



India Affiliate
Hyderabad Chapter

ENGINEERING
PHARMACEUTICAL
INNOVATION

Behavioral Aspects & Practices for Better Regulatory Compliance



Vijay Kshirsagar
Director & CEO
TRAC Pharma Consulting
Mumbai

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Changing Landscape

- India's pharma market valued at 72069 Crore (INR) in 2013 (65654 in 2012)
- 9.8% growth in 2013 as against 16.6% in 2012
- 1700 new product launches in 2012 (1900 in 2010)
- Need to resolve regulatory challenges by working together with government & other stakeholders
- Need to take 360-degree approach, not only for regulatory compliance but their internal code of conduct & ethics code
- Approvals for clinical trails in India have slowed down

Ref: Nov 13 PWC report entitled “ India Pharma Inc.
Changing landscape of the Indian Pharma industry



Changing Landscape

- India's plan to open inspection office in China is stalled
- Exports to US rose by 32% in 2012. Can it sustain with lot of regulatory issues in hand ?

Ref: Nov 13 PWC report entitled “ India Pharma Inc.
Changing landscape of the Indian Pharma industry



Food for Thought

As per Mr Ajaj, former head of compliance at FDA, “The root cause of compliance issues in Indian units is often linked to human elements, including the culture & attitude of the people at the facilities & in the Senior Management ”

Other side of the coin?



We don't have to look too far !



Truth does not pay homage to any society, ancient or modern. Society has to pay homage to Truth or die. Societies should be molded upon truth, and Truth has not to adjust itself to society ... That society is the greatest, where the highest truths become practical. That is my opinion; and if society is not fit for the highest truths, make it so; and the sooner, the better.

- Swami Vivekananda

Where are we?

- ❖ Approximately 25% products sold in UK come from India
- ❖ Every fourth pill consumed in US is from India
- ❖ FDA established office in India (Delhi & Mumbai)
- ❖ Mutual collaborations between regulatory bodies
- ❖ Inspection reports are shared amongst each other
- ❖ Growing discomfort of regulators



Current News

API's From Asia at Risk

- ❖ Current estimations are that around 70 to 80% of the total volume of APIs used for the manufacture of medicinal products for the European market is sourced from Asia.
- ❖ The EDQM announces frequent suspensions of CEPs.
- ❖ Many of these CEP's are held by Indian manufacturers
- ❖ New challenge thrown by Falsified Medicines Directive of EU

Current News

- ❖ US FDA will be doing unannounced inspections in India at par with what they do in India
- ❖ Is it an opportunity, threat or challenge?



When can we get out of this?

- Many QA Managers consume full ink refill within 25 days before regulatory inspection
- During the non-inspection period one refill lasts for > 4months

What does this indicate?



Is preparation itself Out of Trend ?

Do the trending for following activities done within 1 month before inspection Vs same activity during non-inspection period

- No of New SOP's prepared
- No of Changes done to existing SOP's
- No of Change Control, Deviation, Market Complaints, OOS closed
- Man hours spent
- Revenue expenses
- No of internal audits & reviews



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Source: Thomson One

Human Element of GMP

- Never disregard the human element
- Historically disgruntled elements have caused a greater damage to Indian pharmaceutical industry
- Work towards a cultural change inculcating OCTAPACE values i.e. Openness, Healthy Confrontation, Trust, Authenticity, Proactiveness, Autonomy, Collaboration & Experimentation



***Let's go and build strong
pharmaceutical work culture !***

Integrity

- “There can be no friendship without confidence [trust], and no confidence [trust] without integrity.”
 - [Samuel Johnson](#)
- “Transparency is the key to trust.”
 - [Steven Hill](#)

Lack of Data Integrity remains the root cause of maximum no. of 483's & warning letters issued by regulatory authorities.

Lab Data Quality No Task for a One-Man Band

- Data Initiator
- Reviewer
- Lab Manager
- QA Manager
- Regulatory Officer
- Head Regulatory



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Corporate Policies Reflect Values

- Hiring practices - Checking References
- Ethics training
- Data integrity training
- Complete technical training
- Well defined quality system

Have Ethics Policy

- Conduct all business with integrity and in an ethical manner
- Responsibility of each staff member and manager to hold to the highest ethical standard of professional conduct in the performance of all duties

Frame Data Integrity Policy

- To ensure that work is of highest integrity
- Employees are responsible and accountable for the integrity and validity of their own work
- Employees respect and adhere to the principles of ethical conduct
- Fabrication or falsification of work results are direct assaults on the integrity of the laboratory and can't be tolerated

It boils Down to People behavior & Communication



Cracks in the Quality System (QS)



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Can We See Them? How?



Pointers to the Cracks in QS

- Poor hiring decisions
- Lack of online documentation
- Lack of training
- Missed SOP updates/ internal audit plan/ calibration schedules
- High Turnover of people
- Repeated failures of the same nature

Address the major causes?

- Rs Rs \$\$\$\$\$\$\$\$\$\$ = GREED
- Management Pressures
(Making clients happy)
- Unrealistic Contractual Requirements
(hold times, low detection limit requirements)
- Loss of Qualified Technicians
- Unethical Personnel



Red Flags

- No OOS or nominal OOS
- No unplanned deviations
- Expired Standards/Reagents
- Shared log-on and password access
- Inadequate internal assessments
- Absence of Repeat Analysis Register

Red Flags

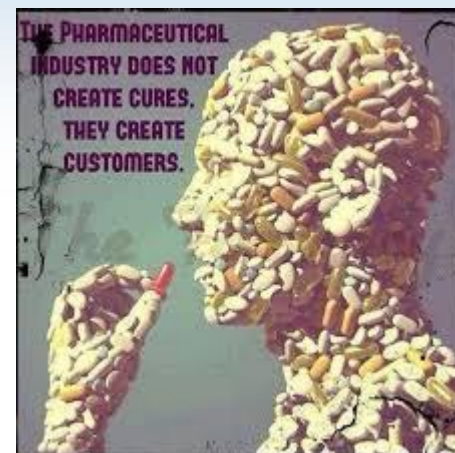
- Transcription errors, date/time discrepancies in sample Receipt Records
- Inappropriate sample sequencing
- Improper changes or corrections in Logbooks, sequences, data sheets, run logs
- Improper & manual peak integration
- Improper background subtraction

Red Flags

- Critical differences in the productivity of analyst
- Missing review, signatures, dates
- “Reappearing” QC results
- Non-standard report formats
- Unjustifiable & Non Chronological chromatograms
- Skewed Production levels
- No Mechanism for Reporting Problems

Red Flags

- Too perfect QC results
- Disabled Audit Trails
- Presence of pencils or whiteout
- Extremely clean, neat logbooks
- Logbook entries all aligned
- QA staff lacks direct access to senior management



Red Flags

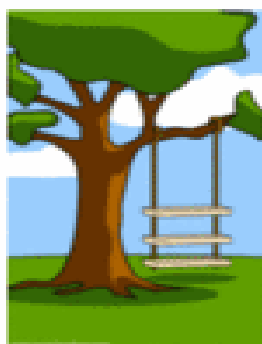
- Inadequate backup & reviews (personnel & equipment)
- Skewed overtime hours
- QA staff lacks direct access to senior management
- Management review if seen as a formality



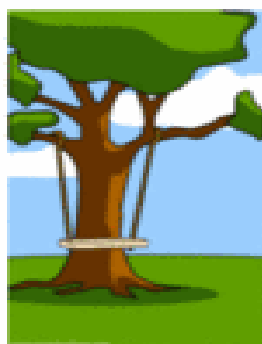
Giving Instruction, following it & documenting the work

The Behavior Effects

Create your own cartoon at www.projectcartoon.com



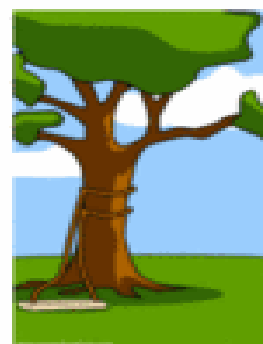
How the customer explained it



How the project leader understood it



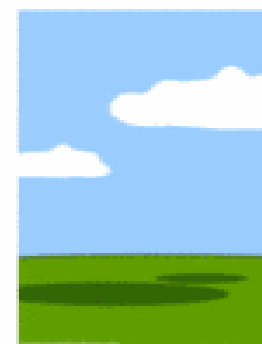
How the analyst designed it



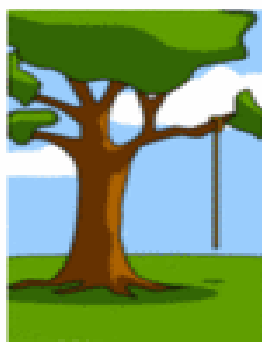
How the programmer wrote it



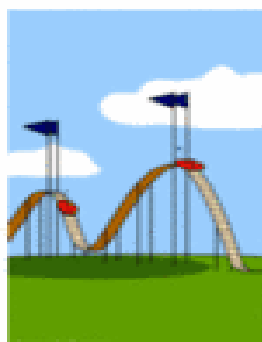
How the business consultant described it



How the project was documented



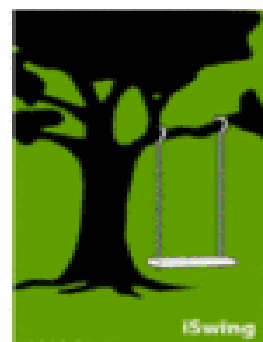
What operations installed



How the customer was billed



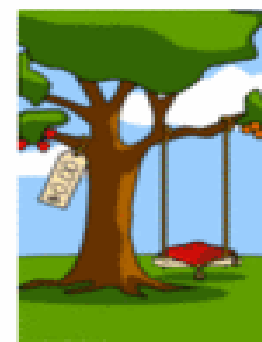
How it was supported



What marketing advertised



What the customer really needed



The Open Source version

Case Study

An analyst who performs Suphated Ash test remembers on his way home that the balance calibration check for that day was forgotten. He performs the balance calibration as soon as he arrives at work the next day. Results are OK. The analysts is unsure how to proceed. He should:

- A. Record the calibration check and not mention it to anyone?
- B. Repeat the analyses on the entire batch?
- C. He asks the co-worker for advice

Case Study Contd....

The co-worker says “No harm, no foul” and advises him to just record the calibration results and keep quiet. The analyst should:

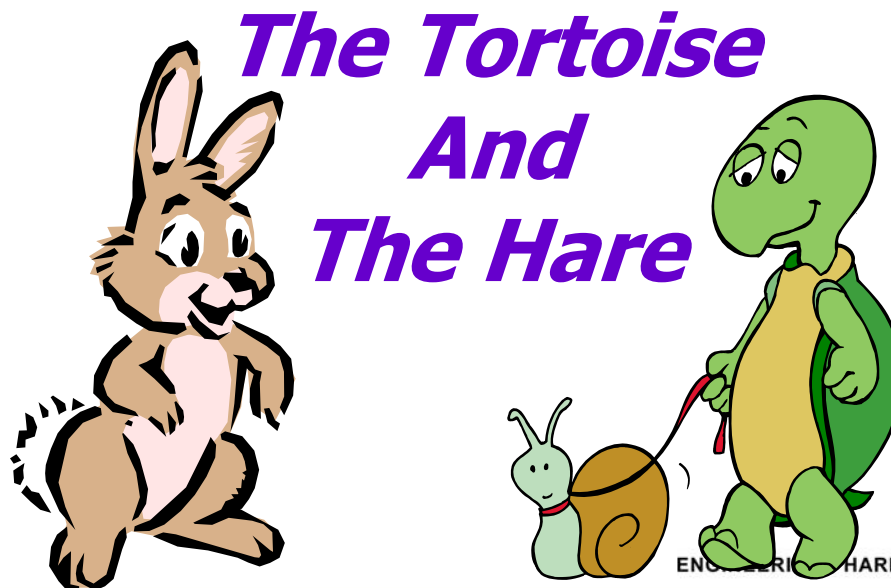
- A. Follow the co-workers advice ?
- B. Tell his/her supervisor that the co-worker is unethical?
- C. Go to upper management and spill everything?
- D. Seek counsel from lab supervisor and QA manager ?

Or Do Something Else?

Important Behavioral Traits

- *It's good to be individually brilliant but unless you're able to work in a team and harness each other's core competencies, you'll always perform below par as there will always be situations at which you'll do poorly and someone else will do well.*
- *Teamwork is mainly about situational leadership, letting the person with the relevant core competency for a situation take leadership.*
- *When we stop competing against a rival & instead start competing against the situation, we perform far better.*

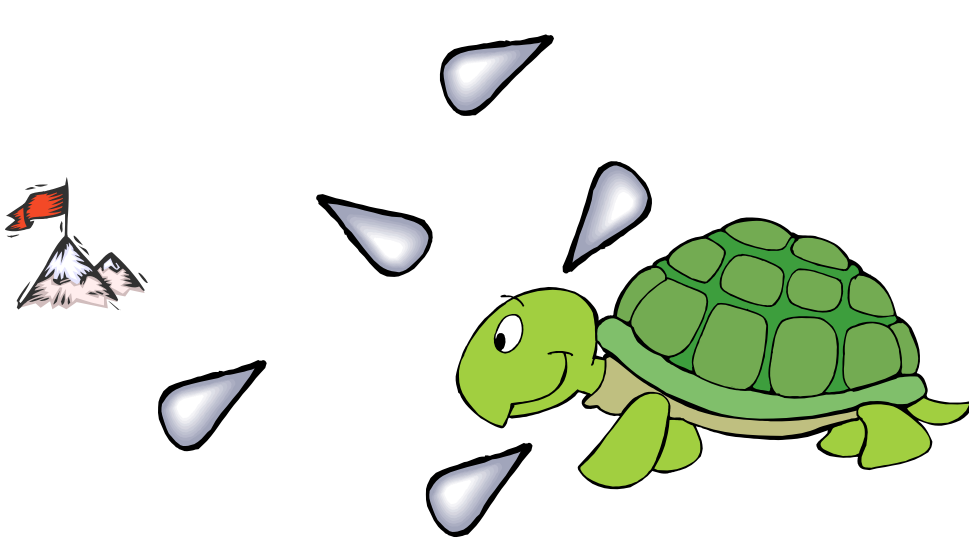
Good old lessons in *teamwork* from an age-old fable



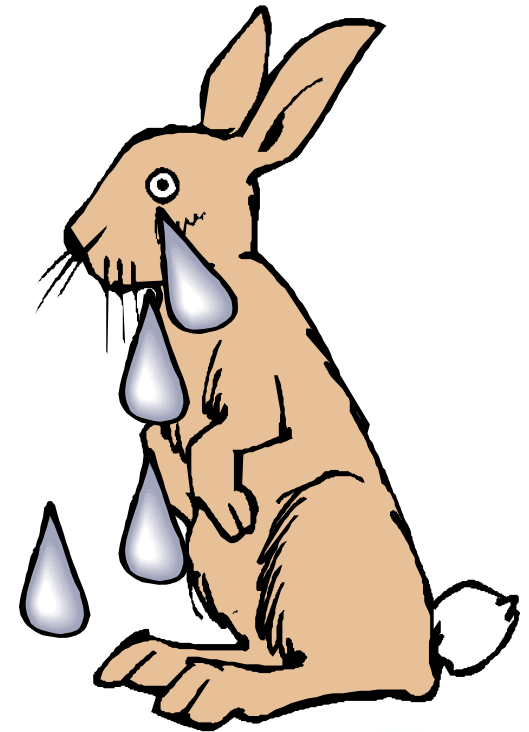
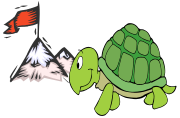
He sat under the tree and soon fell asleep.



The tortoise plodding on
overtook him and soon finished
the race, emerging as the
undisputed champ.



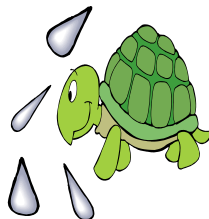
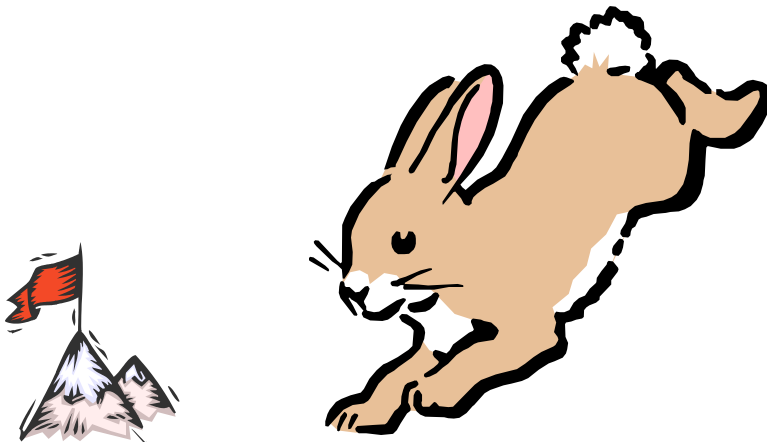
The hare woke up and realized that he'd lost the race.



The moral of the story is that *slow and steady wins the race.*

This is the version of the story that we've all grown up with.

This time, the hare went all out and ran without stopping from start to finish. He won by several miles.



The moral of the story?

- *Fast and consistent will always beat the slow and steady.* If you have two people in your organization, one slow, methodical and reliable, and the other fast and still reliable at what he does, the fast and reliable chap will consistently climb the organizational ladder faster than the slow, methodical chap.
- *It's good to be slow and steady; but it's better to be fast and reliable.*



But the story doesn't end here ...

The hare sat there wondering what to do. In the meantime the tortoise trundled along, got into the river, swam to the opposite bank, continued walking and finished the race.



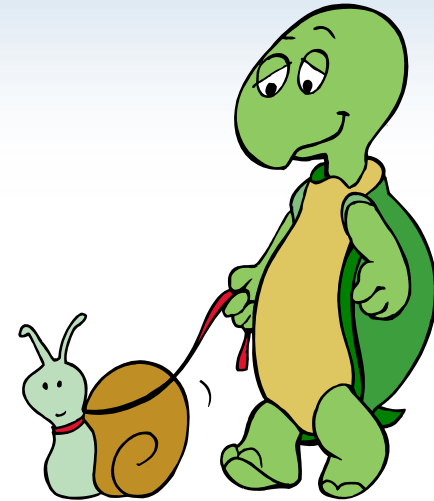
Moral of the story

- *First identify your core competency and then change the playing field to suit your core competency.*
- *Working to your strengths will not only get you noticed, but will also create opportunities for growth and advancement.*



The story still hasn't ended ...

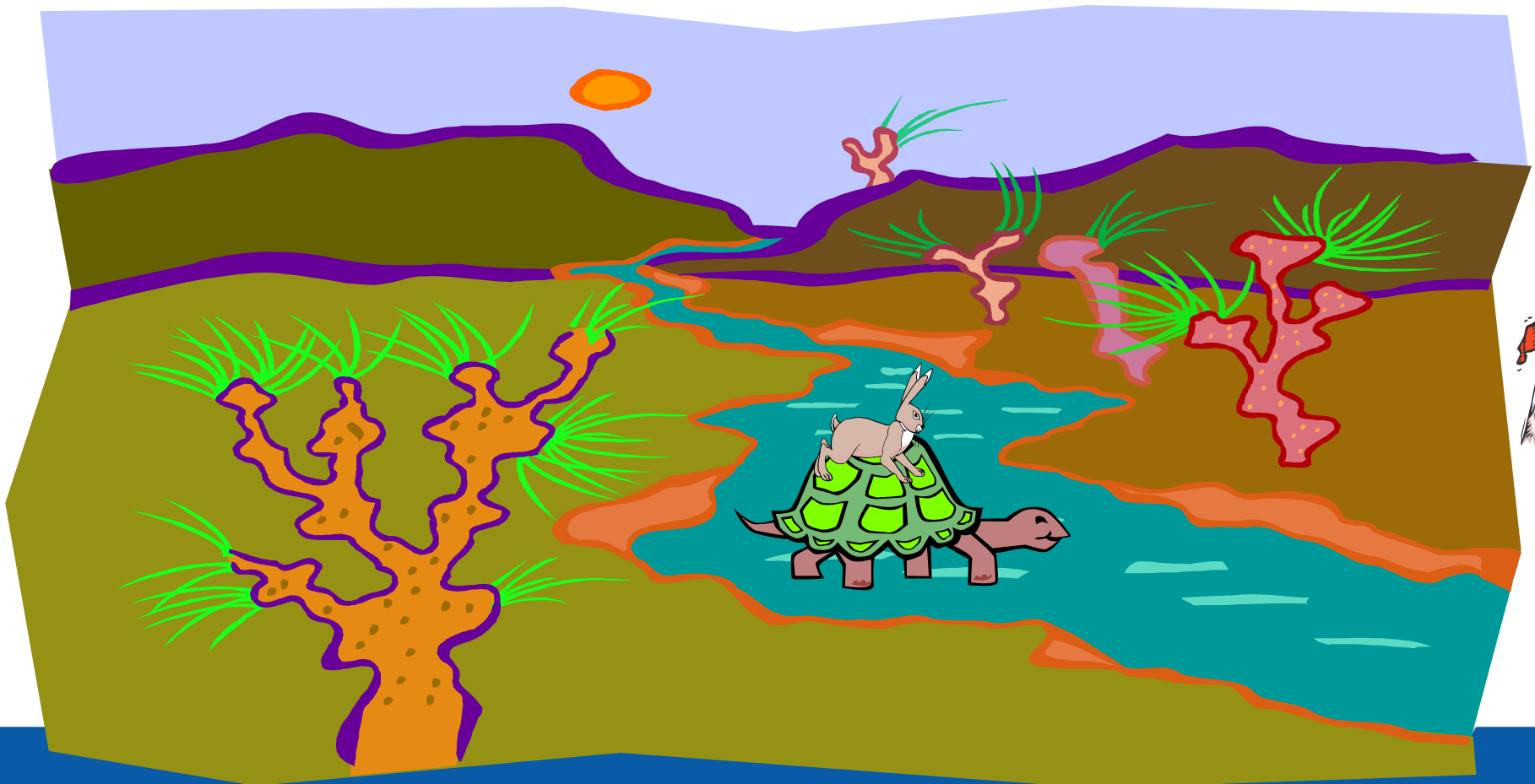
The hare and the tortoise, by this time, had become pretty good friends and they did some thinking together. Both realized that the last race could have been run much better.



They started off, and this time the hare carried the tortoise till the riverbank.



There, the tortoise took over
and swam across with the hare
on his back.



On the opposite bank, the hare again carried the tortoise and they reached the finishing line together. They both felt a greater sense of satisfaction than they'd felt earlier.





At the end of the day feel like this!

OUR BIGGEST RESPONSIBILITY



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THANK YOU!
vukshirsagar@gmail.com

