflective.

A prescriptive approach to organizational learning can also be found in recent research. A senior partner with The Boston Consulting Group [12], declared that with the intense competition for skilled workers and increase in employee mobility, the one limiting factor to success might be having sufficient resources to meet the goals of the organization. He proposed that growing your own work force may be the answer to a number of challenges such as finding resources, aligning resources to the tasks of the organization, having the resources in the right place at the right time, and retention. Managers can "grow" their talent by providing training, education, mentoring, and motivations to learn the skills needed by the organization.

Experis and Intego Group are learning organizations

An examination of the training model being showcased supports the premise that both Experis and Intego Group are learning organizations. These organizations are places where employees excel at creating, acquiring, and transferring knowledge as defined by researchers [8]. The described training model employed the three blocks that are found in the learning organization, (a) a supportive learning environment, with a structure built to ensure support at each stage of learning, from the university experience to the internship (b) concrete learning processes and practices, which were supplied by the university and technical staff and (c) leadership that reinforces learning which is inferred by the creation of the training plan as well as the internal leadership components which support all the stages of learning from the university through the internship.

The creation of this training plan certainly challenged the usual assumptions and values of operation that existed in both Experis and Intego Group, which supports that transformative learning was taking place. Strategic leadership forged a plan that was new and daring, forming the necessary coalitions with each other, the university, and selected clients to make it work. Their approach encouraged a climate of openness and examined assumptions, as proposed by [11].

Based on the prescriptive learning organization provided by [12], the formulating team of Experis and Intego Group devised a plan whereby they "grew" the resources they needed exactly in the fashion described. The training model supports premises from multiple theoretical sources that would label both Experis and Intego Group as learning organizations. The components placed into the training model included factors considered important in research as well as implementation of plan that included transformative learning as well as response to market conditions that mandated growing your own resources if needed.

Learning in Teams

When considering learning in the organization, it is important to consider the research which explored what level(s) learning occurs in the organization. Early in the 21st century, researchers reached consensus regarding the levels at which learning occurs in the organization [2,13,14]. Asserted the premise that the team is the level at which the organization learns, particularly in interactions between members of the team [14]. Concurred with Edmondson that one needed to understand the learning that occurs at the team level in order to understand organizational learning [15]. Additionally, research supports that learning takes place in the organization both informally on the job, in groups, or through conversations [16]. Despite the growing interest in understanding the team dynamic in the context of learning, little empirical evidence indicates exactly how this dynamic operates in the organization [14,17]. Research demonstrated that team structures and shared team beliefs were significant antecedents to learning thus supporting an integrative perspective of learning [18]. Research further supported the notion that team outcomes result from a combination of context [14], leader support, and shared beliefs [19]. Noted that the most effective facilitators of learning processes were the line managers, who he defined as those who manage units within the organization. Having an understanding of where learning takes place in the organization provides focus in planning and observing team learning. This further allows management direct impact in that learning while providing direct oversight of the team.

Training Model demonstrated Learning in Teams

One of the aspects of this training model was that students worked in groups, both as a member of a student group at the university and as a member of a mentor group. In both of these groups there were discussions where learning occurred informally, in work environments, casually, and through conversations. This supports the research presented that learning occurred among the students as a result of specific interactions between members of the group. Additionally, both the strategic management group and the group team of managers had similar learning as they helped implement the learning by the students.

There were several teams in operation within this training model, the student team, the instructional team at the university, the mentor teams at Experis and Intego Group permanent staff, the technical staff integrating with both, the functional management team, and the strategic management team. This working model

supports Edmondson's research which found that team structures and shared team beliefs were significant antecedents to learning. Further, the training model supports her notion that team outcomes result from a combination of context, leader support, and shared beliefs.

Adult Learning

When discussing a learning model in the organization, another factor to consider is individual learning and in particular, adult learning. There are a number of active areas of research in adult learning, among which are transformative learning and teaching methods that are proposed to work best with adult learners.

Transformative Learning (TL) has become a learning theory of great interest to help to understand how adults learn [20] is a prominent researcher in this arena. He and others have proposed that transformational learning involves a "transformation of the adults' core frame of reference, often in response to disorienting dilemmas-situations that challenge adults' previous ways of thinking about the world and prompt them to reflect critically on previously held assumptions" [21]. The research on transformational learning focuses on both learning that occurs in the educational organization as well as learning that occurs as a result of adult life situations. Proposed that curriculum designers and educators can create a transformative learning experience by using teaching methods that foster critical reflection [22].

There are a number of research studies that substantiate adult students' preference to an active learning strategy as well as a preference for immediate application of knowledge which has been gained and opportunities for self-direction [21]. This particular finding is more applicable to students that are continuing their undergraduate studies after high school training. Not unlike learners of all ages, adult learners have a variety of learning styles and are highly influenced by their past encounters with higher education as well as by their social and cultural backgrounds.

Training Model for Adult Learning

The presented training model was designed with the purpose of formulating industry-ready workers, with the necessary skills to be ready to work. This exemplifies the premises of the TL learning method which proposes that students learn best when the learning can be immediately applied. With of goal of having students ready for industry when they graduate from the program has built into it the immediate application of learning. The training model also exemplified Cranton's research which supported use of teaching methods that foster critical reflection. The skill set required for successful SAS programming requires critical thinking; the curriculum design as well as the mentoring structure of the training program supported this outcome. Further, the training model had built-in incentives for success which encouraged individual responsibility to succeed. Among the incentives were (a) the opportunity to be prepared to take the SAS exam, which if passed, was portable to positions within many organizations, (b) the opportunity to be selected for a paid internship with the major pharmaceutical client organization, and finally c) the possibility of being hired into a number of global world-class pharmaceutical organizations.

Leadership

Some links have been established between specific leadership capabilities and the organization's ability to learn, such as the role of strategic leaders in managing exploration and exploitation [23] and the importance of leadership roles in a team learning setting [18]. However, more empirical evidence is needed to solidify understanding of how specifically leaders influence learning at all levels in the organization [15,24]. For the purposes of this exploration, leadership will be defined as a process which involves activities of influencing and teaching constituents to understand how their work should be accomplished and why [15,24].

Leadership was identified as a critical component in both of the organizational learning models presented above. To effectively implement organizational goals, all teams from top management to the production team, need to be aligned in the same outcome vision. Strategic leadership is needed to provide context, vision, and design for the organization, product development team is needed to develop new products and implement the strategy. The middle management team is needed to execute and continuously improve operations in the organization, and the internal services team is critical to coordinating activities among all teams, and the product development team executes and continuously improves the product that the organization is creating. Each of these groups is varied in purpose and activities but together are needed promote the goals in the organization, in this particular case, ensuring success of the training model.

Mentors were identified as a part of leadership structure in the training model. Mentoring is an entire branch of research but for the presented model was framed as part of the leadership in the model because of the relationship between the mentors in the program and the interns. There was one research outcome that particularly related to desired outcomes built into this model. Found that benefits other than personal learning by the mentee resulted from the mentor/mentee relationship and that was [25], mentees understand their role better and have more job satisfaction which might impact personal success in the career pathway.

Working Model Leadership

Possibly the most difficult task in implementing successful learning is coordinating separate teams to ensure that the learning occurs in a joint fashion and in sync with planned goals. How does an organization assure this outcome? Even though the research does not offer a clear picture of exactly how leadership impacts learning in the organization, the strategic and tactical leadership in this training model offered clear examples of what would be

considered a factors of success. First and foremost, the strategic leadership initiated the model by asking a critical question about how the goal of training and placement could be orchestrated. Would suggest that this alone had the power to impact action in the organization [26]. They would support that the joint strategic leadership in both Experis and Intego Group did employ strategic thinking to envision both the opportunities and mitigate the risks of the business landscape to build this training model.

The training model illustrated built-in strategic management, middle management, internal services (technical), and product development (team) leadership. The strategic leadership provided vision and stated specific goals, established context, placed tactical and technical leadership in place, and provided follow up to ensure the plan was tracking as expected. There was a well-established middle management team which executed the day-to-day operations and was in alignment with the strategic leadership vision. At the team level, senior programmer provided both mentoring and leadership for the students.

The strategic leadership further ensured that all of the working groups were in place, the university staff, the operational staff, and the technical staff. Not just to ensure their creation but as a constant source of support, financially, and with the commitment to hire at the conclusion of the internship.

A final comment about then mentoring leadership built into this training model. Strategic leadership envisioned mentoring as a piece of this training model which is aligned with the research finding that having a mentor in the organization has been linked to the overall career success for the mentee.

Conclusion

The joint strategic leadership team from Experis and Intego Group found a way to respond successfully to competitive market conditions by creating a training placement model that involved cooperation between industry and academia. The working model was described in detail, declared a success by its formulators in meeting the goal of placing graduates of the program in an industry position. Current research in organizational learning was perused to reflectively examine why this model met with success. Research findings in the areas of organizational learning, team learning, adult learning, and leadership were highlighted as it applied to the working model. The goal of the training model was met, substantiating an organizational change, to promote success in the organization.

Future efforts of designing training models might benefit from understanding components of a working successful training program which is supported by research in organizational learning. The components of the demonstrated training model which led to success were a (a) well-defined team in place both for the organization and the students, (b) strategic management with a clear vision and support throughout the program, (c) line management aligned with the vision and ability to manage to the goals, and (d) technical management, also aligned with the vision and with the ability to answer questions and to trouble shoot technical issues. These critical components are also supported in organizational learning research as features for successful implementation of learning in the organization.

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