

## Stick or Carrot?

### *What will eventually wake up the US Pharma industry to the importance of Quality; the stick, or the carrot?*

Roll the clock back to the early 2000's - groundbreaking discussions between FDA and Industry that led to the 'cGMP for the 21<sup>st</sup> Century' philosophy – science and risk-based approaches to quality.

Scroll forward to 2008 – the issue of ICH Q10 'Pharmaceutical Quality System' – a model QMS that should drive improvement in products and processes.

Now - bring yourself back to 2012 – the current day, what do we see?

- **Shortages** of essential medicines due to quality and supply issues
- **Empty spaces** in Pharmacies / Supermarkets where OTC brands used to be
- Drugs and devices **recalls** routinely in the news
- Massive **fin**es, site closures, warning letters, consent decrees resulting from FDA enforcement upon firms who don't meet the standards, or bend the rules
- A firm's **reputation destroyed** overnight when previously seen as good citizens
- **Lack of industry integrity** and ethics being spoken of



To quote Janet Woodcock, CDER Director at FDA - who has championed the need for quality over many years, speaking at a recent public event in 2012:

*“Pharmaceutical Quality Management is lacking and we are not anywhere near where we need to be”. It seems that industry’s objective today is to continue to meet regulatory standards, which are minimal expectations, versus adopting a commitment to high quality medicines. Most of the recent high profile recalls can be traced to complete failure of a firms’ Quality Management System. The subsequent problems that then have occurred have led to lost revenue, damaged reputations, lost jobs, and in some cases possible loss of the company”.*



Hard words indeed but looking at the industry as we are able to do at NSF-DBA LLC, a US based pharmaceutical consultancy, audit and training company, Janet's comments resonate too. Whilst some firms do establish a strong, management led, quality culture and robust quality system, there are many more that either don't get it, or choose to turn a blind eye until caught out.

What never ceases to amaze us is how many of these firms are suddenly able to find hundreds of millions of dollars when put under a consent decree. If the Pharma industry followed a true 'Cost of Quality' model (or maybe we should call it the Cost of non-Quality?) executives might realize that a good balance between prevention and appraisal costs might actually prevent the horror stories that we are seeing occurring in the first place.

NSF-DBA has been a strong advocate of a good Quality Management System driving business benefits and operational excellence for many years – when will the industry culture overall change to get it?

Or will they still roll the dice and wait for FDA to tell them – a false economy by anyone's book?

Maybe the problem lies with short-term thinking, driven by short-term goals and incentives at senior management levels driving the wrong culture, decisions and behaviors, particularly in today's difficult economic climate? There do seem to be some nice bonuses, retirement and/or severance packages in our industry hitting the headlines for all the wrong reasons.

### **So the choice is yours – the carrot or the stick?**

And by the way, Deming had some answers 50 years ago.

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