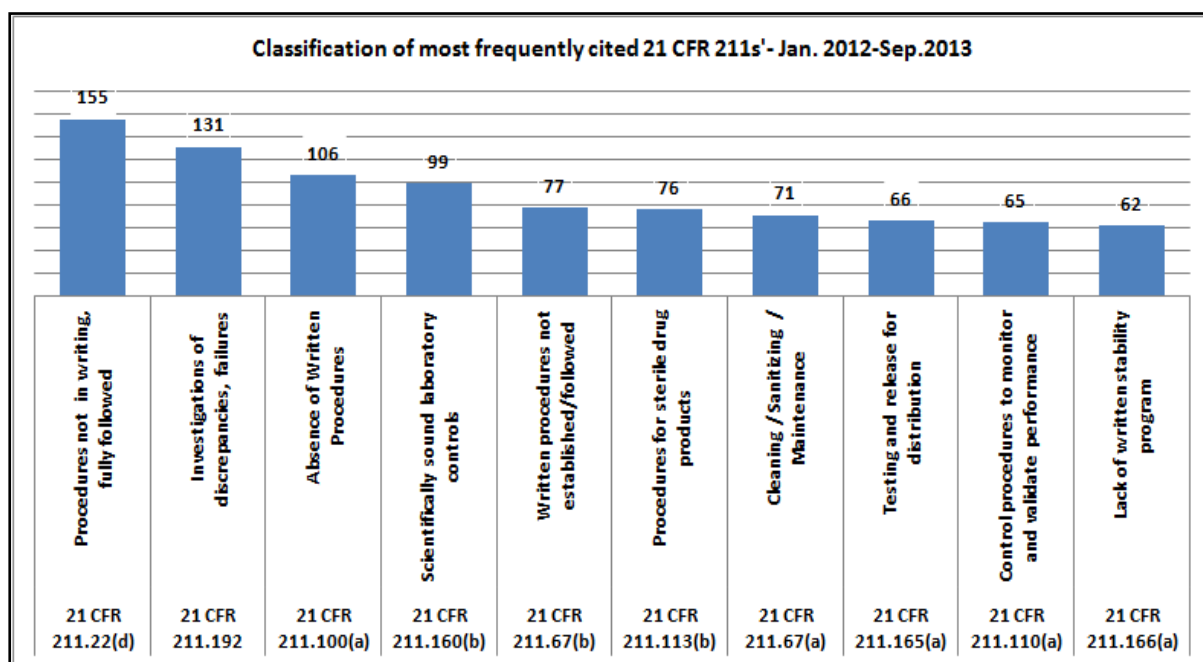


In 2011, The *MV Pavit*- a rusting ship floated gently, unnoticed almost until it nudged the shores of Mumbai's Juhu Beach. It was a 1,000-tonne Panama-flagged merchant ship that had been abandoned by its crew and reported sunk! After having spent more than 100 hours in Indian waters and remained undetected by the Navy, the Coast Guard and pristine police patrol boats (purchased after 26/11), the dangers and potential to kill, in retrospect, were clearly identifiable. No official investigation of the systemic failures or lessons thereof that enabled the *Pavit* to drift ashore, were made available. We are unsure of how many more *Pavits*' lie concealed. And almost after 3 years, now the year 2014 opens up a classic example of presumed breach with human intervention- that remains unresolved is the MH370 airliner mystery. Does this bode well for us? Why are there failures of coordination despite the technology that is advanced?

Many countries across the world have not been very successful in preempting threats or thwarting attempts to derail the economies. Despite coupling "technology advancement" with the intellectual tool called "speculation", fighting "terrorism" and preparing for the unimaginable remains mysterious, to almost all professionals. Pharmaceutical operations or healthcare operations- that deal with human lives are no different and have a dangerously poor record of not having to be proactive, with being ahead of the detect-ability radar!



Data from the www.fda.gov

Almost all operations, despite the technological advancements have the underlying human factor, at all levels. Consider "human intervention" in the most insignificant activity, such as housekeeping in a pharmaceutical set up. One wrong move and the implication to the environmental conditions, where products are being manufactured, may have outcomes that are unfathomable. Another example is the procedures not being in writing, those procedures not being followed [21 CFR 211.22(d)]. Yet, at the end of the day, the product-worthiness assessed is the outcome of those results, of tests {that are currently under deep scrutiny} with human intervention! Thus, any product or process being "within specifications" remains tenuous.

There are so many unnoticed and un-deciphered reasons why unlawful behavior is not noticed unless the regulatory agency walks in! One of the oft-quoted reasons is the missing piece of Quality review in its uncovered form. To this day, operations in the pharmaceutical industry do not have a central command centre, where all functional officials can observe and liaise on real time threats, from a real time quality review or data authenticity point of view. In emergencies, such as to deal with an aftermath of a debilitating regulatory inspection, power rests with the Crisis Management Group, chaired by the CEO/COO/CSO or the head of the operations. This mechanism although allows for effective decision-making after a crisis, remain ineffective to preempt quality issues and take a call. The terms of data integrity, falsification, and lack of time-bound escalation are all various hues of “obscured terrorism” in its factual form. If terrorist activities amount to breach of security, then wrong data capture, intentionally or otherwise is also equated to a breach of professional codes.

It is time for the community, to realize that human “intervention” and therefore “human error” is inevitable. The term “human error” is often used very loosely. We assume that when we use it, the understanding is universal. Quite the contrary! The fundamental problem is that the term human error has at least three meanings:

- (a) It can mean the cause of something
- (b) It can mean the event itself (the action)
- (c) It can mean the outcome of the action.

Generic definitions do alter behaviors because of the fundamental human psychology, and hence emerges the need for clarity in definition of the term, and taking recourse to rectify/minimize the root causes identified.

The responsibility of having human errors to be the only reason for mishaps or near-mishaps lies in the patterns of thinking. Like in the aviation industry, pilot suicide is a potential threat that needs urgent attention, similarly, when incidences occur/deviations are notified, the intention or pattern of individual or systemic thinking is what one needs to dig-deeper into. Rushes to pull all stops for a continuance of operations will not assist to identify the real root causes. Despite a well-promulgated and proven regimen in the pharmaceutical industry, data falsification and modifications to captured data does not stop occurring. Sadly, psychiatrists say that tests will not reveal a person’s intentions, if he or she chooses not to answer queries honestly.

Apart from delivering on technological solutions such as automation, experts will now have to factor in the following:

- operation-worthiness of all operational personnel
- integrity-worthiness of operational & quality personnel

assuming that there is a healthcare, which is being administered every minute. The ongoing investigation of MH370 is expected to provide some clues to predict psychological aberrations and one could wait to see how the pharmaceutical industry should look to insulate operations and safeguard against both technical flaws and human subversion.

In an era where integrity cannot be taken for granted, it is vital for experts in pharmaceutical operations to sit together and spell out concrete proposals to make pharmaceutical operations safer

and predictive from a human angle, with respect to the online documentation. Culture and thinking, despite all initiatives taken, is extremely difficult to change. It is equivalent to attempting to change the direction of a spinning top without having to bring it down. This change needs a dictatorial direction, a top-down approach, to begin with, and eventually funnelled into systematize the culture of integrity –making it a rule to live by. There are no short-cuts in this journey and all leaders need to vouch by the same sets of belief- regimented and almost fanatical!