

WE CAN'T SPELL Q_UALITY WITHOUT...

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Why are U here?

- You perform work in a regulated industry where compliance with various regulations is necessary
- The work that you perform may be submitted to various regulatory authorities throughout the entire life cycle of a product
- Your work may be highly scrutinized by regulatory authorities and ultimately by the public
- Government agencies regulate for different reasons - first and foremost to protect public safety



Good Laboratory Practices (GLPs) and other regulations

Describing processes and conditions to ensure that studies and data reporting are conducted in a thorough and standardized manner accepted for various activities in multiple jurisdictions

International Organization for Standardization (ISO)

An independent, non-governmental organization bringing together requirements, specifications, guidelines or characteristics that can be used consistently to ensure that products, processes and services are safe, reliable and of good quality

Excellence through Stewardship (ETS)

A global not-for-profit organization promoting principles, guidance and resources for the responsible global management (handling, governance, oversight) of agricultural technology

How can “U” ensure quality?

- Generate data under scientifically sound conditions as outlined by internationally accepted guidelines, requirements, certifications
- Monitor each study for conformance with regulations and ensure the integrity throughout the entirety of the study
- Allow authorized regulatory inspections of facilities and all records required to be retained
- Retain/archive records for the life of the product to ensure retrievability and reconstructability

How can “U” ensure quality?

- Data generation and documentation evolves
 - Increasing use of electronic data capture, automation and use of remote technologies
 - Increasing study complexity with multiple sites involved
- Purpose remains the same
 - Having confidence in the quality and the integrity of the data generated
 - Being able to reconstruct activities

Atributable
Legible
Contemporaneous
Original
Accurate

What could go wrong?

2017 - Kobe Steel, a large supplier of steel parts to manufacturers of cars, planes and trains(including bullet trains that travel over 320 km/hr)

- Admitted to supplying products with falsified specifications to over 500 customers, throwing global supply chains into turmoil
- Data fraud had been going on nearly 50 years in the 112-year-old company
- Inappropriate actions were widespread, and were carried out with the knowledge and involvement of many, including management

“What you see is a pattern, a culture,” said Steven Bleistein, CEO of Tokyo-based consultancy Relansa. “Company culture is something that a leader creates, so the very least you have to do is to remove the leader and the people who were complicit, from the CEO downwards.”

But wait, there is more...

2015 – Volkswagen, an automaker founded in 1937

- Caught circumventing the emissions control system; in as many as 11 million vehicles worldwide
- Volkswagen models could meet the standards in a laboratory test, thanks to a sophisticated software algorithm that distinguishes testing from real-world driving
- German politicians say the emissions cheating scandal damaged the global reputation of the German car industry

Hiltrud Werner, VW's chief of integrity and legal affairs, said the company was working hard to transform its culture through a wide range of measures, including asking managers to be more pro-active about compliance issues.

But wait, there is more...

- 2010 – BP oil rig explosion in the Gulf of Mexico and the Environmental Protection Agency accuses oil giant of a '**lack of business integrity**' over its behavior following 2010 Gulf spill
- 1986, 2003 – Space shuttle explosion(s)
- 2017 – Nissan Motors announced a recall of more than a million vehicles after admitting that **staff without proper certification routinely carried out final vehicle inspections**
- 2017 – Takata, an airbag manufacturing company went bankrupt after its defective products were linked to 16 deaths and scores of injuries worldwide.

How did this happen?

“Failure is not a single, cataclysmic event. You don’t fail overnight. Instead, failure is simply a few errors in judgement, repeated every day.” - Jim Rohn



**“Maybe we can turn it around ...
I mean the chart, not the business.”**

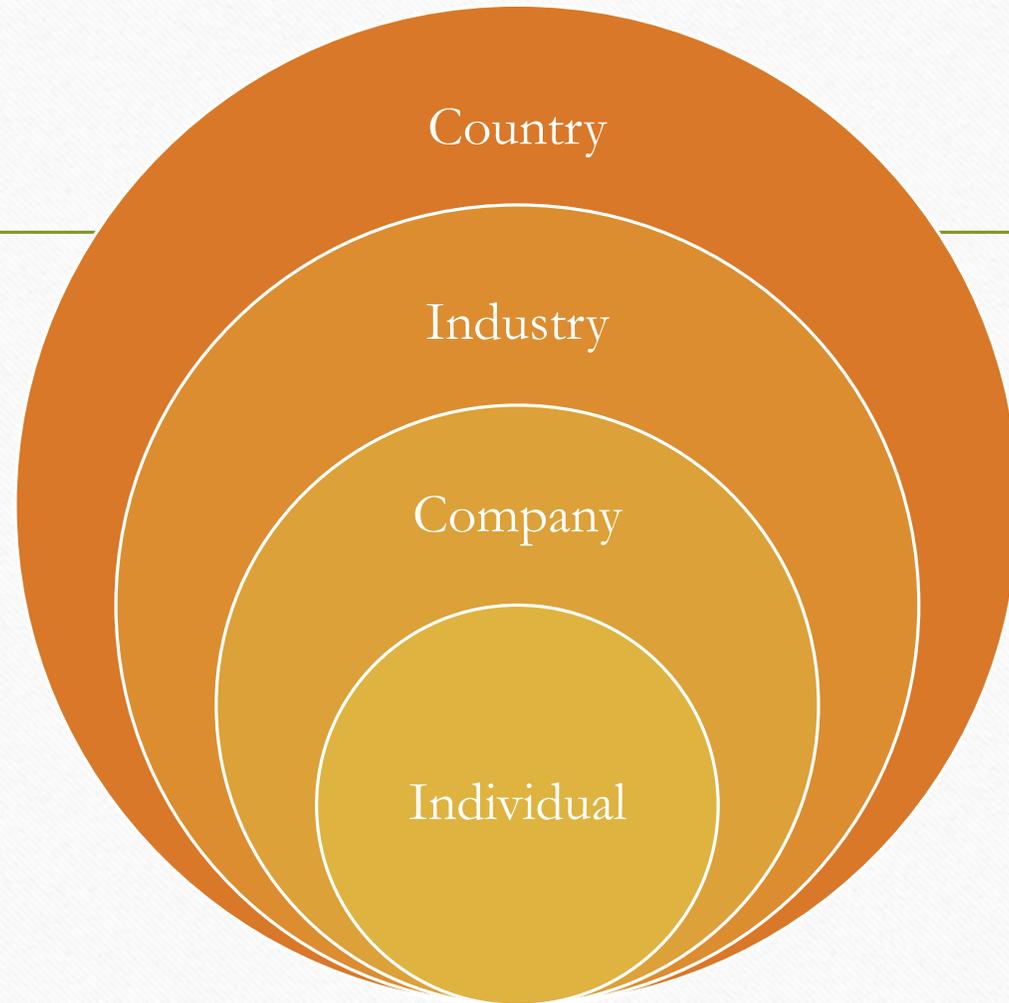
Where was QA?

It's an unfortunate truth in quality assurance and control (QA/QC) that the only time most people recognize the importance of the job is after something has gone horribly wrong. Like air traffic controllers and IT departments, quality professionals tend to garner the most attention when disaster strikes and everyone is looking for someone to blame. But some of the biggest engineering failures in history had nothing to do with QA/QC. If you're looking for examples, NASA has plenty.

- <https://www.engineering.com/AdvancedManufacturing/ArticleID/12550/3-Engineering-Failures-That-Had-Nothing-to-Do-with-Quality-Control.aspx>

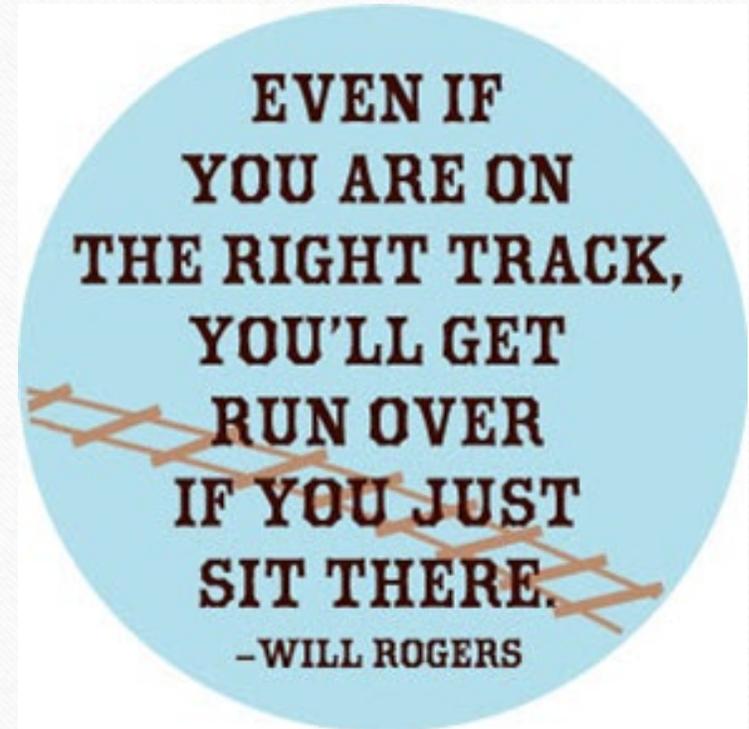
What are the costs of quality?

- Damaged reputation
 - Lost trust
 - Decline in sales
- Monetary
 - Stock price
 - Legal fees
 - Cleaning up the mess
- Loss of life



What else can U do?

- Continuously improve
- Know when to ask questions
- Check your moral compass
- Hold yourself accountable
- Partner for success



SQA Code of Ethics

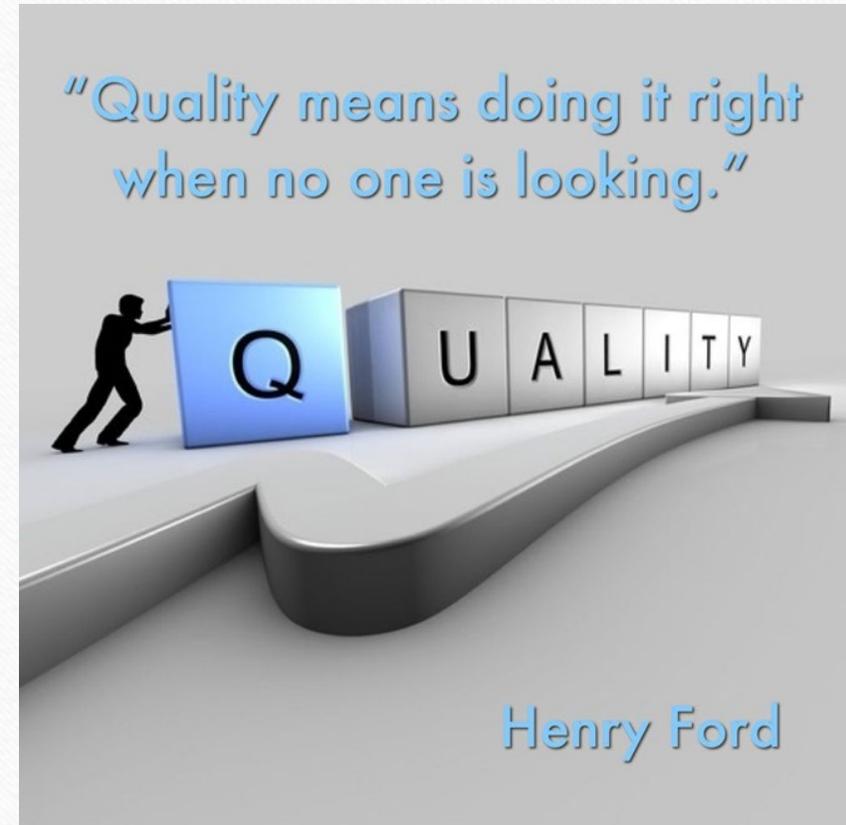
Adherence to ethical standards is a key criterion in earning and preserving the trust placed in the research quality assurance profession and is a requirement for membership in SQA and participation in its activities.

I, as a member of the Society of Quality Assurance, shall:

- Maintain a high level of personal integrity and professional competence;
- Act always in a manner that reflects creditably upon my profession;
- Maintain an objective attitude towards evaluation of facilities, studies or product integrity regardless of any internal or external influences;
- Protect confidential information;
- Report findings accurately and honestly and make recommendations impartially;
- Avoid situations where my professional judgment may be compromised;
- Understand, promote and implement the laws, regulations, guidelines and standards applicable to the field of quality assurance and specifically to my position; and
- Uphold this Code of Ethics in the conduct of my duties and in my professional associations.

Remember

- Failure to comply with regulations can result in loss of marketing permit, civil penalties or criminal prosecution
- As an industry we have to ensure our studies are adequate and well controlled and that our products are safe
- It is not “the responsibility of the <sponsor, study director, QA, fill in the blank>”
- Quality is everyone’s responsibility!



THANK



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SQA GLP Specialty Section – EPA Sub-Committee

NAICC Annual Meeting Planning – QA Education Sub-Committee