



SoBran BioScience

# Managing Change for Research Integrity

Lessons from an ISO-Certified  
Research Organization

John DeLeonardis

October 2014



BioScience



## Table of Contents

Change Happens .....	3
Factors Driving Change .....	3
The Role of SOPs .....	4
Managing Change .....	5
Lesson #1 .....	5
Lesson #2 .....	6
Benefits .....	7
Embrace Change .....	7



## Change Happens

When is the last time something didn't change at your research organization? Change occurs incrementally every day; it's a fact of life. Similarly, the process of doing things alters over time. Small, incremental every day changes eventually add up to doing things differently over time, call it an additive effect.

Improperly managing change, or ignoring it, can challenge the integrity of your research and jeopardize animal welfare. ISO certification is the global benchmark for quality management; as an ISO-certified research support organization we have to continually monitor our processes to meet these high hurdles. The lessons we have learned meeting the rigorous ISO standards are the foundation for this white paper. Our goal in sharing these best practices is to help you and the pre-clinical research industry overall to become more effective and deliver research with integrity.

### Factors Driving Change

Internal and external factors impact every organization; and they impart how quickly things change. Beyond fact, (scientific or otherwise), we have various regulatory requirements, accreditation standards, business practices, and state and local

#### Key Benefits of Managing Change

- **Quality Assurance:** Improve research outcomes and use resources more efficiently
- **Job Satisfaction:** Reduce employee turnover, attract higher quality employees, and create improved workplace culture

mandates driving how we operate. External contributions include your customers, technology, and perhaps social or demographic conditions<sup>1</sup>. Do you live in a metropolitan area where the population is more transient and personnel turnover is comparatively high? Doesn't some incremental observation of change walk out the door with an employee departing? Doesn't a person entering an institution come with

different perspective? Internal factors may include your systems, structure, and people<sup>1</sup>. You can argue that the trend for moving from "dedicated use" research space to shared "collaborative" spaces offers more opportunity to impact others in a research environment, exacting even more potential change.



## The Role of Standard Operating Procedures (SOPs)

In the research arena a primary method of communicating and informing people how things are done is through written standard operating procedures (SOPs). SOPs are used as a tool offering structure and process to how things are accomplished. They are aligned with expected outcomes for consistency, efficiency, and safety.

Some industries generally accept that documented processes and procedures are evaluated annually (and when there is obvious and significant change to an established process). There is agreement that over one year's time there are likely improvement opportunities and changes to a number of the standard operating procedures we follow on a routine basis. Therefore, actively managing this information will help us respond effectively to an actively changing environment.

**“To improve is to change, to be perfect is to change often.”**  
**Winston Churchill**

## Managing Change

Quality management is not done through static arbitrary procedures, but through routine testing and acknowledging current best practices. In fact, quality management systems such as ISO demand that we evaluate our processes on a routine basis; clearly defining tasks, filling gaps of information, all leading to better expected outcomes. Optimally, we are looking for “process and procedure” that is **understood, followed, tracked and managed for continual improvement.**



### Lesson #1: Be Inclusive

Being that consensus is often the norm, process and procedure require buy-in from multiple stakeholders if you want success. Buy-in is not the same as being sold, people need to own it<sup>3</sup>. Understandably, most of the standard operating procedures we see are performed by front line staff, the individual operators doing the work. Doesn't it make

Where the formal ownership system is operationalized such that it leads to psychological ownership, a bonding or integration of the employee-owner with the organization occurs.

It is through these processes that employee ownership exercises an influence upon group and individual outcomes.<sup>2</sup>

sense to include the front line worker as a stakeholder in most of the SOPs then? After all, they are doing the work. *“I work at a large institution; we can't have everyone in on developing SOP content.”* Of course not, at least not everybody all at one time.

Management should delegate to supervisors and front line personnel, asking for constructive analysis of

the current standard processes. When presented to management, they should pick up on indicators of positive change and squelch those on a negative bent. Explaining why one is positive and one is negative in terms of forecasting an outcome reinforces understanding and accountability to the line staff. This helps drive ownership. It is often said that ownership then spawns worker satisfaction, which in turn imparts positive change on employee morale. Higher worker moral achieves a better work product; this is not a leap of faith.

## Lesson #2: Fully use the SOP Review Process

A stabilizing foundation to constant change may actually be found in your SOPs and how you simply manage their review. The SOP review process should offer a better outcome, even if that is simply documenting the process more thoroughly. Evaluating the processes, procedures, methods, work practice instructions (whatever you call your standard operating procedures) should be done on a routine basis, part of your business practice.

Your business practices should outline the management tools used to evaluate, gather feedback, and track the information. Decide what works best for your organization and get the processes going.

1. Start by **listing the SOPs**, their effective date, the last time they were reviewed.
2. Decide how long this process should take, **give it a deadline**. You can do this in groups of SOPs or by individual SOP. Some organizations choose to concentrate their SOP review into a small window of time, others spread it over months; some simply put a simple metric in place such as reviewing five SOPs every month.
3. Figure out **who the primary stakeholders are and request their feedback**. Have a method in place for including this feedback. You may sit over a cup of coffee and discuss the changes or you may memorialize them with tracked changes submitted through an electronic document. Perhaps it is an area needing visual feedback and will be best served with a site visit. Any of these may be the right choice given a particular institution and the distinctions each brings. If one method isn't working, consider changing to another.
4. Constructively **evaluate the content** of each one.

Consider the implication of procedural drift over 3-4 years... when a mistake is made it may be a tidal wave when it lands.

Organizations that *proactively* manage change to SOPs have a consistent and more reliable outcome; those that are *reactive* are likely going to have a very different outcome.



## Benefits Reach Beyond Documentation

The by-products and benefits of effectively managing SOPs as a business practice also lead to efficiencies and opportunities for quality improvements across other program areas.

**Planning** Your information will remain current this year and to the next; mid to long term planning is a good management quality.

**Ownership** People are continually reminded of how things are done; leading to ownership and accountability for the results.

**Training** Training programs will have implicit structure where mature SOPs are continually improved and new SOPs are established.

**Quality Assurance** Does your management and QA team ask your line staff “What can we do better on this issue?” An interactive approach with front line staff can get to the root of an issue and ward off issues in the future.

**Team Building and Safety** The group outcomes also provide for continual feedback leading to mutual benefit of scientific exploration as well as animal welfare.

## Embrace Change

Science and discovery are contrary to “standing still”. Internal and external factors create additional complexity when trying to standardize processes in an ever changing environment. Implement business practices associated with SOPs and their review. Craft methods to track what information you have. Solicit feedback from the appropriate stakeholders. Establish deadlines on the feedback so change doesn’t linger. Managing change in this manner benefits reliability, job satisfaction, training, and quality assurance. **Change is going to happen, and you can shape better outcomes through managing your SOPs.**



## Footnotes

<sup>1</sup> Hartzell, Sheri *"How Internal and External Factors Drive Organizational Change"*. Education Portal, Accessed Sept, 2014.

<sup>2</sup> Pierce, Jon L., Rubinfeld, Stephen A., and Morgan, Susan; "EMPLOYEE OWNERSHIP: A CONCEPTUAL MODEL OF PROCESS AND EFFECTS". *Academy of Management, Review*. January 1, 1991 vol. 16 no. 1 121-144.

<sup>3</sup> Heathfield, Susan M., *"Big 5 in Managing Change"*. About.com, About Money, Accessed September 2014.





## About the Author

### **John DeLeonardis - Director, Academic and Commercial Operations, BioScience**

John leads division-wide efforts in contract management and administration for SoBran BioScience. His clients include over a dozen academic centers, pharmaceutical companies and commercial biotechnology firms. With over 24 years' experience in the laboratory animal environment, John is a subject matter expert for large scale, complex program management, operations, facility design, ramp-up, and technical services for laboratory animal based research programs.

John has been involved with the accreditation process of Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) for over two decades. In addition, John has been a senior manager within several AAALAC-accredited institutions over his career. In that role, John ensured that work performance, program operations, and infrastructure were consistent with the high standards set forth by AAALAC and compliant with the Public Health Service Assurance (PHS Assurance), the United States Department of Agriculture (USDA), and the Drug Enforcement Agency (DEA). John has been involved in over a dozen AAALAC-accreditation assessments and all achieved successful Full Accreditation letters for the programs under review.

## About SoBran BioScience

SoBran BioScience has nearly 20 years of experience supporting the nation's most complex biomedical research. The company leads the industry in designing animal care programs. SoBran also has over 500 biomedical professionals experienced in all aspects of *in vivo* research managing animal facilities and providing high quality technical support for laboratory animal research projects. SoBran is certified to the ISO 9001:2008 standard and has consistently been listed on the *Inc. 500* and *Black Enterprise Top 100*.



SoBran, Inc 2677 Prosperity Ave #200 Fairfax, VA 22031 703.352.9511  
**[www.sobranbioscience.com](http://www.sobranbioscience.com)**