



# WHY INTELLIGENT PEOPLE IN RESPECTED ORGANIZATIONS DO IRRATIONAL THINGS!

by Martin Lush

As a leading consultancy and training provider to the pharma, biotech and devices industries, we are privileged to work with people who are both motivated and smart. In fact, our industries employ more PhDs and graduates than many other sectors! Yet, when you read through some recent 483s, you are left wondering why respected organizations, staffed with intelligent people, do some very illogical things. Take for example these recent non-compliances:

- > "393 customer complaints that had not been investigated"...
- > "Widespread SOP non-compliance..." companies spending millions of dollars on writing SOPs that are too complicated to use...
- > "Audible alarms switched off"...
- > "Risk assessment used to justify poor practices"...
- > "Ineffective and under-resourced training programs"...
- > "Absence of planned maintenance program (breakdown only!)"...
- > "Over reliance on poorly trained contractors"...

So why do organizations with a collectively high IQ do such things? Why is common sense not always translated into common practice? Over the last 27 years, NSF has gained an enviable reputation helping companies improve compliance, efficiency and decision making. Here are some reasons (contributing factors) why we think intelligent people do strange things. Any sound familiar?

## CONTRIBUTING FACTOR 1: INSTITUTIONAL ARROGANCE

A good compliance history combined with impressive business growth can, in our experience, lead to a false sense of security. Even institutional arrogance. This apparent lack of failure can be dangerous since failure acts as an emergency stop that forces companies and individuals to reassess what they do, learn from the experience and move on. The absence or suppression of any failure results in organizations believing their own propaganda. Critical thinking and analysis stops only to be replaced with arrogance and complacency which then leads to poor decision making. This is where an open and honest culture, supported by robust governance processes and structures, is vital.

## CONTRIBUTING FACTOR 2: INSTITUTIONAL BAD HABITS (ACTING WITHOUT THINKING)

People and organizations are creatures of habit (acting without conscious thought). One company habitually ignored its change control system because of its overwhelming complexity. Most engineers habitually used the emergency change control system without thinking. Bad habits can creep in due to a number of reasons:



- > Lack of educated personnel who understand the why that underpins the how, particularly in leadership and supervisory roles ultimately responsible for standard setting. They don't know how to set a good example
- > Leadership disconnected from the shop floor, with managers who have forgotten what MBWA stands for (management by walking about)
- > Leadership failing to walk the talk and live the values of the company
- > Performance measures that drive the wrong behaviors and habits. Encouraging people to reduce deviations by n% creates a mindset that deviations are "bad"
- > Insensitive or inadequate internal surveillance systems.
- > Good audit, self-inspection, deviation and CAPA systems are vital in detecting and correcting bad habits
- > Governance processes and behaviors that regard quality metrics and reporting as a "beauty contest" between departments and sites
- > Peer pressure and group think. Bad habits are recognized but not addressed due to peer pressure or group-think that leads to justification of bad practices
- > Inward thinking and failure to benchmark against external standards and improvement in best practice

### **CONTRIBUTING FACTOR 3: IGNORANCE DUE TO POOR EDUCATION**

Many bad decisions and inappropriate behaviors can be due to people at all levels in the organization not knowing any better. This can happen when companies invest in training rather than education. Remember, we educate our children and train our dogs. If we apply a pure training approach to people, we end up with a workforce that knows what buttons to press without knowing why or understanding the consequences for getting it wrong. When people are educated to know

these things, they take personal ownership for their activities and behaviors. More than this, only then can their full potential be realized and the company benefit from the intellectual capital that is present in the workforce. This is a prerequisite for any continuous improvement activities.

### **CONTRIBUTING FACTOR 4: CULTURE OF FEAR AND BLAME**

Continuous improvement needs an educated workforce but it is only possible when people have the freedom to challenge the status quo, bringing problems to the surface for sharing with all, no matter where they are in the organization. When blame and fear exist, problems remain, issues are hidden and bad practices go unchallenged. Without openness and transparency, continuous improvement and management of risk is impossible, corporate governance is doomed to failure and the working environment becomes "toxic".

### **CONTRIBUTING FACTOR 5: SYSTEMS THAT ENCOURAGE BAD PRACTICE AND POOR DECISION MAKING**

System complexity and inappropriate design can encourage people to do crazy things. Some examples include:

- > Excessive signatures in a batch record leading to signatures being completed after the task rather than during
- > Overly complicated batch documents encouraging poor aseptic practice in the cleanroom
- > Poor equipment design leading to excessive interventions
- > Poor staffing levels in the cleanroom resulting in rushing around and poor aseptic practice
- > SOPs that are so complex they can't be used, leading to inconsistent practice



## CONTRIBUTING FACTOR 6: LACK OF PERSONAL INTEGRITY AND HONESTY

On very rare occasions, bad practice and inappropriate behaviors come down to the individual. People do things they know are wrong because they are either dishonest or lack personal integrity. Poor decision making on the part of individuals can also be attributable to the following:

- > They simply don't care and have very little pride in what they do. In our experience this is often the fault of the company rather than the individual. When companies care little about their employees, the culture can impact the behavior of individuals by creating a predominating mentality of "If they don't care about me, why should I care about what I do?"
- > Previous experience in another company
- > Arrogance can also be a contributing factor, with thinking like:
  - I know best
  - I am beyond the law; the rules don't apply to me
  - I won't get caught

## CONTRIBUTING FACTOR 7: HIERARCHY

Hierarchy, where group members are distinguished by seniority and power, is evident in every society, let alone company. Hierarchy can be both constructive and destructive in equal measure. Best-in-class companies have an enabling hierarchy and focus on engaging the entire organization to drive personal ownership of quality and personal responsibility for continuous improvement. Underpinned by effective education, this can be achieved using a number of mechanisms symbolic of a healthy and productive hierarchy that uses the talent of the entire

### ABOUT THE AUTHOR



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