

Deming, Finally!

Pharma Industry Has Misunderstood Deming for 30 Years but Can Catch Up



Photo credit The Deming Institute

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Thirty years ago, [Edward Deming](#) was recognized by the National Medal of Technology & Innovation by the President of the United States, marking the official recognition in America of his groundbreaking work initiated decades earlier in Japan. Today, everyone in the manufacturing quality world has read, heard, spoken about Deming. His vision for

quality and “[14 points of management](#)” as well as the “[System of Profound Knowledge](#)” in particular are inescapable reference points.

However, Pharma may have got this all wrong for the last 30 years. By focusing on processes, control and exhortations, manufacturers have missed the essence of Deming’s message.

Deming advised us to actually put the Human at the center of quality and to focus on how the system works. This is what Sanofi Pasteur has been doing systematically for the last two years, through corporate activism and a very structured approach to culture (mutual trust, empowerment), competencies (knowledge), and compliance. An in-house

global social movement for change and quality, and a resolute investment in education have allowed the company to achieve unprecedented quality gains – out paying the investment by far. In the light of this experience, the authors review Deming’s 14 points and highlight what the pharmaceutical industry has missed until today.

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“The father of modern quality” is what many say about W Edwards Deming. His thoughts and theory have been taken into use worldwide. He has brought a lot of structure to how we see quality, do our work and reduce variation in manufacturing operations. But it seems that there is one side of Deming’s work that at least the pharmaceutical industry has not fully tapped into: the human element – or the ‘psychology of change’ as Deming calls it in his book [‘The New Economics’](#). In particular, we may have overlooked the role of leadership.

Pharmaceutical companies have a tendency to go through cycles of ‘good’ and ‘bad’ Good Manufacturing Practice (GMP) compliance. Going bad can lead to Warning Letters or even adversely affect patients. The inflection point often comes with a change of leadership philosophy. Currently, as a pharmaceutical industry we talk about the link between quality metrics, quality culture, and quality performance as exemplified with [FDA’s draft guidance on quality metrics](#). However, in all of this the human element and the role of leadership seem to have been almost forgotten. Or maybe more correctly – we talk about it, but in action **as senior leaders we are often the last to see the need for change, including our own change needed**. We most often talk about what others (‘they’) should change.

Almost three decades ago, Deming described the role of leadership to achieve sustainable

quality performance in his ‘System of Profound Knowledge’ (in his book ‘The New Economics’, 1992), which follows the seminal ‘14 points of management’ (described in [‘Out of the Crisis’](#), 1986). Our assumption is that most who read this post have already read these theories and believe they have implemented much of the teachings.

However, after having started a real cultural change with tangible results built on [corporate activism](#), [John Kotter’s 8 accelerators](#), [Myron Rogers’ Maxims](#), significant investments in education using modern learning techniques, and our own experience we went back to Deming’s teachings and read them from a new angle – with the human element in focus. What intrigued – and excited – us is that we found a massive potential for ways in which the pharmaceutical industry could further improve how we work and perform. We may implement a fraction only of what Deming advised us to do a quarter of a century ago.

This post is about how Deming’s 14 points, and his [System of Profound Knowledge](#), can help achieve a sustainable quality performance, and change the culture of your company – provided you apply his teachings fully. We invite you to join us on our journey and learnings. Below, we will first state each of Deming’s 14 points, then our interpretation and experience. Everything we write here are our own views and interpretation of Deming’s theories.

1. “Create constancy of purpose toward improvement of product and service, with the aim to become competitive and to stay in business, and to provide jobs”

How it's been misunderstood: 'purpose' has morphed into soulless, top-down 'mission/vision' statements

What it really means: engage employees to co-create a purpose that connects everyone in the organization to the identity and true mission of the company

In the 21st Century, the company you work for is becoming less important than the cause it serves. On a continuum from 'company most important' to 'cause most important' often the older generation (those who also in general have the senior most positions) are the ones weighing 'company' over 'cause', while the opposite is true for the younger generation entering the job market. Purpose in the job is becoming more and more important for employees. Increasingly, employees want to find meaning in what the company does, connect with its purpose. Dan Pontefract describes this in his book ['The Purpose Effect'](#), John Kotter speaks about the need for establishing a 'Big Opportunity' (as the basis for need for change) in several of his books including ['Accelerate'](#), and [Myron Rogers](#) talks about the importance of moving from 'role to whole' – each employee identifying themselves to more than their own role, to a larger community of action and purpose.

Many companies believe they address this need for purpose by rolling out corporate mission and vision statements – often shaped by communications professionals and elaborated behind the boardroom doors – cascaded out in the organization with very little impact on behaviors, and thus even less on quality. Interchangeable, soulless, the corporate mission

& vision statements are far from the shared purpose (“the aim”) that Deming had in mind.

In our work, we have seen that without purpose you can't engage people individually or collectively over the longer run. **A purpose can't be rolled out to people.** And your purpose might be somewhat different from other employee's purpose. In October 2014, we gathered about forty people from different sites and various levels in the organization, to **co-create** our purpose, our Big Opportunity. Many wondered why we spent time on this, since the company already had a “mission and vision” statement – and a great one. It is because when you find ways to develop collectively a shared purpose that people connect to individually, the possibilities are endless and the company becomes much more competitive through the results created at all levels. Our success is very much linked to the significant time we spent on co-creating a shared purpose, and on letting conversations happen around it. Peer-to-peer conversations made people relate authentically to it, and helped build energy for change. Spending time on purpose before focusing on issues and solutions is time well spent. Without including the employees in the process, your mission and vision remains a sequence of words on glossy paper and plaques stuck on walls in the C-suite.

2. “...management must awaken to the challenge, must learn their responsibilities, and take on leadership for change”

*How it's been misunderstood: Leadership has been reduced to management. The burden of processes and control stifles leaders' capabilities to lead change. “Change management” is done for **the others** to change.*

What it really means: Replace control by trust. Grow network leadership. Invite leaders to change themselves and operate as co-facilitators for systemic improvement.

Try to think back to 1978. How the world worked technology wise. That's almost 40 years ago. It was the year where the US GMPs went into effect – and they haven't changed significantly since while the rest of the world and the workforce certainly have. As leaders our work styles must cater and adapt to every generation, every person in the workplace.

Unfortunately, those who are the last to see the need for change and actually change themselves are senior leaders. There are probably a number of reasons for this.

Machiavelli wrote in 'The Prince' almost 500 years ago (1536): *“It ought to be remembered that there is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things. Because the innovator has for enemies all those who have done well under the old conditions, and lukewarm defenders in those who may do well under the new. This coolness arises partly from fear of the opponents, who have the laws on their side, and partly from the incredulity of men, who do not readily believe in new things until they have had a long experience of them.”*

And haven't we all experienced what Machiavelli writes; organizations change all the time. Many times it seems like senior leaders think that by creating a new governance structure or a new organization problems will be solved. But are we as senior leaders ready to change what really needs to change to make the whole organization and the system improve sustainably? We believe not. When you think about it the real work in a manufacturing

company takes place at the shop floor, but all these organizational changes are usually taking place at the top levels only, and not by changing how the top leaders work to improve the system.

Our role as leaders has changed. Leadership focused on being at the top of a hierarchical pyramid is outdated no matter whether or not we are willing to accept it. 21st Century leaders *“...have a way of building community and bringing people together to co-create solutions...They don't talk about how their organization is structured, they focus on bringing their shared purpose to the world through their communities”* (Ayelet Baron, author of [‘Our Journey Towards Corporate Sanity’](#))

In our work at Sanofi Pasteur, we ask ourselves the question *“What will I do differently today to save more lives tomorrow?”* More often than not, discussions about change start with what *others* should change. Or people try to make change happen by using the same old recipes (project management... change initiatives... communication campaigns...) – but as [Myron Rogers](#) writes: *“the process to get to the future is the future you get”*. **Change is not an externality you add to a task; it is by doing this task differently, that you create change.** Replacing control by trust is a big change that impacts how you operate as a leader but also how you see yourself as a leader. It entails giving up what has made you successful until now, taking risks, adopting new habits.

For change to be successful, we need to move away from our employees doing things only

because they 'have to' and instead provide the conditions to bring change because people individually 'want to'. Volunteerism is the new way of bringing about change in the work place. This is well described by John Kotter and is a cornerstone in his work with the '[dual operating system](#)' ('[Accelerate](#)'). On the one side sits the traditional management structure which is robust and reliable, good at managing 'complicatedness', but heavy and slow. On the other side, almost operating like multiple

internal startups, volunteer networks and communities of practice bring speed and agility, engagement and adoption. How close these two operating systems work together is critically important to the success of the overall system and – for our work – has been the absolute key part of the culture change. For it to work, every single leader in our organization has had to change habits and really ask themselves: "What will I do differently today to save more people's life tomorrow?"

3. "Cease dependence on inspection to achieve quality.

Eliminate the need for inspection on a mass basis by building quality into the product in the first place"

[How it's been misunderstood: Release testing of the final product is still the norm](#)

[What it really means: Quality by Design everywhere – built-in quality, effective Knowledge Management](#)

This may be one of the 14 points where we as an industry have done best. We have started work on Quality by Design, we validate processes, use LEAN, 6 Sigma, Process Analytical Technology etc. However, we still perform release testing ('inspection') of all batches produced. In the vaccine industry, which we work in, additional testing is done by health authorities. This creates huge redundancy of work and creates bottlenecks that slow down or even limit the availability of vaccines. Several authorities and manufacturers have started to brainstorm together about how to evolve towards limiting release testing, or even making it unnecessary, as quality would be built in to the manufacturing processes. This is a very promising path. For this to happen, we must really improve in how we manage knowledge and be able to implement innovative technologies timely, without the need for heavy regulatory oversight.

Knowledge Management is one of the two enablers described in ICH Q10 (Pharmaceutical Quality System, PQS). We all know that it only takes one person's mistake to cause the rejection of a batch of drug product. Deming talks about the importance of engaging the

ENTIRE organization in Quality assurance activities. To do so each employee must feel that they own the processes, which is actually possible to obtain if you are willing to trust the employees to be able to co-create.

As an industry, we are notoriously lagging behind in the pace with which we implement innovative new technologies. One of the reasons is that the regulatory approval processes for any change after the initial product approval is extremely cumbersome and very lengthy (up to 5 years per change) bordering impossible. How would it look like if Apple had to wait for every single country's approval for changes to the iPhone or a new version – and wait up to 5 years for such approvals? Yes, innovation would be killed. The solution here includes establishing more trust both in the company's Pharmaceutical Quality System and between countries regulatory agencies so that each actor accepts to depend more on each other's assessments.

A knowledgeable workforce and an effective Pharmaceutical Quality System are keys to getting closer to Deming's 3rd Point of Management.

4. ***“Minimize total cost. Move toward a single supplier for any one item, on a long-term relationship of loyalty and trust”***

How it's been misunderstood: an organization-centric focus, transactional relationships with suppliers and other partners. Self-interest and cost prevails over overall value

What would Deming do now: Partner with suppliers and other external stakeholders. Connect to co-create quality products or services for the benefit of all

Although we believe that always going for single suppliers might be somehow risky, it is important to appreciate that working with suppliers should be a partnership and not a traditional customer/supplier relationship where the company's procurement organization only thinks about short term lowest cost of goods. Both parties should be successful.

Supply chains keep getting more and more complex. Being able to trust each other as producer and supplier is an important element in achieving a sustainable supply of high quality and reasonable cost. How companies do business is less so the company's own business, with employees working for a cause (that is larger than just the company's output) and with the widespread use of social media (that connects beyond traditional boundaries). All companies have a corporate social responsibility and must act as a responsible partner in the larger health care ecosystem.

In our case one of the things we are actively engaging in is how we can do our part in enhancing innovation and availability of

vaccines worldwide (reducing shortages) and at the same time ask other stakeholders to do their part. We do that in a co-creation mode with the ambitious objective of improving public health globally.

Social and digital technologies make it possible to connect and engage at scale – not just for awareness, but in the objective of creating solutions together. What may sound like a challenge in a highly regulated industry is actually possible when organizations shift from being self-centered to addressing healthcare in a holistic perspective. An example of a [shared value approach](#) is exemplified in the [Break Dengue Alliance](#) which Sanofi Pasteur contributes to. Besides manufacturing safe and efficacious vaccines against dengue, we actively contribute to an **engaged and efficacious ecosystem** that combines the strengths of technology, people, vaccines and any other useful element. An organization-centric approach wouldn't have allowed this initiative; a connection mindset for the greater good does.

5. ***“Improve constantly (...) quality and productivity, and thus constantly decrease costs”***

How it's been misunderstood: Cost reduction and budget targets have become the focus, rather than long term value creation. Continual improvement and operational excellence are now ritualized exercises with little consideration of the human factor and long term quality

What it really means: Put things back in the right order: focus on quality first and cost reduction will come as a consequence. Put the employees everywhere, not just in Finance or Industrial Performance depts., back in charge of operational excellence programs

Amidst growing competitive challenges and overall pressure on the cost of medicines, the pharma industry has been keen on cutting costs, reducing headcount, integrating business units to generate economies of scale. Purchasing departments everywhere are incentivized on finding the best low cost deals, and quality isn't always considered with the right level of attention. We have numerous (too many to count) examples where focus on costs has resulted in an overall reduction in value. In one case the Purchasing department saved 2 million \$ upstream for some raw materials, only to cause a loss of 6 million \$ worth of product downstream.

Deming described already in the 1970's that 'quality' equals 'results of work efforts' divided by 'total costs'. When people focus on quality total cost will decrease over time. However, when you focus on costs, costs tend to rise and quality to decline over time. It is interesting to see that **a lot of the LEAN and general Operational Excellence activities are focused on cost reduction, and that as a consequence quality declines over time.** This can be in the form of regulatory actions (Warning Letters always cost in the order of hundreds of millions of \$), or simply too high write-offs.

Prevention is cheaper than correction. However, because investing in improved quality is a budget topic, whereas failure is a cost on the P&L, companies often accept the cost rather than increasing budget with improvement

activities. There are many examples where a company doesn't invest 1 million \$ to reduce a risk, but is ready to spend 10 million \$ to fix the issue once it has occurred.

Part of our work as Quality leaders consists in quantifying the financial gains of quality improvement. Quality needs to speak the language of the CFO: *"It's now time to shift the dialog from a cost-based conversation to a value-based conversation"* ([Magnani & Vinther, PDA](#))

While leadership generally is focused on finances this is not as much the case for employees, where a much more appealing currency is simplification achieved, saved doses of medicine, etc. Changing the currency has for us resulted in amazing results achieved by our employees at all levels, feeling a much stronger ownership for products and processes – and it has drastically improved overall quality performance in terms of timeliness, reduced deviations, and improved financial performance as well.

When we focus on our employees co-creating solutions, being inclusive, use massive volunteerism and truly empower decision making further out in the organization we see results that are amazing – even beyond what we as leaders thought possible. Continual improvement doesn't only start from the top. Everyone wants to and can help to continually improve and simplify processes.

6. "Institute training on the job"

How it's been misunderstood: The "school" model, where students sit in class and absorb knowledge delivered by a teacher, prevails. Slide decks or their modern version (e-learning) are unidirectional and disconnected from the actual work environment

What it really means: Peer-to-peer learning with subject matter experts, peer coaching, lessons learnt, "manager on the shop floor" programs, adult education methods... "allow people to succeed when given the opportunity to use their brains to continual improve"

The better educated the workforce, the less errors made, and the better overall performance will be achieved. Companies

know this well, but rarely is enough time allocated to the on-the-job training activities. This is where employees increase their

knowledge about processes, equipment and where competencies are built. With a focus on cost containment and sometimes little knowledge of modern, adult education methods, companies default to the easiest – and less effective – ways of educating their employees: classroom courses, one-size-fits-all e-learning, etc.

But, the best way to learn job functions is not to have new employees sit and read Standard Operating Processes (SOPs), or to receive one way PowerPoint slide presentations, but to be involved and learn on the job itself. *“Tell me and I forget. Teach me and I remember. Involve me and I learn”* as Benjamin Franklin said. Coaching, peer-to-peer training, learning on the job from actual mistakes done in the past is way more effective.

So how good are we at that? The answer will differ from company to company and likely from

department to department. Asking people who have started recently directly how they feel they have been trained and master the job functions will give you a very good indication of the quality of the training.

In our case we started a massive education and on-the-job training program to boost competencies broadly and in-depth on technical and quality topics. We use modern learning methods and include effectiveness checks. We have become better at correlating training activities to actual performance improvement. In our experience we have seen very good results of increased shop floor coaching with a focus on the ‘why’ rather than just the what. We realized that the shop floor managers did not spend enough time on the shop floor, and instead spent their time in meetings. That has changed now, and performance has improved.

7. “Institute leadership. The aim of supervision should be to help people (...) do a better job”

How it’s been misunderstood: Leadership has been reduced to management (‘business administration’), with a focus on controlling employees instead of trusting them

What it really means: Trust people more, help them do their job better, connect them with the network. Remove unnecessary control and bureaucracy

This point resonates with our experience of balancing control with trust. Pharmaceutical manufacturing and testing of products is fundamentally and historically based on control because we must document complying with the Good Manufacturing Practices (GMPs). The GMPs were developed in response to events that caused drug products to be unsafe, ineffective or of inadequate quality. Hence, controls are needed. Controls are part of the GMPs, but how they are applied can be done in a way of inclusion and co-creation. [Standard operating] procedures should be written by the people who actually do the work through co-creation, rather than having them being written solely by supervisors in their offices.

Traditional leadership is also to a large extent

based on control. How many of you still have to ask for permission to do your work, permission to suggest and implement improvements, permission to travel within your budget, etc. Hierarchy-based control is such an integral part of traditional leadership, that even if you do want to move from control to trust it may be hard at first.

The interesting thing however is that overall performance is so much better when you show trust in people. Full control is an illusion in a complex system. Granted, control can be helpful and fix a problem short term, but longer term it becomes a roadblock preventing its own objectives. *“The opposite of control is not chaos; it is trust”* ([Holger Rathgeber](#)). Trust and freedom bring out the best in people. A good way to look at the two metaphorically is that control can be seen as a closed box, where you

will never get more than you plan for, and people will deliver to a predetermined objective at best. Trust opens the lid of the box: you get more and better performance of each person individually and collectively and most likely objectives will be surpassed.

So why is it that we run our companies, and to a large extent our society, with controls? It stems from historic reasons that are so ingrained in how we behave and organize ourselves. Leaders in many cases feel that because they are leaders they must be able to come up with the best or right solutions. Controls also are in place because individuals/companies misused the trust to be 'non-compliant', and by controlling everyone 'non-compliance' should be less likely. However in a culture of trust, everyone knows that trust grows like a coconut tree (slowly), and it drops like a coconut when misused (fast and... it hurts!). So few or no one will misuse the trust. An interesting recent example happened at a

performance discussion when the person said: "*I love my work. I work really hard as I don't want to disappoint you because of the trust you have in me.*" We asked her how that had been before and she said that she always felt controlled, and therefore she didn't feel the interest to achieve outside pre-determined goals.

The change from control to trust based leadership is not easy for many leaders, and it is important to help them in practicing trust. This can be with little things first, then gradually expanded until it simply becomes the way of working.

Control-based leadership often leads to win-lose situations rather than win-win, and it often results in competition in the workplace instead of collaboration. The Management vs Leadership topic is a discussion of its own, and we will limit that to simply stating that true leadership can never be achieved in a control culture but only in a culture of trust.

8. "Drive out fear, so that everyone may work effectively for the company"

How it's been misunderstood: Assertiveness mistaken for leadership, controlling cultures with blame from leaders and finger pointing from peers; conservative talent management perpetuates blame culture and fear.

What it really means: Solutions can come from anywhere, but only if people feel they are respected and it's accepted to fail. Human errors are opportunities to learn.

A couple of years ago, we were facing a complicated issue that was difficult to resolve. It was having dire consequences on supply. At some point, two employees went to the function leader to share a solution they had thought of. They were yelled at for not coming sooner. What do you think would happen if there was a new problem? These people wouldn't dare bringing up their idea – or wouldn't even bother thinking about solutions.

"Ingrained quality", "Transparency", and "Speak up culture" are all words that should characterize an organization that has driven out fear. However, driving out fear completely

requires that it is acceptable to fail, where trust is prevailing, and internal competition is eliminated. Although we can all agree that driving out fear helps improve performance are we all truly in our actions showing the right behavior?

In our experience the answer to the question "do we have a 'speak-up' culture?" is answered differently by leaders and employees. Often, leaders are surprised when faced with feedback that they blame their employees instead of driving out fear. In the pharmaceutical industry we often talk about 'human errors' (which in actually in most cases have other true causes).

Do you speak about these ‘human errors’ as learning experiences? We suggest calling them this way, as they are always relevant and they are a great way to improve processes and enhance knowledge amongst the employees. However, we very often see finger pointing and blame when something goes wrong. Are people rewarded and recognized for improvement suggestions?

In a culture where people can’t or don’t speak up freely and share good and bad results people will tend to hide things when they go wrong. Solutions can come from anywhere, but only

when employees feel safe.

Our work has put a lot of emphasis on reducing the “power barriers” that prevent people from speaking up, but also on creating a strong community of purpose-driven activists. It acts as a support group for those who wouldn’t dare speaking up if they felt isolated. In this movement, people identify themselves as change agents. To publicly recognize their contribution and achievements – on internal social media for example – empowers them and invites more people to challenge the status quo. We encourage leaders to seek feedback from people with no ‘vested interest’.

9. ***“Break down barriers between departments. People in research, design, sales, and production must work as a team”***

How it’s been misunderstood: Silos – both vertical and horizontal – are still very strong. Connections are “organized” through designated connection persons / events based on organization or where people work physically, creating filters, bottlenecks and sub-optimization.

What it really means: Expand people’s identity beyond their role or geography. Connect the system to more of itself. Leverage internal social media and cross-layer teams. Anyone can be a connector, if they want to and are encouraged.

It is amazing to see how much people in general work in silos based on the physical location of their workplace, the manufacturing site they work for, the language they speak or their position in the organizational hierarchy. Rather than speaking directly with peers working in similar positions much communication goes up and down the organizational ladder. Barriers results in sub-optimization rather than what is overall best for the company. We have heard FDA inspectors (US Federal Drug Administration) coming in to different manufacturing Sites of the same company feeling that they were visiting separate companies.

One way of breaking down barriers in a GMP regulated company is to have the same

Pharmaceutical Quality System (PQS) apply everywhere. However, what really matters is that we as leaders foster an environment of relationship building and information sharing within the company. It is much better when information sharing doesn’t have to involve us/leaders but can happen freely between employees whichever way works for them in their job. Collaboration is key for success at all levels.

We have two recent examples of how we have been able to break down silos/barriers between departments, Sites and organizational levels.

The first example is building-to-building visits (‘meet your neighbor’) arranged by volunteers. Everyone involved have been very excited about this activity, and to our surprise we heard

several times that people working in one building for more than 10 years never really knew what was going on in the other buildings at the Site.

The other example is the [use of internal social media](#). The network we use, Yammer, is a great software platform for informal sharing of information. We have people connecting with each other all over the world in our company with no supervisory control and at all levels. The software has also been a way to break down language barriers as you can simply pick a translate option and immediately you are connected with people around the world. People are connected across continents, Sites, hierarchies and language. Instead of solving problems within the silo you belong to, you have the whole company to speak with. By making ideas and achievements public, the Yammer group makes it possible for anyone to pick up an idea and implement it. Sharing and adapting each other's wins has multiplied very significantly. Our [social media story](#) can be

found on Microsoft's website.

As leaders we should think about whether we are building bridges or walls in how we operate. We must accept that in many cases we are the roadblock or bottleneck preventing success. Solutions can come from anywhere. [Myron Rogers](#) talks about how we change the way we want to work when he says "Start anywhere but follow it everywhere" and that we need to "Keep connecting the system to more of itself".

[Corporate activism](#) uses the tools and techniques of social movements, for corporate and social performance. And that is exactly what we do in changing the way we work and breaking down barriers. Movements are driven by a cause, fueled by people's passion and sense of purpose. They mobilize and connect energies against inertia. Digital enables massive, rapid connections, and we have seen that we as an organization have become more creative and more agile. Deming would probably be a corporate activist if he lived today!

10. "Eliminate slogans, exhortations, and targets for the work force asking for zero defects and new levels of productivity. Eliminate work standards (quotas) on the factory floor. Substitute leadership. Eliminate management by objective. Eliminate management by numbers, numerical goals. Substitute leadership"

How it's been misunderstood: Management by objective is stronger than ever. Quality is very much a Red/Green world: red indicators trigger exhortations to turn them to green. Belief that quality culture can be turned into an equation.

What it really means: Move from 'Have to' to 'Want To' so that quality result from people's will, not submission. Stop with slogans, exhortations and targets. Understand that humans can never be put into equations.

In our view the human element has been taken out of much of the Operational Excellence activities in the Pharmaceutical industry, and we have left it to

experts and management consultants to run our business focused on cost reductions, rather than our leaders leading the work focusing on quality. We seem to believe that operational

performance can be achieved through some sort of equation and measured in a few quality metrics. It couldn't be more wrong. The red/green metrics have become a mere race to get to green without the underlying focus on continually improving the system.

Variation should be **reduced** for equipment, systems, and processes to ensure consistent output batch after batch. However we can't apply the same approach to our employees. They are humans, not machines. Instead, variation of individuals should be **leveraged** to continuously co-create and improve quality. When people are involved in findings solutions and are not feeling 'standardized' that is when quality will improve.

Obviously, it would be neat if quality

performance was an output of a simple equation, and even if quality culture could be achieved through a few metrics, but we all know that is not the case. FDA's current thinking on the topic of quality metrics is summarized in a draft [guidance for industry document](#). Our view on metrics is that metrics are good when a company wants to focus on a certain area and only picks a few metrics. This could be to improve timeliness, effectiveness or similar of an element of the PQS (Pharmaceutical Quality System). However, the quality metrics should not be static in which case there seems to be a tendency to focus on everything and nothing at the same time. In our view the [metrics focus should be dynamic](#) and based on which specific areas the company would like to improve. Also, continual improvement is more important than actual numbers.

11. “Remove barriers that rob the hourly worker of his right to pride of workmanship”

How it's been misunderstood: Shop floor employees are expected to work in a standardized manner, take orders and following procedures like it was common 40 years ago. We assume employees are pure rational minds that just need “information” to do their work (“Head” only).

What it really means: Create space for anyone, at any level in the organization, to bring about ideas and improvement. Write procedures in a modern fashion with diagrams, videos, etc. Celebrate achievements, cultivate motivational dignity. Engage both Head and Heart, to achieve sustainable performance.

Most companies write standard operating procedures like it were common 40 years ago – page after page of details. However, today people want to see flow diagrams, pictures, videos – and help create these procedures. Just think about your own preference – when was the last time you read a manual to solve an issue vs 'google' it? In one of our workshops involving volunteers of all levels, one woman suddenly broke in tears. A long time shop floor employee, she was comforted by the other volunteers and asked about why she'd cried. *“I have been working here for twenty five years... I have never been*

asked for my opinion before” she said. How successful can an industry be if shop floor employees are not considered worthy of opinions? How much does it affect these people's self-image, dignity at work, engagement and motivation? It certainly has a limiting effect on their ability to avoid errors, to respond adequately to the unexpected, to bring about improvements.

People in general come to work to do a good job. They are more effective when they engage both head and heart at work. *“Getting people to ‘want to’ requires that you speak to both reason*

and emotion, and this is what it means to focus on [both the head and the heart](#) of the change you are asking for”.

It may sound uncommon to older generations to speak about ‘heart’ at work. But times have changed, and so have expectations of the workforce (and consumers as well). “We’ve gone from an Industrial Economy – where we hired hands – to a Knowledge Economy – where we hired heads – to what is now a Global Human Economy – where we hire hearts” ([D. Seidman, Forbes, April 2015](#))

As stated previously less and less employees work for a company but rather for a purpose and a cause. Try to ask your employees if they

feel pride in their work, and see both what they respond and with what level of energy they respond.

Instead of work-life balance, more and more are talking about [work-life integration](#): people now want to be their whole self at work, not fragmented as one at work and another off-work, and don’t want to be just told. As supervisors and managers it is important to work with each individual as a person with unique personality, skills, competences and thoughts. When each person is listened to and feel that they help co-create, that’s where real change takes place in the workplace.

12. “Remove barriers that rob people in management of their right to pride of workmanship. This means, inter alia, abolishment of the annual or merit rating and of management by objective”

[How it’s been misunderstood](#): Outdated performance models turn performance discussion into box placement, which is detrimental to engagement and performance.

[What it really means](#): Ditch models that compare people instead of helping each person. Focus on whether the system enables the job to be done and well.

In his book “[Drive](#)” (2009), Dan Pink describes what truly motivates us at work: Autonomy, Mastery and Purpose. Contrary to popular belief, extrinsic motivators such as money and punishment are not most important. However, most companies hardly work on these levers and instead still use outdated performance models and tools that actually demotivate people.

In the still widely used [‘9 box’ performance evaluation model](#), employees are assigned a number evaluating their performance on a double axis of “what was achieved” and “how it was achieved”. Employees are rank ordered in this ‘box’ against people they just happen to work with; compared like the outcome of machines. Instead of focusing on areas of

strength and areas of improvement opportunities at performance conversations, we see too often that most of the time is spent on justifying a box placement. Employees in the red corner (box ‘1’, ‘2’, ‘3’, ‘4’, ‘7’) disagree and do not see themselves as ‘lower’ than average performance; employees in the ‘5’ feel they are better than average; people in the green corner often want to discuss whether they are a ‘6’ or an ‘8’ and why not a box ‘9’; and box ‘9’ employees expected to be there anyway. **Rank ordering employees are simply not a motivation for anybody.** Rank ordering leads to competition instead of working together. Many companies also have a forced distribution irrespective of actual performance.

Each employee has strengths that can be further

enhanced, and areas of improvement that can be worked on. And why would that be a topic only once or twice a year during performance review? Shouldn't this be something employees and supervisors should be talking about on a regular basis?

One of the most important roles of leaders is to set the vision and direction; communicate progress to plans and to coach the employees. It is not to micromanage and control their employees and put them into performance boxes.

13. “Institute a vigorous program of education and self-improvement”

How it's been misunderstood: Companies don't invest enough in the education of their employees. Box-ticking training programs where “Learn” is understood as “absorb”.

What it really means: Massive learning effort where “Learn” is understood as “lead” – in a system. Create opportunities for people of all levels to grow their technical, quality, leadership and influencing skills, so they can together continuously improve the system.

Some companies don't feel they have the time or money to invest significantly in their employees, yet at the same time accept mistakes happening simply due to inadequate level of competencies.

We decided to invest massively in competencies building, we allocated the time for people to attend and complete the education, included self-generated action lists, and we monitor the effectiveness in actual performance as a company. Our experience is that with massive investment in our employees we have more engaged employees, reduced errors, and we have seen [significant improvements of our processes](#). It really is a simple equation – you invest and you gain in engagement and performance. People need to know not only what and how to do their job but also the ‘why’, understand the processes, equipment, etc.

A very important factor is how the education is done. Sharing experiences and new knowledge amongst the workforce at the time of events happening is a great way to learn. We are more and more going away from traditional education/training by only reading Standard Operating Procedures or being given a lecture by means of PowerPoint slide decks as it is our

experience that this type of education is not effective enough. In other words, it is not a matter of hours spent on education, but how it is delivered and experienced by the employee. We are using adult learning methods, which ensure knowledge is gained effectively. It also enables individuals to be competent and thus do the right things, making the right decisions.

Besides learning technical skills needed for the job, self-improvement skills are also extremely necessary in a work environment characterized by interdependence and rapid changes. Self-improvement skills are seldom acquired in a class; they come from what the individuals experience as they face barriers and manage to overcome them.

Our work puts an emphasis on the creation of leadership opportunities for people at all levels. [Volunteers](#) get together around some ideas they are passionate about, and try to make them happen, in the absence of a roadmap, a clear environment, or a hierarchical structure. They have to work as a community to create a path forward and influence their environment because most of the time their ideas need the contributions of others. This is where real self-improvement skills are learnt.

14. “Put everybody in the company to work to accomplish the transformation. The transformation is everybody's job”

How it's been misunderstood: Change is still seen as the top leaders' job, helped by consultants, change management experts, or a few internal “change agents”

What it really means: Everyone can be a leader and own transformation – not just a change in how people feel at work, but how the system works. People own what they help create

We are back to the very first Point, the importance of a common purpose. In Deming's later work he talks about the appreciation of the system itself. We call it the living quality ecosystem. An ecosystem because it is not static but dynamic, it has several 'stakeholders' and you can't optimize the system by optimizing it just for one stakeholder. At the same time we want to reduce variation of processes and leverage the difference between our employees. At the end of the day, pharmaceutical drugs are made by humans.

When people feel a shared purpose it is easier through corporate activism to mobilize everyone to accomplish the transformation. You can't demand people to own the transformation ('have to'); it must happen through

volunteerism ('want to') in order for the transformation of culture to be sustainable. We have started our culture change (the system) with a movement centered around what we call our Big Opportunity (our aim) based on the work of John Kotter combined with social media, Myron Rogers Maxims and things we have picked up elsewhere and which have proven to work for us.

Deming said that the “definition of Quality Assurance evolves to include “How the ENTIRE” organization is managed”. He also said that “Quality starts in the Board room”. The leadership's role includes building competencies of the workforce and empowering employees throughout the organization to share ownership in the purpose/identity.

Conclusion

Although [Deming's 14 Points of Management](#) have been around for more than 25 years, as an industry we still can learn from his wisdom – and in particular when we combine the 14 Points with his System of Profound Knowledge. The pharmaceutical industry has implemented many of Deming's ideas, however focusing on the technical quality side of his learnings. It is time to put the human beings in the center. It is time to implement the 'full Deming' and not only the 20 % related to technical quality. Deming explained this when he said that **“A change in philosophy requires unlearning industrial thinking evident in**

departmentalization, scarcity of knowledge and information competitiveness”.

At the 2017 PDA FDA [Conference on Quality Metrics](#) David Churchward, MHRA, spoke about quality culture and discussed an incident causing 5 people to die due to contaminated infusion fluids at a hospital in England in 1972. In the report published to the Parliament after the incident in the conclusion it was stated that *“The committee heard of no imminent technological advance in the field of production of intravenous fluids which eliminate the need for skillful men devoted to their work”.* This is

still valid. (The report also spoke about the importance of adequate skills/competencies of employees.)

We started a change that was needed to improve quality performance in our company and have shown results that were previously not achieved. We chose to work differently together and to invest massively in education. We were encouraged and helped by several great people sharing their experience. In the midst of all this work we re-read Deming's 14 points of management and the System of Profound Knowledge. What was striking to us is how we

feel that the pharmaceutical industry has only implemented a limited part of Deming's message by focusing on processes, control and exhortations. When you put the Human at the center and focus on how the system works, reading Deming takes on a much bigger and important meaning. We have shared that in this series of posts and hope that you will start the necessary discussions in your workplace to engage every employee, improve your system, and ultimately improve public health by ensuring a sustainable supply of high quality medicines.

In short, our learning is that:

- People engage around a common purpose and identity; not around an organizational or company setup
- Real culture change starts with leaders changing the way *they* work moving from control to trust of people; facilitating relationship building, sharing of information, and leveraging volunteering – where people contribute because they want to (not because they have to). And of course by setting the strategic direction for the company
- Sustainable quality performance is only achievable if you engage the entire organization (every employee) to co-create solutions
- The currency of motivation for employees is rarely company financial performance, but more in how each one contributes to a bigger objective like improving public health
- Continual improvement can come from everyone at all levels, all positions – as leaders we must foster an environment of idea sharing
- Traditional learning methods have limited effectiveness, the importance of knowing the 'why' of what your job function requires cannot be underestimated; spending time coaching on the shop floor is how people often learn the best way
- Human errors are learning experiences – treat them that way and reward effort and not only results
- Creating social media networks for informal information sharing and relationship building is needed to accelerate connection between people
- Humans are not machines; when we leverage differences between people to enhance creativity and agility the business results improve
- Engage people's head and heart
- Rank ordering of people doesn't achieve engagement and performance improvements in the longer run

Anders Vinther



Celine Schillinger



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