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Implementing an Effective Business Continuity Plan at the Contract Laboratory

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INTRODUCTION

Why are you writing a Business Continuity Plan (BCP)? In our case, a client auditor reviewing our quality systems for cGMP compliance noted that while we had SOPs in place on Disaster Recovery, Backup Power Generation, Preservation of Raw Data, Safety and others to deal with adverse events that can disrupt the business of the laboratory, we did not have a formal BCP. It was to meet our client's expectations, not to comply with the cGMPs, GLPs or ISO standards, that we wrote the BCP. In the process, we learned that the BCP, to be more than a document, has to be part of a Businesvs Continuity Management (BCM) system. The BCM system supports the plan and fosters its continual improvement. As a GLP and cGMP-compliant laboratory, we already had dedicated competent personnel and well-established, tested quality systems in place, such as a document control system, a CAPA program, a quality assurance system and others. We had only to decide what to put in our plan and to integrate it into these. We suspect many contract labs in the pharmaceutical and medical device industries are in a similar situation.

In the present article, we describe the plan that we implement in our contract lab. As our understanding of our requirements developed, it became clear that the BCP and larger, BCM system help fulfill a number of important objectives, in addition to the immediate intended ones.

OBJECTIVES

Immediate intended objectives include the following:

1. To document in one place, namely the BCP, courses of action to take in response to a number of severely adverse events (e.g. explosion, chemical release, cyber attack, power failure, etc.) that will minimize the impact of the event on the business, ensure continuity in the business of the laboratory through the recovery and after, and shorten the time to recovery.
2. To serve as the kernel of a program to test, maintain and document the company's readiness to handle relevant adverse events.
3. To incorporate the BCP into our existing quality systems. These systems ensure that the BCP (a) receives the proper level of review and approval (b) is a controlled document (c) is trained on by all personnel (d) is periodically reviewed and revised (e) is readily available to all personnel and outside auditors and agencies (f) is supported by top management (g) that deviations are identified and (h) corrective and preventative actions (CAPA) are taken.
4. To meet the expectations of clients, employees, the company's owners, regulators and outside auditors and/or agencies.

Less immediate, but equally important objectives include the following:

5. To continuously review and improve how we respond to emergencies by keeping important matters in front of management, getting issues resolved in a timely manner and not letting any fall through the cracks.

6. To see the business as a whole entity and from a higher vantage point. To provide a level of management.

APPROACH

We took the approach that the BCP is ours, written by us, for us. We are not doing this to check off a box on an auditor's checklist, for example. Neither are we oblivious to the various sources online and elsewhere of information on templates, software, consultants and guidance related to BCPs. Guidance found in the ISO literature was very useful, particularly references 1 and 2. It is tempting to write a very large, all encompassing plan and, in fact, the plan must be "comprehensive enough" – it must address your most immediate needs and those of your clients. For the contract lab drafting the first version of their BCP, we think it is smarter to start by focusing on a smaller, minimally-sized plan that includes many details. This is for two reasons: First, our intuition tells us that the plan will require revision and maybe multiple iterations, before it is really good. Second, we know from experience that until you work out the details, you cannot get a clear view of all the problems. The process is not an exercise in logic; employees have to actually be able to perform the actions detailed in the plan.

THE RESPONSE MATRIX

We determined to use "adverse event" in place of terms like disaster. For the laboratory operation, there a number of adverse events that we must plan for and protect against that are not disasters. For example, the complete loss of chemical fume hoods would be a very serious adverse event and we want to plan for it. Furthermore, we determined not to consider every possible adverse event, but rather those deemed most critical and credible and we defined these up front in the BCP. We started with the following: Power/energy disruption, computer server disaster, fire and/or explosion, flammable gas leak, hazardous chemical release and/or emergency, large chemical spill, complete failure of laboratory fume hoods, cyber attack, theft of DEA-controlled substances used in client studies, intruders/violence from outside, bomb threat and tornado.

We asked ourselves "What are we trying to protect"? We found the following answer: Personnel, the environment, client experimental studies, company resources (including intellectual property, lab materials, supplies, samples, equipment, instrumentation, computer software/hardware, computer servers, metrology data and company records), the Pine Lake Laboratories business (in general) and Pine Lake Laboratories reputation in the industry.

In this way, a matrix naturally forms: Columns giving the array of credible adverse events and rows, of things we must protect from these events. We refer to it as the Response Matrix and illustrate the idea in Table 1. We enter into each cell of the matrix specific instructions intended to (a) minimize impact (b) ensure continuity and (c) shorten time to recovery. As an example, consider the cell formed by our response to a large (>4L) liquid chemical spill in order protect personnel. This is shown in Table 2. Every lab will have responses to an adverse event that are particularly their own. Ours are provided only for example. The Response Matrix can, of course, be an electronic spreadsheet. Consider adding approval signatures, completion dates, etc. to make it a "living document".

WORKING SCENERIOS

Each entry in the Response Matrix is a scenario. As we work through a scenario to come up with a suitable "response", we find all those points where we must depend upon a system or a person in order to complete the response. Using the large chemical liquid spill from Table 2 as an example, we see that the incident generates a CAPA item that will necessarily involve re-training. Following our practice, such training must be documented. It also generates lab waste and has the potential to necessitate reporting to federal, state and local authorities and the client. The persons involved in this example are the analyst, the CHO, a quality assurance staff member and perhaps a client representative. The systems involved are: Safety, Lab Waste Management, CAPA, Document Control, Training and Quality Assurance. Persons must be trained, competent and empowered to carry out their duties in a response. Systems must possess the attributes of a quality system.

RESULTS

Preparedness is the single-most important element for implementing an effective BCP and ensuring business continuity at the contract laboratory, since it directly influences how well the lab responds to minimize the impact of an adverse event, allows for the continuation of operations and shortens the time to recovery. "Preparedness" is facilitated by integrating the BCP into the cGMP/GLP quality systems already in place. For example, as an SOP, the BCP is a controlled document, reviewed and revised on a schedule and all changes to it require justification and approval. As another example, consider that protecting against damage to equipment and instrumentation is facilitated by having a GLP and/or cGMP-compliant metrology program in place, since the master equipment list, instrument logbooks, records of preventative maintenance, etc. are required for the lab to remain in compliance and these things all support the BCP. As a final example, consider that protection of client confidentiality, client samples, client study data, etc. are all critical to the client and addressed in the BCP while being critical to the lab striving to maintain GLP and/or cGMP-compliance. As such, disaster recovery of computer servers and monitoring of environmental conditions and other quality systems are in a perpetual state of preparedness. Hence, in most cases, the level

of preparedness is typically very high. The state of preparedness is monitored by the quality assurance group as well as the safety group (or chemical hygiene officer) who both report back to senior management.

Still, adverse events happen and it is important to get some practice dealing with them as per the BCP. Prior to an actual event, the lab should stage mock events and use them as exercises. Also the lab should perform tests on systems. Simple examples are a fire drill and a test on the fire alarm system. Real and mock trials along with tests generate results that should be evaluated against key performance metrics, as spelled out in the BCP. Furthermore, the old GMP rule that "If it isn't written down, then it didn't happen" is applicable here, so that all quality assurance and safety observations (including CAPAs and investigations) and all results generated from tests and exercises should be written up in formal report to be discussed in the annual management review and used to drive continuous improvement.

CONCLUSIONS

We presented a simple, systematic way of thinking about what should go into the BCP and how it can be integrated into the pre-existing quality systems at the contract lab to facilitate its implementation. We pointed out that the BCP should be the kernel of a comprehensive business continuity management system and that it should contain many details and be put to the test through mock trials and evaluated periodically against key performance metrics.

A lot is learned in the process of developing and integrating the BCP and, these are lessons not learned the hard way – in contrast to the hard lessons learned when planning for eventualities is not done. The contract lab learns a lot about its core values, and the integrity and details of its operation. In order to write a good plan, the authors and reviewers must know the functions of the lab and the daily work routines and get above them i.e. they must think as managers.

REFERENCES

1. ISO 22301:2012 Societal security - Business continuity management systems – Requirements
2. ISO 22313:2012 Societal security - Business continuity management systems – guidance
3. "Business continuity – ISO 22301 when things go seriously wrong", by Stefan Tangen and Dave Austin, 18June2012
4. Guide for Chemical Spill Response Planning in Laboratories, prepared by the American Chemical Society's CEI/CCS Task Force on Laboratory Waste Management, ACS, Washington, DC, 1995.

Table 1: Creating the rows and columns of the Response Matrix

Adverse Event ? To be protected ?	**Power/ Energy Disruption**	**Computer Server Disaster**	**Fire/ Explosion**	**Large (>4L) Chemical Liquid Spill**	**.**	**.**	**.**
Personnel							
Environment							
Client studies							
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Table 2: Example of a single cell taken from the Response Matrix

Adverse Event ? To be protected ?	**Large (>4L) chemical liquid spill**

Personnel	Minimize impact • Evacuate the area • Put up a barrier to the spill • Notify the Chemical Hygiene Officer (CHO), who will notify others • Work with the CHO or your supervisor to identify the hazards by considering the risks (health, flammability, etc.), quantities involved, location and potential impact on surroundings (environmental impact, possibility of nearby incompatible materials, nearby ignition sources, etc.) • Determine if you can pick up the spill. If not, then call the Hazmat number given in the Chemical Hygiene Plan (CHP). • Review the spill clean-up procedure. This will be found either in the Chemical Hygiene Plan or on the Approval to Handle Toxic and Particularly Dangerous Substances form (if applicable).* • Wearing the proper personal protective equipment (PPE), pick up the spill, bag it using heavy-duty poly bags and dispose of the waste through the company's waste management program. • With permission from the CHO or President, remove the barrier and notify personnel that the area is no longer off limits. Ensure continuity: • Determine if the client must be notified: Follow the guidance provided under NOTIFICATIONS found in this document. • The analyst, supervisor and CHO shall determine if experimental work can continue, as per usual. Shorten recovery time: • Obtain an incident report from Document Control and complete and submit it for approval, as per the CHP. • Consider re-supplying the lost material • Quality Assurance shall log the incident in the Corrective and Preventative Actions (CAPA) log. • Training shall be included in the CAPA response. • The CHO shall determine if the size of the spill exceeds the EPA reportable quantity (RQ) as found in 40 CFR 302.4. The CHO shall make all required notifications to federal, state and local authorities.

*At Pine Lake Laboratories, before the analyst can work with a chemical deemed to be toxic or particularly dangerous, they must review the hazards, proper handling, storage, waste disposal and spill clean-up procedures with the Chemical Hygiene Officer and complete and file an Approval to Handle Toxic and Particularly Dangerous Substances form in the Chemical Hygiene Plan binder.

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