MEGA LIFESCIENCES

BUSINESS CONTINUITY PLAN –MANUFACTURING OPERATIONS IN THAILAND

Sr. No.	Scenario	Mitigation	Follow up
	A) Flood	1) The Bangpoo Industrial estate is closed to the sea, there is Sukhumvit road in between the estate and the sea. Sukhumvit road in this area is 1.5 m. above average sea level, while Bangpoo industrial estate road is 0.7 m. above saa level. And there are no large size building in the area between Sukhumvit road and the sea. Sukhumvit road is acting as sea water barrier during high tides period. So any flood in this area if higher than 1.5 m. above sea level will flow directly down to the sea. Chance of flooding higher than 1.5 m. above sea level is low. 2) Plant 1 was built 0.85 m. above our factory road Bangpoo industrial estate road, and our factory road is 0.5 m. above the estate road. So the factory floor is 2 m. above the sea level. 3) Our plant 2 is 1.2 m. above our factory road, and the factory road is higher than the estate road, even we assume they are same level, our plant2 factory floor is 1.9 m. above sea level. 4) The new building floor is 0.5 m. lower than existing plant floor, but there is a 1 m. RC wall below the brick wall for flood protection, so the new building have a protection up to 2.4 m. above sea level. So our plant and machinery in ground floor are safe from flooring. 5) Plant2 construction project has major utility machines like Bry-air and chiller installed on the third floor roof. Air compressor and Nitrogen generator are installed in rooms of existing building. The new second transformer will install on the MEA column and existing transformer will raise to a 1.5 m. height level except for boiler which will be installed on the ground but we will build a RC wall of 1 M. in height around it for flood protection. 6) Plant1, we are constructing utility building, so the MDB room will be shifted	System of Generator back up to be purchased and installed by <<End of 2013 for Soi 8 and End of 2014 for Soi 6>> Flood – Information from Satellite/ internet. Yearly Audit for fire safety done in year 2010 and planned for year 2013 in second half. Building audit (Fire & structural audit) Yearly. Next Audit due 2nd Half 2013. Electrical Audit for electrical installations, lightening, stress test, etc (Yearly). Boiler license renewal on a yearly basis subject to audit certificate. Gas Audit – Yearly Flood Audit to be conducted

		to the new utility building, other utility machine like air compressor and nitrogen generator will shift to the roof of new utility building. All 3 Bry-airs are installed on a 0.85 m. high platform. Chillers are installed in the utility area which is the same height as the building floor. Only the boilers which we will shift them to the new location which will install on the cement floor 0.8 m. height from factory road. So all utility machines, transformer and MDB are in the same or higher level than the building floor. 7) The stability walk-in chamber which used to locate on the ground outside the building in plant2 will be shifted to the third floor of new building. 8) Waste water treatment for both the plants is under construction and shall be underground and water leak proof. 9) The fencing around both the plant is a brick wall. So it leaves only the gate which will need to do temporary protection if there is a flood. 10) We are going to invest in generator for power backing up of computer system and emergency lighting system. This is the backing up for the UPS system which will last only 15-20 minutes. But this system will be able to provide power for necessary equipment during power shut down in flooding period. 11) The data server is located in Bangna, what if there is a power failure in Bangna? 12) Is there a process to get an FDA approval for manufacturing on an alternative site in case the machinery also gets damaged or plant stoppage due to natural calamities? 13) What if the Raw Material is damaged in flood, will the suppliers be able to supply at a shorter lead time? 14) What if the computers are destroyed, will we be able to buy new computers, restore backups and create a fully functional set up in 4-5 days, will Supply chain, Finance, Manufacturing, Quality, etc be fine with this down time? 15) Do we have any arrangement to evacuate staff in case of flood? 16) Does Bangpoo Industrial estate have a flood action plan, if yes, we can request for a copy for our records? 17) Do we need an action plan on the steps to be taken when the factory faces a flood situation i.e. who will remain the company, food provisions for some	by the Building auditor. Engagement letters to be finalized within March 2013. Audit Schedule to be kept ready and signed. Generator for Bangna office, roadmap needed. Lalit to provide the roadmap. 12) FDA may consider to manufacture by 3rd party without 2nd registration for natural calamaties 13) Suppliers can supply in shorter lead time – Air shipments and supplier arrangements exist. 14) Data back up software needs to be checked to ensure that the software is functional 15)Backup – Lalit to check and submit a plan/ evaluate the current back up data credibility and completeness.

		staff in case they stay in the company to report any damage, How the doors have to be shut before leaving? Power to be switched off, etc?	
			18)
	B) Interruption of utilities	1) How do we cope up if the water supply is affected? 2) How do we cope up if there is a electricity stoppage due to transformer damage or service provider having a problem? 3) How do we cope up if the gas supply is affected?	Water supply authorities inform the management if there is any interruption, company has own storage and water supply arrangements are done by tank. Electrical equipment damage i.e. transformer replacement can be done in a few days, the company has alternative transformers which can function as spares and the alternative transformers can be ready by end of 2013. Soi 8 by May 2013 and Soi 6 by end of 2013. Gas supply stoppage can be taken care of by installing Diesel Burner as a spare by end of 2014.
	C) Labour	1) How do we take care of labour shortage? 2) How will we deal with labour dispute if any? 3) Do we have a deal with any agency to provide standby workers in case of dispute or shortage due to other emergencies? 4) Do we have any arrangements for Medical emergencies? 5) Are the labour records stored in a fire proof location? Have they been scanned and kept in a different location?	The economy/ industry faces labour shortage in general and the company is spending on automation and the working hours have been extended to 12 hours. The company has a compulsory overtime policy. No trade unions exist and the company has not had any disputes in the history of operations.

			The company has an agreement with a Hospital in close vicinity. Currently records are maintained as data on oracle but the documents related to staff can be scanned and stored in a central location, lalit to confirm the plan.
	D) Accidents	1) Do we have an SOP for dealing with fire (Fire Drill etc)? 2) Do we have an SOP for dealing with Explosion? 3) Do we have any SOP for dealing with Earthquakes? 4) Do we have any back up if the quality control/ Assurance documents are burnt in a fire? Are they kept in a fire proof storage place? Do we have a scan of those documents? Do we have extra stationery stored off site for such emergencies? 5) Are manufacturing records also maintained manually? What if these are destroyed? 6) How will GMP/ TGA audits be handled if the records are destroyed? 7) Do we have backups for desktop computers in the manufacturing, supply chain and Quality Control departments? Where is the backup information stored? Is it confidential?	The company has a yearly policy of fire drill and fire safety training. The safety committee meets once a month to discuss any concerning issues. SOP for dealing with fire and explosion. The location is classified as a low risk zone for earthquakes. SOPs are backed up and scan image of the signed SOPs are stored on servers. Filled Batch records (including packing records) are with QA – we maintain a scan stored on the server. Hard copies stored in the location for 6 months and older records stored in recall. The company can handle the TGA audits are based on electronic records and certificate copies if destroyed can be

			arranged on a short notice.
	E) Technical	1) What if we fail the Thai GMP? 2) What if we fail the TGA certification? 3) Do we have contracts with 3rd parties to manufacture our key products (Top 20)? 4) Do we have separate GMP/ TGA certifications for 2 plants? Can they substitute for each other? 5) Do we have licensed software on all the computers? Are we equipped to face audits from BSA?	Thai FDA: The chances of failure are very slim. a) Critical findings – Production needs to be stopped immediately and corrective action to be taken. The longest anticipated closure in worst case scenario cannot be more than 6 months. The company has an arrangement for alternate locations which will be ready by end of August 2013. b) Ethical products: The company is in the process of identifying sites for alternative manufacturing. It is difficult to find partners willing to work on a short term contract. c) Supplements, powders, tablets being manufactured in plant 2, we have alternate

			registration from Australia plant for key products.