Biosafety
ISSN: 2167-0331

Girón, Biosafety 2013, 2:3
DOI: 10.4172/2167-0331.1000e142

Editorial Open Access

Biosafety and Quality Issues Must Go Hand In Hand

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Keywords: BSL3 facility; Quality standards; GLP; Good laboratory practice

Introduction

All organizations have their own 'natural' quality systems, though often they are informal systems which do not follow a specific standard (e.g. GLP, ISO, and EFQM). As such, some of the road has already been traveled in any organization prior to any decision to implement any formal quality system in the whole organization or in parts of it.

Research is a continuously evolving process aimed at discovering new facts; basic research work is subjected to changes in response to new and often unexpected results and, sometimes, the end-result of research may be unrelated to the initial aims. Although, in our field, short-term contracts can be common practices leading to high staff turnover, it can also detract from establishing the mechanisms that ensure consistency and reliability of data over the long-term. This approach becomes more dangerous for individual and communitarian health when the facility is dealing with highly pathogenic bacteria and viruses as BSL3-BSL4 facilities do. Something we must to face with quality tools.

The building costs, but also the operational costs for a BSL3/BSL4 facility [1] pose a huge pressure to reduce the area devoted to BSL3/BSL4 activities forcing a controlled transfer of inactivated samples to the outside, with serious implications for both biosafety and biosecurity issues. So, the exit of biological samples after undergoing an inactivation process to render the biological sample non-infectious need also a strong quality approach.

Good Laboratory Practice (GLP) are the recognized rules governing the conduct of non-clinical safety studies, as they ensure the quality, integrity and reliability; they are accepted in many countries [2]. The achievement of GLP status would be of benefit to our own research, as previously described [3]. Moreover, as we were handling dangerous pathogens, some of them zoonotic, we have to assure (and to record) the safety of our workers but also external staff working in our facility [4]. The GLP spirit could be applied on all issues considered as critical regarding the proper performance of a BSL3 facility.

Always, Facility Director (FD) would be ultimately responsible any quality standard implementation although operational issues should be delegated in contracted full-time staff, highly skilled in virology/bacteriology and quality issues (as Laboratory Manager (LM), for instance).

A system for quality evaluation of all activities is also needed. This can be achieved by a Quality Assurance Unit (QAU), which personnel must be highly experienced in implementing quality standards, and operate reporting directly to Direction. The QAU personnel carry out the following activities among others: generate accurate job descriptions and a clear delineation of the decision flow path; follow up of all maintenance and verification plans of critical devices and apparatus; verify inactivation protocols in order to assure their compliance with GLP principles; planning, scheduling, performing, documenting and reporting inspections of facilities and activities to the FD…

At least quality tools must be applied in the following items:

Facilities

Proper procedures to ensure a proper degree of separation of different activities and help to prevent contamination and mix-ups upon receipt, testing and storage of materials. Strictly procedures for the entry and exit of personnel; emergency and contingency plans must be set up.

Apparatus, material and reagents

The apparatus in the facility must be periodically inspected, cleaned, maintained, and calibrated according to internal SOPs. Records of all these activities must be kept by QAU. All chemicals, reagents and solutions should be labelled to indicate identity, expiration date and specific storage instructions. Waste collection, storage and disposal must be designed in such a way as not to compromise the integrity of the health and safety of staff.

Biological experimental systems (also called 'test systems')

The test system is the couple virus plus cell line that responds to the test item with a change in viral titer, or a specific bacterial strain showing resistance to several antibiotics, etc. It is of paramount importance to keep a complete record of all biological species (viral, bacterial, etc.), origin, passages, volumes and titers present in the facility. The proper identification, handling and disposal of the test systems in viral inactivation studies has been previously described [3]. All biological systems, infected or not, are autoclaved in yearly validated autoclaves previously its disposal.

Standard Operating Procedures (SOPs)

SOPs provide documentation of all routine experiments. Strict adherence to the SOPs ensures the quality and integrity of data generated, and allows comparison from different experiments. The SOPs should be written by technical and scientific staff and subsequently approved by the FD. SOPs must be reviewed after a specific time frame; under coordination, distribution and filing by QAU personnel.

Exit of inactivated samples from BSL3 facilities

Every commercial or "in house" nucleic acid extraction kit, thermal treatment, protein extraction protocol, etc., to be applied on BSL3 pathogens to generate samples to be brought out to BSL2 laboratories must be tested and checked to fulfill facility requirements [5-9]. A

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Received November 3, 2013; **Accepted** November 4, 2013; **Published** November 8, 2013

Citation: Abad X (2013) Biosafety and Quality Issues Must Go Hand In Hand. Biosafety 2: e142. doi:10.4172/2167-0331.1000e142

restricted file to record all commercial kits, inactivation mixtures, protein extraction reagents and viruses and bacteria assayed [4] in such internal validation tests should be created. Moreover, is necessary to set up a follow up of all inactivated samples, so a electronic file recording number of vials, volume, identification, animal or human origin, bacterial or viral pathogen involved, inactivation treatment applied, contact time, person in charge, responsible of the exit through the air-lock, and final destination of the samples should be permanently updated.

Training of personnel

In addition to day-to-day training given by LM or BO, all staff should receive at least one day a year of GLP training given by the QAU (SOPs, critical devices, how to record raw data, safety at work, etc.). Training records for all should be kept.

Archive of documentation

All original documents covering the whole core activities of the facility must be filed in a proper space. Access to the archive is restricted to QAU personnel, and documents cannot be taken out the archive without the permission of FD.

Discussion and Conclusions

Setting up a GLP system implies long-term commitment, not only by management, but also by every staff member. A process that starts with the main goal of obtaining a certification, rather than achieving real quality improvement, will be poorly accepted and certainly misunderstood by technical and scientific staff [10].

A second factor to consider is to delimitate well-defined management structure handling GLP issues (appointing directly to Direction) and the strictly clear areas where GLP should be applied (all equipments and its maintenance, cell culture, virus and bacterial strains entry and propagation, and the exiting of inactivated samples), that allowed us to overcome some of the GLP implementation challenges that can prevail in universities [11, 12].

Thirdly, it is the good science and technical competence of all staff, hand-in-hand with GLP principles, which brought the institution to achieve and keep compliance [10, 13]. GLP principles mainly apply to the formal aspects of any study (planning, performance and record keeping) and do not evaluate the technical competence [10].

As expected, the implementation of GLP standards should bring benefit to other areas of research (basic research) in the laboratory: laboratory instruments are properly maintained, and they have become in an excellent training tool for new workers (technicians but also PhD students) in the proper and more rigorous way to record raw data and good record keeping.

On this GLP basis, we can build a wider and deeper quality assurance system that will take into account good scientific and technical performance (as ISO 17025 regulations or indeed, in the own biosafety field, as the outcome of CWA 15793 on Laboratory Biorisk management). Although excellence in research is mostly located in universities and research institutes, "excellence" can no longer be simply based on reputation and promises, but on a well defined quality system, preferably certified or accredited. This system needs to be simple and flexible, to provide added value to the organization, and its implementation is not the end but as a mean to achieve higher technical standards. In the near present, there may be no other alternative than to adopt some kind of quality assessment system; in my experience, GLP principles are probably the most useful way to begin to fulfill this requirement.

References

1. Abad X (2012) Transfer of biological samples from a Biosafety Level 3 Facility. Biosafety 1: e125
2. OECD (1998) OECD principles of good laboratory practice. OECD Environmental Health and Safety Publications: Series on Principles of GLP and Compliance Monitoring. No. 1. OECD. Paris.
3. Abad X, Bosch A, Navarro C (2005) Implementation of Good Laboratory Practice in a University Research Unit. Qual Assur J 9: 304-311.
4. Abad X, Majó N, Rosell R, Busquets N (2012) Assay of several inactivation steps on West Nile virus and H7N1 highly pathogenic avian influenza virus suspensions. Biosafety 1.
5. EMEA (1995) CPMP/BWP/268/95, Revised CPMP Guideline on Virus Validation studies. London.
6. EMEA (1995) CPMP/BWP/269/95, Note for Guidance on plasma-derived medicinal products. London.
7. EMEA (2001) CPMP/BWP/BPWG/4080/00, Workshop on viral safety of plasma derived medicinal products with particular focus on non-enveloped viruses. London.
8. EMEA (1995) CPMP/ICH/295/95. Note for Guidance on quality of biotechnological products: viral safety evaluation of biotechnology products derived from cell lines of human or animal origin. London.
9. EMEA (2001) CPMP/QWP/848/96. Note for guidance on process validation. London.
10. Geijo F (2000) Quality management in analytical R&D in the pharmaceutical industry: building quality form GLP. Accred Qual Assur 5: 16-20
11. Mathur-De Vré R (2000) The scope and limitations of a QA system in research. Accred Qual Assur 5: 3-10.
12. Hancock S (2002) Meeting the challenges of implementing Good Laboratory Practices compliance in a university setting. Qual Assur J 6: 15-21.
13. Dent NJ (1998) Forget compliance, concentrate on science. Qual Assur J 3: 103-108.