Disaster Countermeasures in Laboratories in Japan - Based on the Experiences of Disasters Including the Great East Japan Earthquake -

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On March 11, 2011, Japan was hit by a massive earthquake that mainly affected the Tohoku region. We conducted a questionnaire survey of 153 member companies of the GLP Division of Japan Society of Quality Assurance, on their experiences of natural disasters and countermeasures against them, in order to understand the situation of disaster countermeasures in laboratories in Japan (95 laboratories answered). We report the current situation of disaster countermeasures in Japanese laboratories.
based on the survey results.

(1) Experiences of natural disasters
Fifty six laboratories (59%) have experienced a natural disaster. In Japan, disasters have been caused by earthquakes as represented by the Great Hanshin-Awaji Earthquake in 1995 and the Great East Japan Earthquake, typhoons, lightning strikes, snow disasters, etc.

(2) Experiences of damages caused by the Great East Japan Earthquake
Falling objects and damage to buildings due to quakes were the most common damages caused by the Great East Japan Earthquake. Blackouts, rolling blackouts after the Earthquake and damages to animal housing facilities and waterworks also occurred. Major influences on ongoing studies included study discontinuations, changes in study schedules, and deviations of temperatures and humidity levels in animal rooms and
temperatures of refrigerators and freezers.

(3) Countermeasures of laboratories before and after the Great East Japan Earthquake
Measures for the safety of staff were strengthened in 45% of the laboratories as a countermeasure after the Great East Japan Earthquake. The establishment of a department specializing in the administration of disaster prevention, earthquake countermeasures for buildings and facilities, backups of information systems, data and essential documents, and securing of power source in case of blackout were also enforced in about 20% to 30% of the laboratories. However, about 40% to 60% of the laboratories made no changes in countermeasures from those before the Great East Japan Earthquake. Specifically, the most common earthquake countermeasure was fall prevention measures. Other countermeasures included the adoption of earthquake-resistant measures, seismically isolating the structure of buildings and the
covering of glass with shatter-resistant film. As for inundation countermeasures, many laboratories placed test substance storage areas and document archiving facilities upstairs and stored archives in water-proof bags. As blackout countermeasures, many laboratories installed private power generators and uninterruptible power supplies for major devices. Backups of information systems, data and essential documents included the regular backup of data, backup by installing servers at remote sites, relocation of servers to the facilities of telecommunication companies, storage of electronic media at multiple sites, and the use of cloud storage services. Emergency network establishment in case of disaster, emergency drills, introduction of safety confirmation systems and stocks of drinking water and food were implemented as safety measures for staff and measures against lifeline damages.

The results of the present survey on disaster prevention measures suggest that labora-
tories in Japan, where there are many natural disasters, are highly conscious about disaster prevention, and measures for the business continuity plan (BCP) had already been taken up before the Great East Japan Earthquake and were further strengthened after that.

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How to Successfully Manage a Foreign Regulatory Agency Inspection

Tammy Sayers Lesko
PAREXEL International, Billerica, MA, USA

This session will cover the key areas of consideration as well as the challenges that can arise when your organization is hosting an inspection from a foreign inspectorate. The factors to consider are:
- Authority of the Inspectorate in Another Country
- Scope of Inspection
- Cultural Considerations
- Language/Terminology Differences
- Time Zone Differences
- Logistics of Inspection

Examples highlighted will include personal experiences from hosting inspections by foreign inspectorates, such as PMDA (from Japan) inspections in the USA as well as FDA inspections in Europe. Highlights from other types of foreign inspections will also be included (e.g. EMA inspections in the US).

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Government funded contracts and grants for laboratory bioanalysis in clinical trials are often awarded to academic institutions where the infrastructure for necessary quality assurance entities is weak or nonexistent. The Division of AIDS within the National Institute of Allergies and Infectious Diseases has recognized the obligation to provide quality outcomes from these laboratories and has funded several laboratory-related quality assurance contracts for their HIV clinical trial networks. The latest contract funded is titled: The Clinical Pharmacology Quality Assurance and Quality Control Program (CPQA). Drawing on the principles of global and US laboratory regulations and their principles, a successful and efficient program has been developed and implemented during its first five years of operations. This program is unique because of the collaborative nature of its infrastructure which strengthens its effectiveness and enriches its expertise. An external advisory
board as well as cross-network representation within its organization allows for identification of quality provisions and improvements that will meet the needs of those whose quality is monitored and maintained. The CPQA provides key components of quality assurance systems to DAIDS-funded pharmacology bioanalysis laboratories located in the United States, Asia and Africa. In addition to the monitoring of method validation, laboratory proficiency and laboratory operations, these systems uniquely incorporate prerequisite quality priorities of data and sample collection during clinical trial conduct as well as the outcomes data analysis. These two unique areas of quality management stretch beyond the analytical realm and help assess inconsistencies that potentially impact of laboratory measurements. The model provided by CPQA can be applied and used for academic or other smaller not-for-profit or philanthropic organizations to form quality system collaborations. This presentation will synopsize
the CPQA infrastructure and its programs, provide examples that illustrate the successes achieved, and discuss current limitations that present future challenges. Special consideration for global collaborations will be highlighted.