

# Troubleshooting in pharmaceutical industry automation Vs Manual

*Author: Palash Chandra Das, M.Pharm*



New era of Indian Pharmaceutical industry is going to begin. Major regulatory pharmaceutical companies are under USFDA scanner. Repeated/similar observations are reported against data integrity issues and GMP practices around the industries. Critical Process operations are dependent on the human efforts; however we are standing on the transition phase where human interventions are getting replaced by automation. But it is not like that the automations can replace the human intervention completely. As per the guidance expectations, people those who are involved in the process they should to be well educated, trained and experience in relevant field.

As we know, human are driven through emotions, so the mental stress and trauma directly impacting the process which they are involved. It is the responsibility to management to look after their



employee’s recreation and their day in day out needs. Below mentioned elements are need to be considered, but not limited to,

**Work Time management:** Regular over time disturbed personal as well as professional life. 70-80% employees should go home at the end of their working hours. Basically if we are talking about the discipline then it is expected people should attend in time and people should leave in time.

**Knowledge management:** Recognize the person with proper knowledge for their respective job, if required ensures periodic training and current updates to your employees. Before assignment of any task please ensure that right job is allocated to right person.

**Leadership management:** Identify the leader not rulers. Good leaders not give orders they believed to work together. Choosing leader is a very big and tricky task.

**Cultural program/get-together:** This will make the work place like homely environment. Some time social gathering help to build the good relationship and we all know a good relationship always help the organization for its growth.

Risk assessment for use Automation Vs Manual human intervention,

Category	Requirements	Risk Level	Justification	Disadvantage
Automation	System should be validated Controls should be established Maintenances to be done as per requirement	Low	Due to high controls Probability of failure is very less and meanwhile delectability of any probable failure is very high	Improper maintenance can hamper your business continuity e.g. Partially sealed injectable vial unit loading in the Lyophilizer through ALUS (Robotic system).
Semi-automatic	Addition to automation requirements human controls are required Person should have, a. Relevant Qualified b. Subject Trained c. Experience	Medium	As personnel are involved in the operation hence the Probability of failure is medium and delectability of any probable failure is medium	Machine/process performance partially depended on the Human activity. e.g. Partially sealed injectable vial unit loading in the Lyophilizer through semiautomatic conveyor under RABS/Isolator.
Manual	Activity driven by human being.	High	As the probability of failure is high and delectability is very low.	Process output fully depended on the manual interventions by human being. e.g. Partially sealed injectable vial unit loading in the Lyophilizer by manually tray loading procedure under Grade A with the background of Grade B.

