How do you create a data integrity culture?

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How do you maintain world-class standards?
How do you handle pressure?
What is the secret of sustained success?

In his 2015 book Legacy, James Kerr delivers 15 lessons which evidence why the New Zealand "All Blacks" are and remain to be, the most consistent and successful rugby union team of the last 100 years. Built around a value based culture, the All Blacks have won over 75% of all the international games they have played maintaining a high performance statistic throughout different generations and players. Whilst the personnel change, the resultant success remains the same on account of the culture that they have developed and within which the players operate.

What lessons can be gained from studying their value based culture and how can companies working in the drug development sector use their own values to create and inculcate a data integrity culture. Borrowing "The First Fifteen" template we will explore how the values of Tepnel Pharma Services are being used to deliver the desired outcome of Unconscious Competence and what it means to be a part of a team that is focussed on supporting drug development and improving patient outcomes from within a culture of data integrity.

Data Governance, Integrity and the regulations

The MHRA defines Data Governance as "The sum total of arrangements to ensure that data, irrespective of the format in which it is generated, is recorded, processed, retained and used to ensure a complete, consistent and accurate record throughout the data lifecycle".[1]

Data integrity is therefore fundamental to the maintenance of an effective Data Governance system, a key requirement of a pharmaceutical quality system which ensures that medicines are of the required quality for their intended use.[2]

The concept of data integrity is not a new one in fact for the past three years the topic of data integrity has been one of the top global issues reported by the pharmaceutical industry. As a consequence of this regulators including the MHRA have taken a significantly increased level of interest in data integrity and as a "hot topic" this increased focus on data integrity and governance systems has led to serious consequences for several companies.

As stated, data integrity is not a new requirement, as basic data integrity principles are already described in international good manufacturing practice guidance. Volume 4 of The rules governing medicinal products in the European Union contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively. More specifically, Chapter one, the Pharmaceutical Quality System sets out the foundations through which quality managementis assured throughout the lifecycle of drug development.

"Quality Management is a wide-ranging concept, which covers all matters, which individually or collectively influence the quality of a product. It is the sum total of the organised arrangements made with the objective of ensuring that medicinal products are of the quality required for their intended use. Quality Management therefore incorporates Good Manufacturing Practice."

From the guidance published by the MHRA in 2015, Data integrity is defined as being "The extent to which all data are complete, consistent and accurate throughout the data lifecycle".[1] However, knowing and understanding a definition does not a culture make!

Creating a Culture of Data Integrity

The implementation of a culture to achieve a desired outcome has to move beyond the recognised and traditional approaches towards total quality management. To create a culture whereby all the stakeholders are encouraged to unconsciously incorporate quality into their everyday activities, in essence to be sentient to their surroundings and their actions such that self-inspection is both continuous and inherent, requires a mind-set that is not just reflective of the regulations but which is instilled through values and an understanding that, as in the case of the All Blacks, "many of us are more capable than some of us but none of us is as capable as all of us".

A culture is embraced by everyone and in unison, is lived out by everyone, holding each other to account whilst encouraging each other to constantly strive for the next level of growth and development of the culture.

It has been proposed that to institute a quality culture four bounders have to be moved to facilitate everything else that follows on.[3]

Boulder	Measure
Leadership Emphasis	Quality is a leadership priority.
Message Credibility	Messages are delivered by respected sources, consistent and are easy to understand.
Peer Involvement	Strong network of peers for guidance who hold one another accountable.
Employee Ownership	Stakeholders clearly understand how quality fits with the desired outcomes and are comfortable raising concerns about quality violations and challenging directives that detract from quality.

Unarguably, any culture has to be exemplified by those who lead, senior stakeholders embracing and actively participating is quoted as being the most important factor in driving culture change. It is noted that where leadership has shown both an enthusiasm and commitment to quality through the embodiment of their company's values, that commitment and active participation has trickled down through the organisation and has led to everyone becoming involved and proactive in delivering the desired outcomes.

However leading from the top should not be confused with a constant pushing down from the top. This is in no way the answer and organisations have to be very careful to avoid adopting or being perceived to be adopting a classical command and control approach. Command and control as a vehicle for effective and lasting change is the single biggest leadership style which destroys virtually any chance of success in any transformational change effort. There is even a growing argument that command and control should be unreservedly be consigned to the realms of history, an archaic management structure which is not fit for purpose in any progressive or value centred organisation.

Effective change management, or adoption of a different way of doing things, innovating and seeking to make paradigm shifts in how we embed quality through self-regulation is the preserve of the stakeholders and the values around which those stakeholder coalesce and ardently seek to preserve. It is not a fluke that the All Blacks were, are and remain the most successful team in history. There is a recognition, already discussed which clearly demonstrates that "No one is bigger than the team, the team always comes first". Management may be the catalyst in starting things, they may be the purveyors of the message, embodied by their own commitment and performance, but it is ultimately the stakeholders who will collectively embrace and deliver the change which will deliver success and with it an assured level of data integrity throughout the lifecycle of their involvement.

If we transpose the All Blacks value based culture from sport into healthcare and onto our responsibilities as stakeholders involved in the development and manufacture of pharmaceuticals or treatment pathways, we have to start from a position of ensuring patient safety. To do this a data integrity culture that is built on and delivered through the values that we embrace as stakeholders/scientists has to consistently and continuously create transparent, reproducible and timely recorded data, results and findings. The emphasis of the data integrity culture is in the proposition that it is a company's values, borne out through its stakeholders that ultimately serves in embracing and creating a data integrity culture.

Where the all Blacks have their "First XV, 15 All Black Principles" every organisation should be able, through and from their own quoted values, develop their own manifesto which clearly communicates to the stakeholders what the expectations are, the manner in which they are to deliver on these expectations and ultimately the culture within which data integrity and patient safety will be preserved throughout the lifecycle of whatever aspect of drug development they are involved in.

Together we are Better

The four boulders are only the framework within which a culture can be developed, embraced and lived out. If we are to truly create and maintain a data integrity culture then we need for our values to be the elements that hold the framework together. The All Blacks are successful because they have used their values to create a culture, whereby everyone knows where they stand, the expectations placed upon them and what it means to be an All Black. All Blacks are selected on these values over their talent. The principles tell us that some of the most talented players will never pull on the black jersey because they don't have the right character.

In our data integrity culture there is no such selection challenge but there is the exact same expectation that once you are a part of the culture, you will show it in every aspect of whatever it is that you are doing.

1. Knowledge
Never be afraid to ask.

The cumulative years of experience means that somewhere there should be someone who can help, assist or advise. No one person can know everything and nobody should be seeking to keep what they know to themselves. Everyone's door is always open.

2. Continuity
The same yesterday, today and tomorrow.

We have a quality system which provides a consistent framework within which to operate. It embraces innovation and continuous improvement but never loses sight of the central tenant of Patient Safety.

3. Processes
Step by step, delivering the desired outcome.

Document what we do and doing what we have documented. Our procedures and our methods are the only way in which we do things and our records are our proof that we have done what we said. If it isn't written down, we can't prove we did it.

4. Expertise
Leaders are teachers.

Creating a learning environment. Every day is about learning something new or helping someone else to learn something new. Growing and developing ourselves and our colleagues, sharing what we have and adding to it.

5. Stakeholders
What is in it for We?

The team works together for the collective benefit of each other knowing that when we are successful, we are successful together. We see the bigger picture and how we contribute to it.

6. Eliminating waste
Creating value.

We listen, respond and adapt to the needs of our stakeholders. Always seeking to add value and sharing that value with all our stakeholders.

7. Science
Supporting drug development, improving patient outcomes.

Science is at the heart of what we do, seeking to create better healthcare tomorrow using the knowledge and wisdom we have today.

8. Commitment
Doing what we say.

Our word is our bond, it is our contract with other stakeholders that makes us accountable to each other. We do what we say and we ensure that what we have done is transparent, traceable and re-constructible.

9. Courage
Ask why?

It is the purpose of our organisation to improve patient outcomes. If we constantly ask ourselves why, then we constantly bring ourselves back to understanding how out culture of data integrity is essential.

10. Trust
Keeping things safe.

Every time a stakeholder uses the output of our services they don't want or should be required to consider is this safe. Our processes ensure that we capture all the data required and we subconsciously self-inspect our work to validate that the capture is accurate.

11. Freedom to Operate
Encouraged to challenge.

All stakeholders operate within the system, respecting its boundaries and without infringing those boundaries but we have to constantly be challenging ourselves and others to ensure that what we do is for the benefit of our stakeholders.

12. Honesty
Keep it real.

Transparent reporting and interpretation of results or data are key in maintaining data integrity. The data integrity culture asks that everyone who works or contributes within it has the right character and is true unto themselves maintaining a high level of personal performance.

13. Quality
Aim for the highest.

The quality system brings with it a set of expectations whereby there is no such thing as just enough quality instead there can never be enough quality. In the team the quality of anyone's contribution should be no less than the quality of everyone else's.

14. Ethics
Separating right from wrong.

All stakeholders are expected to know that there is no right and wrong but only right. What we do defines us as an organisation and as individuals.

15. Integrity
Constantly doing the right thing.

It is incumbent on the team to always do the right thing and to support one another in doing the right thing. By building a network of right mindedness stakeholders are accountable to everyone including themselves.

16. Teamwork
Together we are better.

It's all about sharing knowledge, ideas and skills. Through our people and through our principles we are constantly seeking to be progressive in how we work. The best partners have a different mind-set.Providing healthcare in the 21st century requires a different approach to how we ensure that our medicines are only about improving patient outcomes. Through integration of our core principles into the everyday expression and execution of our activities we believe that independent self-inspection should become a thing of the past as our self-inspection is both contiguous, continual and consistent assuring a state of unconscious competence.

References

1. MHRA GMP Data Integrity Definitions and Guidance for Industry March 2015.
2. Good Manufacturing Practice (GMP) data integrity: a new look at an old topic, part 1, David Churchward, MHRA, 2015.
3. Harvard Business Review, Creating a Culture of Quality, by Ashwin Srinivasan and Bryan Kurey, From the April 2014 Issue Harvard Business Review.

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