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Restarting Your Facility – When Disaster Strikes

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Abstract

Recently, there have been a large number of major disasters that occurred around the world. On September 8, 2017 a magnitude 8.1 earthquake hit in Mexico. This was a major earthquake of (Karimi and Narayan, 2017) On Tuesday, September 19, a magnitude 7.1 earthquake occurred in Mexico City, toppling buildings and crushing cars. More than 200 dead have been reported. The earthquake hit about 100 miles away from Mexico City at 1:00 p.m. local time. (National Geographic, 2017) Lesser earthquakes occur in Southern California routinely. (Anonymous, 2017)

In addition to earthquakes, there has been a large number of hurricanes which battered the Carribbean and Gulf Coast of the United States in September 2017, including Hurricane Harvey, which hit Texas, Hurricane Irma, which swept the Carribbean and Puerto Rico, and Hurricane Maria. Hurricane Maria's path took it past Dominica, where it killed 15 people, and Puerto Rico, which has been significantly devastated. (National Geographic, 2017b) In Puerto Rico, more than one half the people are struggling to obtain food and water. At the time of this writing, most of the island does not have power.

These disasters have a major impact on the pharmaceutical, biotechnology and medical device industry. Many of these companies will be struggling to determine how to bring their facilities up to code following these disasters. This paper describes one approach to returning these sites to service.

Background

Puerto Rico has been reported to be one of the top five pharmaceutical manufacturing sites in the world. However, this position that has been declining. Puerto Rico's Secretary of Commerce - Secretary Bacó, says: "I will be honest with you, I agree that we kind of disappeared from the map. It came about basically because we lost a section of the U.S. Internal Revenue Code (Section 936) that provided for profits to be repatriated to the U.S. without paying federal taxes. The law was repealed in 1996, with a transitional period of 10 years to full implementation in 2006. Before this, we were accustomed to having companies come to Puerto Rico by word of mouth. It was so good for them that they literally just came. We failed to adequately prepare ourselves for this change and explain why we are still a destination for the pharmaceutical industry. That is why we disappeared; we got lost in that process and it has taken us too much time to get back on track." (Garguilo, 2014)

According to reports in USA Today, pharmaceutical companies from Eli Lilly to Johnson & Johnson are trying to assess the damage that occurred to dozens of their manufacturing sites and they indicate that short-term drug shortages can occur if these companies cannot shift manufacturing to other areas of the world quickly. (Anonymous, 2017c)

Puerto Rico has over 40 years of experience in the pharmaceutical industry. (Anonymous, 2017d) A drive down the main highway through San Juan and out to other areas of the island, one passes pharmaceutical companies on all sides of the roads, not to mention those companies in rural areas like Jayuya or Mayaquez.

Sixteen out of the top 20 best-selling drugs in the U.S. are manufactured on the island. Puerto Rico has been a world hub for biotechnology even before the term became popular. The well-established supplier infrastructure and human resources available practically guarantees success. Two new centers for biomedical research and the expansion of well recognized Ph.D. programs to include biotechnological specific degrees complement the growing research community on the Island. (Anonymous, 2017d)

According to the most recent government information available on their website, Puerto Rico was home to more than 70 medical device-manufacturing plants. These plants manufacture surgical and medical instruments, ophthalmic goods, dental equipment and supplies, orthodontic goods, dentures and appliances, laboratory apparatus and furniture and so forth. Medical device companies in Puerto Rico are highly regarded globally for their innovations and high-technology products. Some of the companies there include: Medtronic, Stryker, CR Bard, Abbott Medical Optics and Coopervision, which are among the top international medical equipment and supply companies that have found Puerto Rico to be a profitable location for manufacturing. (Anonymous, 2017b)

Disasters that devastate the island, like that occurring from Maria can impact people around the world!

Mexico also harbors many pharmaceutical companies. In fact they contribute 74,000 direct pharmaceutical jobs and 310,000 indirect positions. The industry also has a favorable effect on the Gross Domestic Product (GDP). (Anonymous, 2017e)

With all of these disasters, we need to proactively work to remedy the production in these facilities when disaster strikes.

The Disaster Recovery Plan

For many years we have recognized the need for “Disaster Recovery Plans” relative to the software and computerized systems we have in the plant. These plans are often on a checklist of what we must do to be in compliance for software validation. In reality, there are many other areas of the facility where a disaster recovery plant can be useful. One of those areas is how to bring the plant back up into production when disasters occur. Obviously, the plan cannot account for every possible contingency, but you can provide a good starting point for how to accomplish this task. Ideally, this should happen before disaster strikes.

The following should be some of the considerations for your disaster recovery plan.

Structural Safety and Efficacy

The first concern in any type of natural disaster is whether the structure is safe to enter and use. In most cases, outside personnel are actively involved in this process. This may necessitate police or fire personnel, utility companies, architects and engineers. There is little you can do until you know whether it is safe to enter the facility.

Some of the structural concerns after safety include: inspecting for leaks, water damage, are supports appropriate. Identifying where damage took place so that appropriate mediation can take place, and so forth.

During this phase, you may want to consider things like changing to an antibacterial/antifungal paint on surfaces, fungal barrier drywalls, and other preventatives that are available today, that were not present when the facility was built.

Products like MoldGuardian® which can be implemented in air ducts, interstitial spaces, and non-aseptic areas, can also aid in preventing subsequent mold contamination.

Basic Clean-up

In this phase, you want to remove the trash and garbage that is present due to the disaster. Appropriate safety measures should be taken to ensure that people are not harmed in this process. In this step people often use basic soap and water.

It may be useful to perform any environmental survey during this time period to see if you have new facility isolates that you did not have before. If you do, this may necessitate repeating some of your disinfectant efficacy studies.

Impact Assessments

These may be performed concurrently with subsequent steps, but need to occur before using materials in the warehouse and/or releasing APIs, excipients, and products. The impact assessments should consider factors like whether there was water or environmental contamination possible to the material. One should also determine whether the materials were stored

at the required storage conditions. In some cases, it may be impossible to complete these assessments until other steps in the “recovery process” have been achieved. In addition to all the materials to be used in production, including things like packaging and labeling supplies, similar evaluations should be made for the appropriate laboratories.

Laboratory assessments should include: media, reagents, standards, chemicals, supplies (petri plates, pipettes, and the like), and so forth.

None of these materials should be used for product testing or release until the impact assessment has been successfully conducted.

Verifications of Utilites Function

It is critical that the utilities be verified to be performing correctly. Some of the considerations include: air flows, balancing of air, power, back-up systems and generators, temperature controls, humidity controls, and the like.

This section applies both to the manufacturing and laboratory areas.

Verification of Equipment and Instrument Performance

Whether it is the laboratory area or the manufacturing site, you cannot just “assume” that all the equipment and instruments are working properly. Depending upon your facility and how you completed your qualifications, this may necessitate updating the installation qualification or operational qualification documents. You may also have requirements to update the performance qualifications, but you may need to do this later in the process, e.g., do you need to be cleaned and disinfected first.

It is important to include the various requirements specified in your disaster recovery program for your software applications.

The amount of qualification required should be based upon successful completion of risk assessments.

Cleaning and Disinfection

This is similar to the “go clean” stage in a start-up facility. For most situations this would involve at least a 3X Clean and Disinfect program. Ms. Anne-Marie Dixon recommends a 9X cleaning as being stronger. This should have environmental monitoring to support the appropriateness of the cleaning and disinfection program.

For devices, these minimum of three cleanings with at least three environmental monitoring procedures will usually be sufficient to go back into operation.

For aseptic drugs, placebo runs are recommended and media fills are required.

Process Simulation Studies (Media Fills)

An appropriate number of process simulation runs should be performed to qualify the process. The number of runs should be at least three, but more may be required based upon the number and types of products manufactured.

Conclusion

The ideal time to write a disaster recovery plan is long before you need to do it. If you don’t have one, then it is wise to specify these requirements before you go out in different directions trying to decide what all must be done before running production again. It is critical in this time period to carefully consider the risks in producing at risk in this time frame.

The best disaster recovery plan is the one you never need to use!

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