

Review

Pharmaceutical Organizational Change: Redefining Regulatory Science Learning

Jan Fourman¹, Joseph Smith^{2*}, Geanie Umberger³, Stephen Byrn⁴, Kari Clase⁵

¹BIRS Center, Purdue University, USA

²Doctor's Corner International, Inc., West Palm Beach, Florida Area, USA

³Department of Leadership, Technology and Innovation for Purdue Polytechnic Institute, USA

⁴Medicinal Chemistry in the Department of Industrial and Physical Pharmacy, Purdue University, USA

⁵Department of Technology, Leadership and Innovation. Purdue Polytechnic, USA

Abstract

This paper looks at organizational changes in the pharmaceutical industry's environment using the classic Kotter (1996) 8 Step model and has made an argument that the model can be used successfully in regulatory science learning. The literature on both change management and regulatory science learning was reviewed to see how both topics related to Kotter's 8 Step model. The model has been used previously in health professional education but not in regulatory science training. Specifically, Step 1: Establish a sense of change urgency is the rally cry for the sense of urgency to those instructors of regulatory science. Step 2: Form a powerful coalition of people within the environment that can lead the change calls-out to educators of regulatory science to take the lead. Step 3: Create a change vision and strategy and communicate this to the impacted people is the need for regulatory science educational reform. Step 4: Communicate to the people about the change at every opportunity is pertinent and critical for the regulatory science learning initiative. Step 5: Empower the people to get behind the change to give them a sense of ownership stresses the importance of training in the empowerment process to meet the regulatory science educational challenge. Step 6: Enable short-term wins so that there is energy about the change shows that the regulatory science educational change initiative is paying off. Step 7: Put the short-term wins together to keep the change momentum moving forward stresses the importance to organize regulatory science concepts together to represent the discipline. Lastly, Step 8: Make changes part of the organization's culture for sustainable outcomes develops regulatory science learning modules and institutionalizes the need for the discipline's teaching.

Keywords: Change Management; Organizational Change; Pharmaceutical Industry; Regulatory Science Instruction; Kotter 8 Step Model

Introduction

This paper demonstrates how Kotter's 8 Step model can be used as a useful model to examine innovative perceptions in regulatory science learning. The current rate of medical technology advancement and growing global health needs fosters a continuing need for regulatory science change [1]. Regulatory science changes beget innovative ways to train regulatory science professionals. Many pharmaceutical companies, in an attempt to adapt to the

constant change of the biomedical environment, are adopting more agile regulatory science learning methods. The targeted outcome of regulatory science learning is to meet the demand for professionals with regulatory science expertise both nationally and internationally. Per Richmond (2014), we need a new generation of regulatory scientists so that the competitiveness of the global pharmaceutical industry is not thwarted.

To accomplish innovative ways to both, teach and learn regulatory science, a framework is needed. Kotter's 8 Step model has been used previously in health professional education but not in regulatory science training. From the literature review, Kotter's 8 Step model has been used successfully in nursing education [2, 3, 4] and physician training [5, 6, 7]. Kotter's 8 Step model has also been used in educational initiatives in hospital care settings [8].

Kotter's 8 Step model can be a useful step-by-step model for examining innovative perceptions for the importance of regulatory science learning across the pharmaceutical enterprise. For example, implementing electronic medical records (EMR) is an innovative way to prevent medical errors in health care [9]. Despite the benefits of an EMR, the adoption has been slow. The barriers to the implementation of an EMR are varied. However, one of the barriers projecting outward and upward is poor change management. Even though there are several change management theories available to implement technological innovations in health care, Kotter's 8 Step change management models has been used successfully to break down barriers for EMR. Kotter's 8 Step model was also used to help planning change, implementing change, and cementing change [9]. Since a precedent has been set using the model with health care

***Corresponding author:** Joseph Smith, Doctor's Corner International, Inc., West Palm Beach, Florida Area, USA, Tel: 561-317-8449; Email:dcijoe@gmail.com

Sub Date: June 17, 2016, **Acc Date:** June 29, 2016, **Pub Date:** June 30, 2016.

Citation: Jan Fourman, Joseph Smith, Geanie Umberger, Stephen Byrn, Kari Clase (2016) Pharmaceutical Organizational Change: Redefining Regulatory Science Learning. BAOJ Pharm Sci 2: 022.

Copyright: © 2016 Jan Fourman, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

professional education, the model can also be applied to the training of a regulatory scientist working as a health care professional in drug development [10].

The 8 Steps are paraphrased below to fit regulatory science learning movements [11]

1. Establish a sense of change urgency – people will change if they see the need.
2. Form a powerful coalition of people within the environment that can lead the change.
3. Create a change vision and strategy and communicate this to the people impacted by the change.
4. Communicate to the people about the change at every opportunity.
5. Empower the people to get behind the change to give them a sense of ownership.
6. Enable short-term wins so that there is energy about the change.
7. Put the short-term wins together to keep the change momentum moving forward.
8. Make change part of the organization's culture for sustainable outcomes.

Kotter's 8 Steps and Regulatory Science

Step 1

Establish a sense of change urgency. The rally cry for the sense of urgency is to those instructors of regulatory science. This is due to the major progress in science that has created opportunities for critical advancements in clinical medicine [1]. For example, scientists have discovered many human gene variations that contribute to human illness. Researchers have also developed diagnostic tests based on genetics to better predict responses to targeted therapies. An example of these breakthroughs is with ovarian cancer research and treatment [12]. Meeting the need for advances in ovarian cancer is a current cancer need. Learning how to develop the new approaches to assess the safety and efficacy of the ovarian cancer treatments is a part of regulatory science per our FDA definition [13] and thus the connection with [14] sense of change necessity. Cancer research change is imperative. To support the advancements in cancer research will need regulatory science support. This will make sure that the standards and safety of cancer research combined with principles of the regulatory discipline are part of the new breakthroughs and ethics associated with emerging therapies. The people to do the support need regulatory science training to maintain and move forward with not just cancer but other therapeutic areas as well. Often scientists do not know what is needed to prove a discovery works and that the effectiveness is globally uniform. Regulatory science education can provide this information and guide the scientist through the needed submission process.

Step 2

Form a powerful coalition of people within the environment that can lead the change. Educators of regulatory science need to lead the

change. Taking ovarian cancer, for example, moving from clinical concept of the disease state to applications for future innovation in this space requires basic knowledge of regulatory science [1]. Namely the part of the regulatory science definition that relates to developing new medical approaches. For success, it takes people with drug development knowledge to lead this innovation [14].

The coalition needs both expertise and credibility [14]. Senior management in pharmaceutical industries has drug development expertise, as does the FDA. It can also be argued that that regulatory science expertise is also necessary with the standard lab worker and others in the company [10]. To meet this need, pharmaceutical companies are sending their employees to regulatory science classes both internally and externally. This fosters growth of the learning coalition. It not only builds the coalition but helps employees make smarter decisions and reduce costs when developing products. To this end, regulatory science programs are now teaching working pharmaceutical professionals [10]. These coalitions of successful regulatory science education programs offer core competencies that are transferable to global disease states of need and can prevent drug development setbacks [15].

The first task of the coalition is to develop a vision for the change initiative and to disperse the vision throughout the pharmaceutical organization. This leads to the importance of a regulatory science change vision and corresponds with Kotter's Step 3 [14].

Step 3

Create a change vision and strategy and communicate this to the people impacted by the need for regulatory science educational reform. A needed vision for the change process is well documented in research literature. For example, in the business world, [16] studied Countrywide Financial Corporation which revealed that vision planning was indeed necessary to change learning dynamics [17]. Agrees that a significant relationship exists between the perception of planned organizational change and the response to change along cognitive dimensions. Using the ovarian cancer example again, Kotter (1996) suggests that the change vision be desirable for the long-term interest of the enterprise. Learning regulatory science is advantageous for the pharmaceutical industry per FDA who has developed a strategic plan for advancing regulatory science [13].

Step 4

Communicate to the people about the change at every opportunity. Communication is critical for a change initiative to succeed [14]. This is also true for a regulatory science learning initiative. Taking our example of genetic advances in ovarian cancer [1], the Genetic Testing Registry was developed to enhance patient and healthcare professional communication and information retrieval about this disease state [18]. The concept of a registry once again links back to the definition and importance of regulatory science education as efforts are taken to enhance drug safety and efficacy.

FDA is also communicating the strategy for advancing regulatory science. As a subgroup of the regulatory science stakeholders, the FDA's positive alignment is in agreement with the [18] study arguing that there will routinely be subsets of impacted people that

will embrace the change. In addition to the efforts by the FDA, other agencies like the United States Pharmacopeia (USP) address the need for regulatory science knowledge by hosting a compendium regulatory science series. This consortium was established to foster global strategies for the advancement of regulatory science knowledge and compendia issues. Per the website explaining the initiative, these approaches will require understanding and maintenance of a strong and rapidly evolving knowledge base [20].

To emphasize the importance of a regulatory science change strategy, the FDA [13] has eight priorities for the initiative, which have been paraphrased below:

1. Modernize toxicology to enhance product safety.
2. Stimulate innovation in clinical evaluations and personalized medicine to improve product development and patient outcomes.
3. Support new approaches to improve product manufacturing and quality.
4. Ensure FDA readiness to evaluate innovative emerging technologies.
5. Harness diverse data through information science initiatives to improve health outcomes.
6. Implement a new prevention-focused food safety system to protect public health.
7. Facilitate development of medical countermeasures to protect against threats to U.S. and global health security.
8. Strengthen social and behavioral science and help consumers and professionals make informed decisions about regulated products.

The FDA will apply resources to the regulatory science priorities which will empower the change initiative [13] which takes us to Kotter's Step 5 (1996).

Step 5

Empower the people to get behind the change to give them a sense of ownership. FDA plans to empower their regulatory science change initiative through management of scientific programs within the FDA, and partnering with industry and academia [13,14] stresses the importance of training in the empowerment process, and to meet the training challenge, FDA intends to promote new models to assess safety of gene and other emerging therapies. Correspondingly, part of the biomedical breakthroughs has brought an increase in the need for companion diagnostics – specific tests used to determine whether a particular therapy will work for a given patient [13]. To further illustrate using the ovarian cancer example, there is now a blood test which can detect a protein (CA 125) found on the surface of ovarian cancer cells [21].

To increase the need for training about companion diagnostics, FDA issued the draft guidance *In Vitro Companion Diagnostic Devices* [13]. Pharmaceutical companies are using the FDA information for their internal training programs. This is supplemented by

university programs addressing regulatory science which build on competencies such as scientific comprehension, regulations, quality, clinical expertise, and ethics [22].

The FDA has also invested resources toward initiatives like the Regulatory Education for Industry (REdI) conferences. REdI is a forum that brings together the regulatory educators from FDA's Center for Drug Evaluation (CDER) and Center for Devices and Radiological Health (CDRH). The goal of the conference is to provide information on the key aspects of drug and device regulations since the regulatory principles of drugs and devices are both similar and different [23]. Initiatives like REdI create energy around regulatory science education.

In the university classroom, student innovators can look at cancer drugs already on the market. Especially helpful is the drug's Summary Basis of Approval (SBA), which is public record. Students can do a compare/contrast of the SBA, but also look at labels, amendments and post-marketing requirements. Looking at these documents can show the student's trends and hurdles they will need to overcome when they are the future cancer drug developers.

Step 6

Enable short-term wins so that there is energy about the change. Short-term wins show that the change initiative is paying off [14]. It is also critical for the change movement to find evidence that the initiative has achieved the desired results [24]. For patients with ovarian cancer, wins are the new drugs approved for this disease state that increase the overall survival time of the patient. For example, Avastin (bevacizumab) is a recent drug that can be used in ovarian, fallopian tube, or primary peritoneal cancer. Clinical trial data demonstrated that the overall response rate for patients that received chemotherapy plus Avastin was an increase of over 3 and ½ months [25]. This extra time is understandably important for the cancer patient [26]. Education in regulatory science intended for the health care professional can further improvements for the patient [27]. State that when the industry is complex, such as cancer research, innovation will be found in networks of learning. For example, cancer research learning could start with an oncology workshop or seminar in the university or industry setting.

Step 7

Put the short-term wins together to keep the change momentum moving forward. To keep the health care innovation momentum going, it is important to organize regulatory science concepts together to represent the discipline. Per [27], the first recommendation is to provide a context. Within regulatory science learning, a case study with real-world context regarding an Investigational New Drug (IND) application, for example, frames for the learner practical information that can be transitioned to future submissions. This experiential learning can be a mechanism to help keep the regulatory change momentum moving forward and thus help define an emerging discipline. In regulatory science education, an example of the experiential approach is by using real-life drug development case studies discussed within a collaborative group of students with an expert facilitator from the regulatory science discipline. This makes the classroom an environment where students

and experts come together with practical assessment and learning that can help build success.

The second recommendation [28] is to include clear instructions and materials that will facilitate the learning. For example, if the intent is to learn about optimal drug labeling, an outline like the Target Product Profile (TPP) can be used [29].

The third recommendation is to focus on the learning [28]. A learner mapping out the process of a briefing document for a mock meeting with the regulatory agency can be a beneficial hands-on experience. This activity can provide practice and lower stakes than when the learner actually represents their pharmaceutical company at the FDA.

Lastly, [28] recommends that the learner know why the mock submission practice is important. Per [4], a teaching method to give the learner the “why” is to have them work through a real-life case study. In addition, using case studies promotes critical thinking [4], a regulatory science core competency. Simply lecturing about drug development would be a passive activity for the learner. However, by presenting a case study on an oncolytic drug and giving the assignment to prepare for a mock advisory committee meeting, the instructor is putting the learner in a real-world situation [4].

The above case study assignment could go one step further and have actual drug development experts as the mock advisory committee members. If this learning is happening inside a pharmaceutical company, the expert advisory committee members could be colleagues from across the organization. If the learning event is happening at a university, the committee members could be comprised of pharmaceutical industry people invited to spend the day with the students. Such a situation would demonstrate collaboration between industry and academics, and be a model of active teaching [4].

Using case studies and real-world practice can be viewed as a dynamic activity of a regulatory science learning module. By keeping the case studies pertinent and the mock advisory committee interactions timely, this way of teaching regulatory science can be a sustainable approach [30].

Step 8

Make changes part of the organization’s culture for sustainable outcomes. Developing regulatory science learning modules corresponds to Kotter’s (1996) last step and institutionalizes the need for regulatory science teaching [30, 31]. Support training as a means to sustain change [31] Support training as an effective tool to influence change [32]. Continue with the importance of measurable education outcomes that can lead to achievable goals.

Measurement outcomes for regulatory science learning can be beyond the traditional semester grade. Since regulatory science deals with many aspects per our FDA (2012) definition, measuring the learning process can be collaborative between learner and instructor [4]. This 2-way communication can provide opportunities for input and feedback while building trust and support [33]. In addition, measurement of regulatory science learning outcomes can foster teaching processes that are more likely to lead to sustainable

methods. This is especially true if the participants understand the education outcome goals [28] and what is expected of them as regulatory science learners.

Conclusion

This paper has looked at organizational changes in the pharmaceutical industry’s environment using the classic [14] 8 Step model and has made an argument that the model can be used successfully in regulatory science learning. Per the literature reviewed, Kotter’s 8 Step model has been used successfully in hospitals and for training nurses and physicians but not in regulatory science learning initiatives. The model fosters innovative approaches that can be applied to regulatory science learning in regulatory agencies, pharmaceutical companies and universities that teach the discipline [14]. 8 Step model is presented in regulatory science learning points, taking advantage of its logical sequence.

Step 1 of Kotter’s model is a rally cry to regulatory science educators. There is a sense of urgency to their task of instructing in the regulatory science discipline in order to enhance the possibilities of more positive health outcomes. Kotter’s Step 2 calls for educators to lead the change for curricula of basic regulatory science concepts. Innovation can then follow after basic regulatory science principles are learned. Step 3 calls for the creation of a regulatory science education change vision and strategy. This then is communicated to the people impacted by the need for regulatory science educational reform – industry and research universities. Correspondingly, Kotter’s Step 4 says to communicate the need for regulatory science education at every opportunity.

Kotter’s Step 5 stresses the importance of training in the empowerment process. In the university classroom, educators and students can look at drugs already on the market. Students can do a compare/contrast of the approval letters, amendments, labels and post-marketing requirements. Looking at the Summary Basis of Approvals for current cancer drugs, for example, can show the student innovators trends and hurdles they will need to overcome in future drug development.

Step 6 encourages short-term wins to keep the momentum going. In the case of the regulatory science educator, the wins are enabling advances in safety and efficacy, after instructing on drug development. Kotter’s Step 7 is putting the short-term wins together to keep the innovation moving forward. In regulatory science education, an example to foster innovation is by using real-life drug development case studies discussed within a collaborative group of students with an expert facilitator from the regulatory science discipline. This makes the classroom an environment where students and experts come together with practical assessment and learning that can help build success.

Lastly, Kotter’s Step 8 encourages the changes to be part of the organization’s culture for sustainable outcomes. This can be done by developing learning modules and institutionalizing the need for regulatory science instruction with measurable education outcomes. Further research can monitor the innovations in regulatory science education and measure the impact the students are having in the drug development field.

References

1. Hamburg MA, Collins FS (2010) The path to personalized medicine. *New England Journal Medicine* 363: 301-304.
2. Guglielmi C, Graling P, Paige JT, Cammarata BJ, Lopez C, et al. (2013) Sustaining a culture of safety: Are we one step forward or three steps back?. *AORN Journal* 98(6): 634-646.
3. Edwards C, Seggie J, Murphy M (2012) Redesigning the response to patients with trauma. *Nursing Management*, 19(3): 31-36.
4. Popil I (2011) Promotion of critical thinking by using case studies as teaching methods. *Nurse Education Today* 31: 204-207.
5. Stoller JK (2010) Implementing change in respiratory care. *Respiratory Care* 55(6): 750-757.
6. Krummel TM (2009) Inventing our future: training the next generation of surgeon innovators. *Journal of Pediatric Surgery Lecture* 44: 21-35.
7. Solberg LT (2007) Improving medical practice: A conceptual framework. *Annals of Family Medicine* 5(3): 251-256.
8. Hovlid E, Bukve O, Haug K, Aslaksen AB, von Plessen C, et al. (2012) A new pathway for elective surgery to reduce cancellation rates. *BMC Health Services Research* 12(154): 1-9.
9. Neumeier M (2013) Using Kotter's change management theory and innovation diffusion theory in implementing an electronic medical record. *Canadian Journal of Nursing Informatics* 8: (1-2).
10. Richmond F (2014) MS in regulatory science.
11. Appelbaum SH, Habashy S, Malo JL, Shafiq H (2012) Back to the future: Revisiting Kotter's 1996 change model. *Journal of Management Development* 31(8): 764-782.
12. PLCO (2010) Ovarian cancer research results from the prostate, lung, colorectal and ovarian (PLCO) cancer screening trials fact sheet. National Cancer Institute. Bethesda MD.
13. (2015) Food and Drug Administration. Advancing regulatory science.
14. Kotter JP (1996) *Leading Change*. Boston, MA: Harvard Business School Press.
15. Sivaramakrishan V, Bhide M (2013) A comparative analysis of drug lag in emerging markets.
16. Flamholtz E, Kurland S (2006) Making strategic planning work: A case study of Country Wide Financial. *Handbook of Business Strategy* 7(1): 187-193.
17. Szabla D (2007) A multidimensional view of resistance to organizational change: Exploring cognitive, emotional, and intentional responses to planned change across perceived change leadership strategies. *Human Resources Development Quarterly*, 18(4): 525-558. U. S. Food and Drug Administration (2011) *Advancing Regulatory Science at FDA*. U. S.
18. (2002) *Genetic Testing Registry* National Center for Biotechnology, National Library of Medicine. Bethesda, MD.
19. Nelissen P, van Selm M (2008) Surviving organizational change: How management communication helps balance mixed feelings. *Corporate Communications: An International Journal* 13(3): 306-318.
20. KET Consortium (2015) *Knowledge, Education and Training on Regulatory and Compendia Sciences Consortium*.
21. Mayo Clinic (2016) *Ovarian cancer: Tests and diagnosis*. Mayo Foundation for Medical Education and Research.
22. Clase K, Byrn S (2015) Design and implementation of a professional master of science in biotechnology innovation and regulatory science with global impact. Selected for talk at the Annual Meeting of Experimental Biology, Boston MA.
23. (2015) *Regulatory Education for Industry (REdI)*. FDA Small Business and Industry Assistance REdI Conference.
24. Ford R, Heisler W, McCreary W (2008) Leading change with the 5-p model: Complexing the Swan and Dolphin hotels at Walt Disney World. *Cornell Hospitality Quarterly* 49(2): 191-205.
25. (2015) National Cancer Institute *Drugs approved for ovarian, fallopian tube, or primary peritoneal cancer*.
26. Ryan L (2014) *How cancer changed the way I use my time*.
27. Powell WW, Koput KW, Smith-Doerr L (1996) Interorganizational collaboration and the locus of innovation: Networks of learning in biotechnology. *Administrative Science Quarterly* 41(1): 116-145.
28. Daugherty JL, Custer RL, Dixon RA (2012) Mapping concepts for learning and assessment. *Technology and Engineering Teacher* 10-14.
29. (2014) *Guidance for Industry and Review Staff: Target Product Profile (TPP): A strategic development process tool*. U. S. Department of Health and Human Services. Washington, DC.
30. (2004) Australian Research Institute in Education for Sustainability. *Whole-school approaches to sustainability: An international review of whole-school sustainability programs*, Department of the Environment and Heritage. Macquarie University, Sydney.
31. Jacobs RL (2002) Institutionalizing organizational change through cascade training. *Journal of European Industrial Training* 26(2-4): 177-182.
32. Massey L, Williams S (2006) Implementing change: The perspective of NHS change agents. *Leadership and Organizational Development Journal* 27(8): 667-681.
33. Cawsey TF, Deszca G, Ingols C (2016) *Organizational Change: An Action-Oriented Toolkit*. Thousand Oaks, CA: Sage Publications Inc.
34. Department of Health and Human Services. *Center for Drug Evaluation and Review* Washington, DC.