



Deming's 14 Principles

Background

Recent changes in regulatory requirements for clinical trials pose considerable challenges for the clinical research community. The clinical research Quality Assurance (QA) profession as a whole has not historically utilised quality management tools, and QA professionals may have little to no formal training in continuous improvement methods, to be aware of their value in assessing and improving the impact and value of the QA department to any organisation. This article will present Deming's 14 Principles for Management, paraphrasing them to demonstrate how easily they can apply to the clinical trial project management, Contract Research Organisation (CRO) and clinical department management.

Deming's 14 Principles

Dr. William Edwards Deming is known as the father of the Japanese post-war industrial revival and was regarded by many as the leading quality guru in the United States.

Deming created 14 Principles for Management that summarised his business philosophy. The principles became a basis for transformation of industry. The 14 principles apply anywhere, from small organisations to large ones, to the service industry as well as to manufacturing. They apply to any division within a company.

1. Create Constancy of Purpose Towards Improvement

Replace short-term reaction with long-term planning. Approaching a new clinical trial project, keep in mind that it must be better performed and with a lower budget than the previous ones.

Having the above in mind, analyse previous pitfalls, difficulties, problems, obstacles and identify the current and anticipated problems. Hint: findings from system and clinical trials audits may be a good source of such information. Can these recur? Most probably 'yes', unless you take measures to prevent or, at least, to mitigate them. Hence start with planning and allocate resources for training and education, based on what you've learned from your past experience, and make risk analysis and contingency plans. Acting this way you can constantly improve your service.

2. Adopt the New Philosophy

Management should actually adopt the 'quality philosophy', rather than merely expect the workforce to do so.

When the new clinical trial project is thoroughly planned and the quality matters are carefully embedded into it by the study management, while creating the atmosphere of striving for the best performance, it will penetrate into the study team at all levels, both in-house and at sites.

When the management looks forward, not at the competitors, but at the customers, that will be the moment of major change.

3. Cease Dependence on Inspection

Quality does not come from inspection; mass inspection is unreliable, costly and ineffective.

Of course, we can never cede the monitoring, however 'quality embedded' projects will allow us to reduce the level of scrutiny over clinical sites without giving up on the quality of deliverables (i.e. clinical data), genuinely improving cost-effectiveness.

The data collected by monitoring, i.e. inspection, should be used for better process control.

4. Move Towards a Single Supplier for any One Item

Work toward a single source and long term relationship.

If you're a pharmaceutical company, invest your time in finding 'the one and only' CRO. It will not necessarily be a single one, but if you create a solid group of CROs delivering up to your standards, nurture the relationships, establish a mutual trust and reliance between purchaser and vendor, make them feel like partners, this will benefit you immeasurably. When outsourcing your activities, always remember that price alone has no meaning. Change focus from lowest initial cost to lowest total cost.

If you're a CRO – strive to be a part of such a group. Working with the same customers over time will make your operation more efficient, meaning lower prices and higher profits.

5. Improve Constantly and Forever

Quality starts with the intent of management. Management is obligated to continually look for ways to improve quality.

First of all, teamwork in clinical trial project planning is fundamental. Second, we must remember that chronic problems have chronic causes. Treating the symptoms does not solve the problem. Putting out fires is not improvement of the process. Improvement efforts must shift focus from improving the personnel to improving the processes.

We must identify the systemic policies, practices, belief systems etc. that are dysfunctional and change them. As long as these systemic causes remain, the resulting systemic problems will remain. One of the most efficient tools to reveal the causes is quality audit followed by corrective actions that include investigation, a.k.a. root cause analysis. Clinical trial audits and system audits may open our eyes and indicate the process deficiencies and flaws. Appropriate handling of the latest will inevitably lead to improvement.

6. Institute Training

If people are inadequately trained, they will not all work the same way, and this will introduce variation.

In our business, every new project calls for study specific training, even when very experienced personnel are involved, both in-house and at site. The more we invest in the development of an extensive and comprehensive training programme, the more field, office and site staff are trained, training effectiveness evaluated and re-training carried out when the need is identified, the more uniformity in results, meaning statistically we will achieve valid clinical data.

Management must remove the inhibitors to good work and provide the setting where workers can be successful.

7. Institute Leadership

Deming makes a distinction between leadership and mere supervision.

First of all managers, or should we say leaders, must know the work they supervise. That will assist them to know the difference between special and common cause of variation, or in other words to distinguish between a mere mistake and a weakness of a process.

CRA Managers or Study Managers are not policemen, neither are QA personnel. We all have a common goal – to complete our clinical trial in time, at the lowest possible cost, with scientifically valid results, while strengthening the relationships with investigators and subcontractors/clients. It's everyone's job and everyone's responsibility. When the management message, not verbal but through action devoted to quality, it will make its way to the field personnel, also reaching to the site's staff.

8. Drive Out Fear

Deming sees management by fear as counter-productive in the long term, because it prevents workers from acting in the organisation's best interests.

There's no better way to make personnel feel that every single one of them is responsible for improvement than to allow a free discussion of any subject at any point of time. Attentiveness and responsiveness of the Study Management to the field personnel requests, open door policy, willing to assist and support, fast troubleshooting, backup in case of conflicts and trust, will not only encourage the personnel to report the problems, or to admit their own mistakes, but also will create an atmosphere of partnership which is the most favourable for the project success.

Moreover, remember that the more information, both positive and negative we have, the better we can manage not only the current project, but also the future ones.

9. Break Down Barriers Between Departments

The concept of the 'internal customer' means that each department serves not the management, but the other departments that use its outputs.

Often a company's departments or units are competing with each other or have goals that conflict. They do not work as a team; therefore they cannot solve or foresee problems. Even worse, one department's goal may cause trouble for another.

There is no better example of the involvement of a multi-disciplinary team than a clinical trial project: data management and clinical supplies, laboratory personnel, logistics, operations, administration, and the site personnel. So, first know your internal suppliers and customers. Integration, co-operation, open communication lines, mutual understanding and support are necessary pre-requisites for the success of the project.

We can easily depict interrelations within the team as customer-supplier relationships: operations as customer of clinical supplies, data management as customer of operations, etc.

From the very beginning of the 'quality embedded' clinical project, all parties involved shall have a perception of the common goal and comprehension of success as a result of teamwork; therefore promote the teamwork. This is the only environment in which continual improvement is possible in. Every department shall make its contribution, presenting its needs and expectations on the one hand as a customer, on the other hand meeting needs and delivering expectations as a service provider.



10. Eliminate Slogans

It's not people who make the most mistakes - it's the process they are working within. Harassing the workforce without improving the processes they use, is counter-productive.

Eliminate slogans, exhortations and numerical targets for the workforce. These never help anybody do a good job.

Facing problems and obstacles raised by audit non-conformities, study management must not think of penalties, replacement, rebuke, or any other person-orientated actions as these have proved ineffective in terms of contributing to improvement measures, but rather look carefully at the process, analyse it, understand its strengths and weaknesses, consider the possible resolutions, and only then act. Following this approach, study management will most probably find out that the measures, i.e. corrective actions rather than mere corrections, are process-oriented, and therefore, target-oriented. Moreover, once implemented, corrective actions will improve the entire process as a result, preventing the study team from making additional mistakes.

11. Eliminate Management by Objectives

Deming saw production targets as encouraging the delivery of poor-quality goods.

Have you participated in 'competitive recruitment' to a clinical study? I'm sure you have. Have you ever analysed the number of protocol violations, damage to relationships with site personnel, CRAs' frustration, illegible data for statistical analysis data as a result of such a process?

Quotas only take into account numbers, not quality or methods.

A person, in order to hold a job, will try to meet a quota at any cost, including doing damage to their company.

Initiate a 'seasonal' project when fast recruitment is crucial, encourage your teams by creating the best foundations for the most efficient implementation, i.e. all administrative and regulatory issues resolved, study teams trained appropriately, logistics and clinical supplies standing by. Then set measurable and realistic (!) objectives of performance and make sure they are understood. This way the importance of timely and prompt execution will be perceived as the natural course of things and the employees and the site teams will be proud in their workmanship.

12. Remove Barriers to Pride of Workmanship

People are eager to do a good job and distressed when they cannot. Too often, misguided supervisors, faulty equipment and defective materials stand in the way of good performance. These barriers must be removed.

When the CRA encourages the recruitment, but the site is running out of clinical supplies that for some reason couldn't be delivered in time, or hasty allocation of resources makes the field personnel struggle through more work than they are able to handle appropriately, when the site personnel are inadequately trained or communication in an electronically managed trial constantly fails, what pride can people possibly take of their workmanship?

'It's not people who make most mistakes - it's the process they are working within. Harassing the workforce without improving the processes they use is counter-productive.'

13. Institute Education and Self-improvement

Invest in the education of your work forces (including sub-contractors), encourage self-education and introduce training programmes, worship knowledge and professionalism. This is the only recipe for commitment to lifelong employment and business success.

As the CRA (that does not necessarily have a clinical background) acquires more knowledge, of the therapeutic area of the study protocol, the better the CRO team is trained on the internal sponsor's processes (SOPs, internal communication lines, etc.), as the site staff have more understanding in regulations, the more study management is educated in the topics like teamwork, statistical techniques, risk management, project management and, of course, quality tools, the more chances that our mission - to complete our clinical trial in time, at the lowest possible cost, with scientifically valid results while strengthening the relationships with investigators and sub-contractors/clients - will be successfully accomplished.

14. The Transformation is Everyone's Job

It will require a special top management team with a plan of action to carry out the quality mission. The critical mass of people should be included in the change. Workers cannot do it on their own, nor can managers.

The leadership model must replace the bureaucratic model of the boss deciding on what and how everyone else must change. Once consensus is reached, it is feasible to focus collective energy, intellect, experience, etc. on priorities for improvement.

Summary

Deming preached that to achieve the highest level of performance requires more than a good philosophy - the organisation must change its behaviour and adopt new ways of doing business. Indeed, his 14 Principles pose a challenge for many companies to figure out how to apply them in a meaningful way; however CRO or clinical departments will benefit immeasurably by finding this way and implementation of the principles in the management practice.

Deming's Fourteen Points of Management

1	Create constancy of purpose for improvement of product and service	8	Drive out fear
2	Adopt the new philosophy	9	Break down barriers between staff areas
3	Cease dependence on mass inspections	10	Eliminate slogans, exhortations, and targets for the work force
4	End the practice of awarding business on the basis of price tags alone	11	Eliminate numerical quotas
5	Improve constantly and forever the system of production and service	12	Remove barriers that rob people of pride of workmanship
6	Institute training	13	Encourage education and self-improvement for everyone
7	Adopt and institute leadership	14	Take action to accomplish the transformation



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