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Standardisation of Staff Training to Increase Efficiency

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ABSTRACT

In any industry or organization, personnel training is emphasized with reference to National Regulatory Authorities (NRAs) guidelines and other globally accepted guidelines. In spite of many refresher training programs, the pharmaceutical industry still faces significant variations in individual/ team efficiency and productivity. Individuals/teams given the same task, SOPs, environment and materials continue to produce significantly different results reflecting the possibility of operating on different sets of theoretical and practical information, which may stem from differing trainer, training program or training method. This study focused on using a standardized manual for training two teams A and B involved in vaccine production, as a tool to increase employee efficiency, productivity and quality**,** at a Livestock vaccine manufacturing company, with an objective to shorten the supply chain of vaccines (starting with Newcastle disease vaccine I-2 strain) to improve product quality, availability and affordability up to rural household level and back yard farmers. Baseline data was collected from four pre-training production batches and compared with data collected from three post-training production batches. The results showed that a tailored standardized training was effective in achieving the same level of efficiency, regardless of how late or soon the member joined the facility, and who conducted the training. The process of training staff, using a company tailored standardized manual, was shown to be successful within this company's set up and could potentially be applied to other industries that are struggling with implementation of uniform information to their staff.

KEYWORDS

Keywords, standardization, personnel training, pharmaceutical industry, productivity, efficiency

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1. INTRODUCTION

There is a perception that the pharmaceutical industry recruits only qualified personnel with consideration to academic qualification. This perception ultimately leads to a higher expectation in personnel efficiency and productivity.

Access to quality, safe, effective and affordable livestock vaccines is an important step in changing household nutrition and income in sub-Sahara Africa. The current livestock vaccine supply is dependent on effectiveness of cold chain from Europe and Asia. According to the project site in this study, a vaccine manufacturing company in East Africa, quality products begin with quality staffing and training of employees. Effective local production of vaccines, will benefit the livestock from a shortened the transit to the farm/farmer and adoption of thermo-stable vaccine products to reduce the risk associated with cold chain monitoring over several hours in transit.

Problem statement

The vaccine production has experienced a continuous discrepancy, where two Lots of the same batch consistently producing different yields for the same bulk of raw materials, same parameters, time and environment. The volume produced by team B is close to 50% lower than that of team A, impacting the projected batch yield, causing our product to be in short supply, expensive, resulting in losses to the company.

The project objective is to bring both teams to the same level of efficiency, productivity and quality by standardizing the training manual for all the staff involved in production, assuming that individual operational errors are the cause of production inconsistencies.

It was observed that, though the facility scheduled annual training programs to meet the Good Manufacturing Practice (GMP) requirements for training there were no standardized training materials, no training method. Although the trainers seemed to be experts in the field, no information reconciliation was observed.

The assessment /evaluation methods if any could not reflect the impact of training conducted in relation to productivity and efficiency.

WHO recommends an adequate number of personnel with necessary qualification and practical experience. WHO also recommends for appropriate training on duties assigned in addition to basic theoretical and practical training on GMP (World Health Organization, 2006, p. 5,7). This may be falsely interpreted that, minimal orientation by the supervisor following NRA guidelines, which are also extracted from WHO and other accepted guidelines, will impart necessary skills for individuals and teams to work efficiently and consistently produce quality product.

The Pharmaceutical industry in East Africa faces the following challenges during recruitment:

The kind of practical experience expected is had to come by.

Personnel gaps are therefore, filled to meet adequate numbers but not necessarily practical experience.

The cost implication of hiring the practically experienced personnel.

The hiring cost of external training.

Karen Vaughan (2008) argues that: transition from school to work is no longer a linear process…workplace learning has become a tool through which businesses can competitively gain advantage (recruitment and retention of workers, development of innovative practices and production of new knowledge).

According to a study performed by the American Society for Training and Development (ASTD), 41 percent of employees at companies with poor training planned to leave within the year, but in companies with excellent training, only 12 percent planned to leave (Branham, 2005). Retention of valuable employees is a direct benefit of implementing an excellent training.

It is evident through queries during GMP inspections that the guidelines do not fit all situations or the interpretation for implementation varies from facility to facility, or trainer to trainer about personnel training, productivity and efficiency.

World Health Organization (2006) raises a need to consider these questions among others, before implementing training: Who is responsible for the training? Can all experts be trainers?

The varying interpretation in training implementation go on to reflect in the way personnel are trained and produce varying results in individuals working in the same facility, same field and same assignment. Most of the time, the person conducting the training is one of the team members who volunteers or who has shown to have knowledge in a certain subject area. These would be considered informal workplace trainers, and they “do not occupy an organizational position that is formally or explicitly linked to employee training” (Poell, Van der Krogt, Vermulst, Harris, & Simons, 2006).

According to Kum, Cowden, & Karodia, (2014) ineffectiveness in training and developing of employees in the organization reduces the organizational productivity.

Das, (2017) argues that,

> “A trainer is one of the most important elements in any training program. The key attribute of a trainer must be the knowledge he/she possesses on the subject of the program. However, mere possession of knowledge is not sufficient; the trainer must be articulate enough to reach out to the participants with the concepts being covered in a program. The results obtained have important implications for trainers as well as for the organization conducting training program; these findings prompt us to delve into which attributes of a trainer are significant in training effectiveness. Is a trainer merely an instructor in a lecture-based training program or beyond?”

It is important for a trainer(s) to be fully designated, trained and empowered with an understanding of organizational objectives, standard training materials, process and knowledgeable in management of skills.

Standardization is defined as the process of making something conform to a standard (Lexico, n.d.). When an organization knows what it wants, or the best product it can achieve, it is standardization that makes operational steps in an activity produce the best product every time you implement this process regardless of who performs it.

Standardization: When done correctly, putting standards in place can increase efficiency.

Standardization creates a mutual knowledge in teams or staff, given that employees join an institution with different levels of skill.Rather than taking each situation as it arises, individuals react according to a set list of instructions and protocols.

The goal is to make sure every action, is done the same way every time. Training is a key element of implementing standards.

An important implication is that standardization efforts need to be seen as a long-term strategic initiative that drives the creation and adoption of standards and innovations (Xie, Hall, MacCarthy, Skitmore, & Shen, 2015).

Guided innovation is more effective as one can easily pick the source of error when a process is not followed and therefore participate in reviewing the process depending on how often the standardized process has fallen short on results.

Training depends almost entirely on standardization in any successful company. When there is only one correct way to train a new employee, all employees learn the same amount of information. This reduces or eliminates knowledge gaps, thus creating a stronger work force (Bailey.n.d). It is necessary for teams to have “a shared understanding of the processes that will aid them in achieving their goals” (Morgan, Paucar-Caceres, & Wright, 2014)

In the absence of standardized training, errors are hard to predict and corrections are difficult to implement due to ambiguity surrounding the correct output (Brandall, 2018). Lack of standardized training accumulates into costs to the industry, if considerations are not made to: who is training, what they are training about, how the training is conducted and what the measurable are. Inconsistencies continue to occur in productivity and efficiency, even when staffs have the same qualification, raw materials, facilities and motivation. In spite of many refresher training programs, pharmaceutical industries still face significant variations in different teams or individuals performing the same operation.

A standard training is expected to create structure and standardization among employees to produce efficiency and increase productivity. According to Shallock, Rybski, Jochem, & Kohl, (2018), training should pursue activation, interaction and empowerment of participants. The design should alternate in series of observation, while theory and practice aim to achieve significant learning and implementation, which follows the didactical approach of training (Figure 1). A well implemented training approach helps the individual to unlearn past experiences from previous work places or school and creates room for learning the skills necessary for the current task.

Hodges (2011) argues that, while the evaluator must determine how effective the program is in teaching skills and knowledge and in ensuring what is learnt is transferred to the participants' work environment, lengthy time-consuming studies seem impractical in the fast paced work environment today.

Efficiency is defined as the ability to do things well, successfully and without waste (Cambridge University Press, 2021); for staff to be efficient it has to be measured against a standard by which they have been trained towards a targeted productivity.

According to Prokopenko (1992), Productivity is defined as the efficient use of resources, labor, capital, land, materials, energy and information in the production of various goods and services. Higher productivity means accomplishing more with the same amount of resources or achieving higher output in terms of volume and quality from the same input. This is usually expressed as **output/ Input** = productivity.

Ruch (1994) demonstrates the importance of improvement of individual productivity to affect organisation productivity.

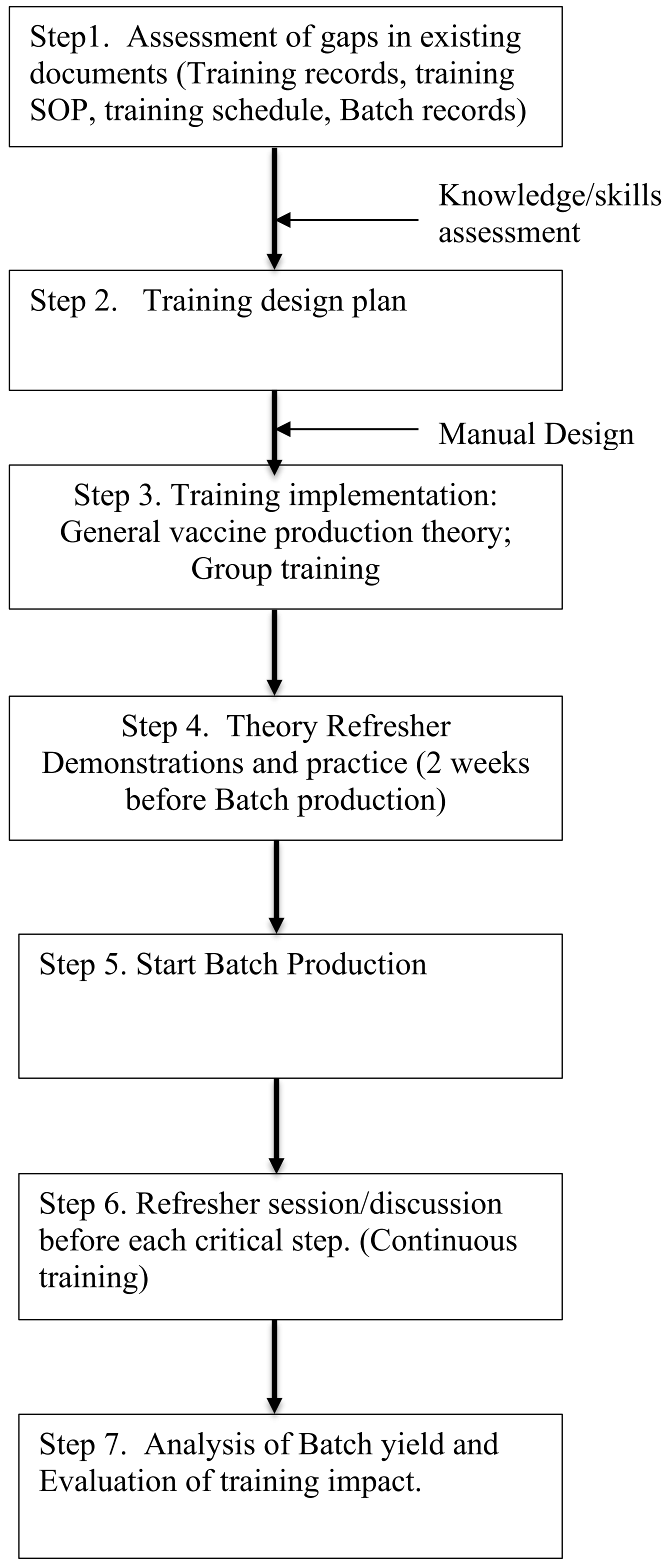
Standardization assumes that heterogeneity and variation are inherently undesirable properties that should be eliminated, or at the least, nuisances to be minimized (Wears, 2015).

However, this can be taken as a reduction in the way of spontaneous activities as it limits individual innovativeness and intervention where immediate action is required. While it may be viewed as limiting individuals, at the industry level coincidental innovation cannot be relied upon in the pharmaceutical industry. A well-trained individual may turn out to be more innovative as they are empowered to ask questions and perform meaningful investigations within the boundaries of practicing standardized processes informing the review of the training manual. This encourages exercising professional judgments, which this study will attempt to implement. Employees represent events, situations and interventions unique to their stake holder grouping. Their observations can bring about an investigation and root cause analysis (Welty, 2013).

As stated and concluded in in several studies emphasis has been place on assessing the trainee. The pharmaceutical industry sets up all personnel working on a line or the same set of activities. They must be equipped with the same knowledge and skillset to produce the same product on every batch. Inconsistencies in training results in different products and un clear methods for correction of errors when they occur. Therefore, a gap remains in making sure the trainer gives the same information to all the trainees, which can be achieved through standard and routinely revised information (in the form of a standard training manual), which is given to all personnel through training. A knowledge and skills assessment evaluates participants' level of prior knowledge, as well as previous training and experience in the area of interest (Management Science For Health, 2012). Initial steps of evaluation take place during needs assessment and analysis process. The five levels evaluation provide a comprehensive approach to assessing learning and training impact in the work environment therefore ensuring that a skill is acquired and applied as soon as possible (Philips, 1998).

This study focuses on how to increase employee output using a standardized training manual for the trainer tailored to a vaccine production process at the project site, by assessing the effect of training by collecting data from batch yield before and after training.

Figure 1. Process flow standardisation of training



2. METHODS

Knowledge level assessment

This project began by understanding why there was so much difference between the two teams assigned production. This was done through analysing of the available records of training, training SOP, training schedule and batch records.

The aim of this analysis was to: understand what the previous trainings were like; the frequency of training; the kind of assessment given; how much was implemented; whether any targets were given.

Baseline data collection

Four Batch Manufacturing Records (BMRs) an equivalent of eight sub lots were requested from Quality Assurance Department, chronologically up to the current batch before training starting from May 2018 to May 2019.

Batches 87, 88, 89 and 90, sub lots A and B were selected. The batches were analysed for critical steps in vaccine production that can effectively be captured for batch performance as variables.

The allantoic yield and egg death were selected as baseline performance indicator of each sub lot against the projected yield. Projected allantoic yield is calculated from the eggs that have survived through post inoculation incubation. Survivability of eggs is significant to batch projection and directly linked to finished product, even though there are several factors that can affect release of the final product.

Training

Key steps in production that can form the core of training were identified. A standardize training was developed to cover the five critical steps in vaccine production. These are steps that involve manual interaction with the SPF eggs as well as the allantoic fluid more likely to generate operator errors and loss of product.

Using the didactical approach to train (Figure 2), all members were trained together on the five critical steps.

Given that these were existing teams, training was done concurrently with implementation to enable alternation between theory observation and practice (there would be a slightly change for a new recruit without changing the content of training). All of the theory was done before new batches were issued, followed by a short theory refresher and observation during the two days before the given stage/activity in production.

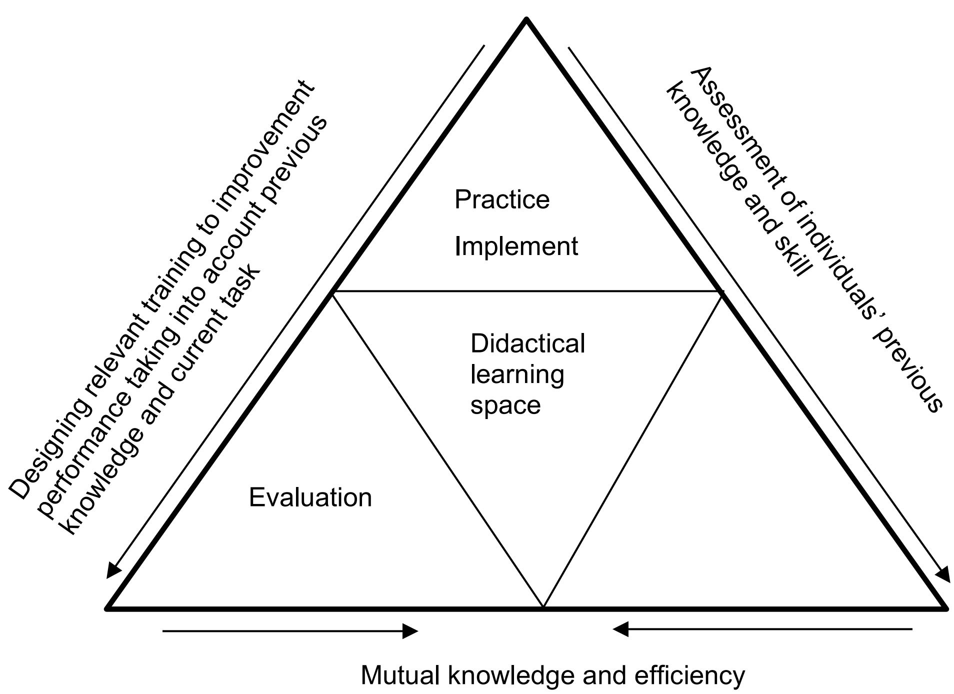


Figure 2. Standardisation of training Didactical concept

Implementation

The production teams/shifts were maintained as per the company grouping and teams were assigned new batches as a practical follow up on training between November 2019 and February 2020.

The consignment for eggs per batch were received as usual in a bulk of batch 91 (1200) by quality control and then acclimatized together over 48hrs at 18°C.

The eggs were divided into two lots of 600 and assigned randomly assigned to the different teams. Consignments for batches 92 and 93 were received in January and February respectively. These were divided in lots of 450 eggs which is a batch size.

Lot sizes change from 300 to 600 from time to time depending on the product demand based on the customer orders.

We collected there post implementation BMRs; batches 91, 92 and 93, sub lots A and B. All quantitative data was collected and tabulated for easy calculation of percentage loss in egg death and allantoic yield as an assessment for impact of training.

Post training with pre- training results were charted and compared chronologically to given the small amount of data collected.

Table 1. Pre and Post implementation SPF egg survivability data

Batch	Lot	Total SPF Eggs in-put	SPF Eggs Accepted	Eggs Inoculated	Eggs approved for Harvest	Percentage loss in eggs	Average	Standard Deviation
Pre-87	A	600	551	426	399	33.5		
	B	600	564	350	326	45.7		
88	A	300	285	263	223	25.7		
	B	300	283	192	113	62.3		
89	A	400	388	327	319	20.3		
	B	400	369	303	283	29.3		
90	A	600	563	482	437	27.2		
	B	600	533	484	423	29.5	34.2	13.5
Post-91	A	600	534	480	475	20.8		
	B	600	539	470	450	25		
92	A	450	428	387	349	22.4		
	B	450	425	379	364	19.1		
93	A	450	427	390	320	28.9		
	B	450	416	367	339	24.7	23.5	11.6

Table 2. Pre and Post implementation allantoic data

Batch	Lot	Total SPF Eggs in-put	Projected Allantoic Yield	Actual Allantoic Yield	Percentage Loss in Allantoic Yield	Average	Standard Deviation
Pre-87	A	600	4684	3342	28.7		
	B	600	4794	2126	55.7		
88	A	300	2422	1852	23.5		
	B	300	2405	1014	57.8		
89	A	400	3298	2818	14.6		
	B	400	3136	2080	33.7		
90	A	600	4785	4266	10.9		
	B	600	4531	3137	30.8	31.96	17.16
Post-91	A	600	4539	4050	10.8		
	B	600	4581	3469	24.3		
92	A	450	3638	2000	45		
	B	450	3613	1552	57		
93	A	450	3630	1548	57.4		
	B	450	3536	1700	51.9	41.07	19.24

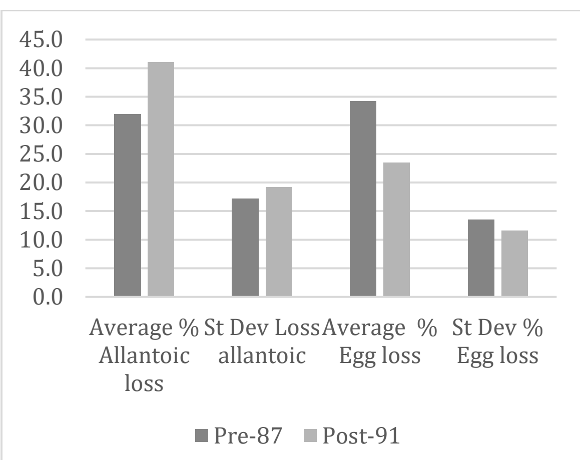


Figure 3. Pre and Post mean comparison

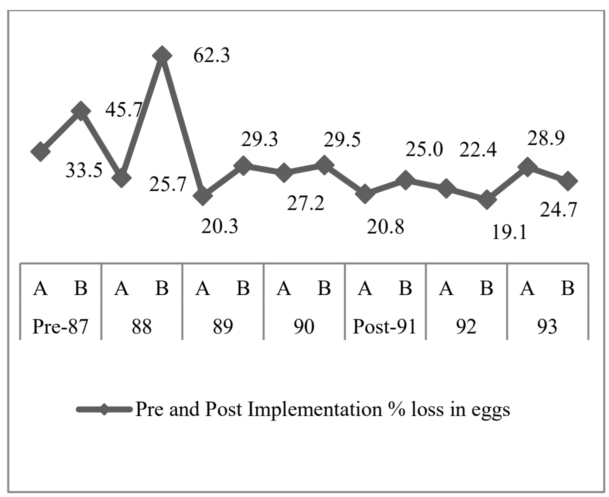


Figure 4. A chronological plot of pre and post results shows a reduction in egg loss

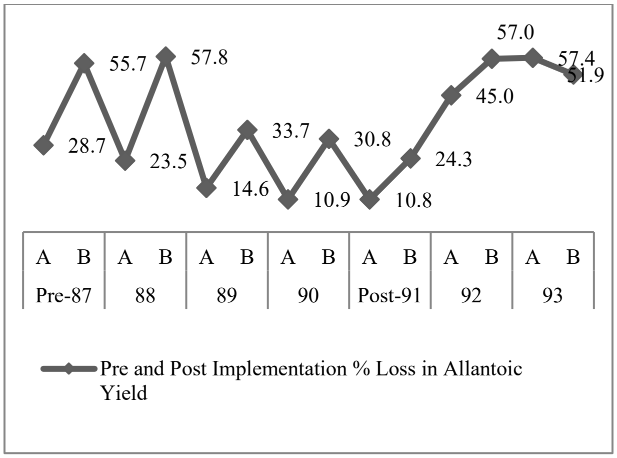


Figure 5. A chronological plot of pre and post results demonstrates same level of efficiency

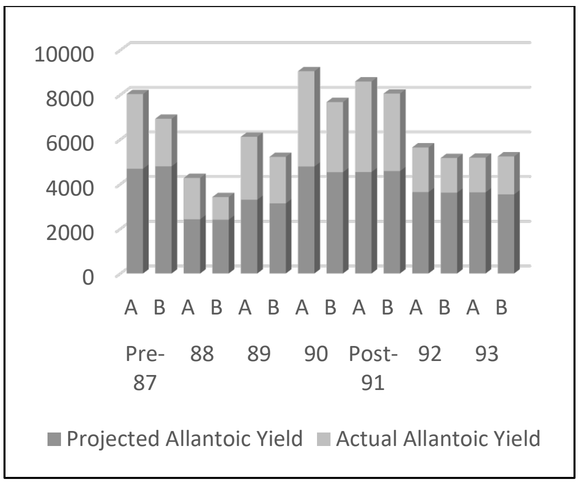


Figure 6. Allantoic yield comparison in litres

3. RESULTS AND DISCUSSION

Relevant data to percentage loss in allantoic yield and percentage egg survivability as captured in Table 1 and Table 2 was used to generate Figures 3, 4, 5 and 6

Table 1 represents the relevant data for analysis of percentage loss in eggs and generation of Fig.4. There is trending in post implementation Batches 91, 92 and 93, all teams show a significant reduction in percentage loss of eggs to below 30%. Additionally, all points are within one standard deviation, as compared to pre-implementation, where lot B consistently displayed losses ≥29.5% (Figure 4). This bring the mean to 23.5% and standard deviation to 11.6 (Figure 3).

Table 2 represents the relevant data for analysis of percentage loss in allantoic yield and generation of Figures 5 and 6. The percentage loss in allantoic harvest however has risen above 30% in both teams; this emphasizes the shift from operator error attributed to training (Figure 5). Representation of actual gap in projected and actual allantoic yield by volume as well as sub lot comparison (Figure 6).

The results, as presented in Figure 4, are an important indicator to improved individual/team productivity. Survivability of the eggs is directly proportional to the projected allantoic yield. A reduction in material loss/waste positively impacts the capital input, product output, and pricing.

The results of post-implementation (Figure 5) showed that there was a significant loss in post-implementation allantoic yield across the teams. After an out-of-specification investigation it was observed that this loss had nothing to do with the training, but rather deviation not detected at the time, arising from supply a different gauge of an inoculation needle. The consistence in efficiency across the teams is attributed to the improvement in practical application after training, given that pre-implementation there was no close correlation in the yield.

As shown in Figure 6, although projected yield based on a calculated average yield per egg obtained from three pilot batches, a number of operator errors and deviations are capable of impacting this yield can be prevented or investigated, if the operator has acquired the right skill through training.

The results showed that a tailored, standardized training will bring all team members within the same level of efficiency, regardless of how late or how soon the member joined the facility, and who conducts the training. The project demonstrated that a tailored standardized training manual puts together all the practical methods proven over time to enable delivery of uniform training to all staff.

This bridges the gap for what would be experience based differences in performance. A standardized manual can be adopted by all trainers and therefore the uniform information at all times even with changing the trainer.

The study focused on pre- and post -training implementation performance considering uniform information and skills. However, this does not factor changing the trainer and other factors associated.

4. CONCLUSION

In conclusion the findings of this project in vaccine manufacturing demonstrate three key points.

1. The process of training staff from a company tailored standardized manual was shown to be successful within this company's set up.
2. The training process described in this report can potentially be applied to other areas of the industry or industries that are struggling with the implementation of uniform information to all staff.
3. Training should be accompanied by analytical and investigative judgement considering that, even though the teams improved in efficiency, they failed to observe the accidental change in the inoculation needle which impacted the yield.

5. RECOMMENDATIONS FOR NEXT STEPS

Developing a standardized training manual at a facility level should be considered a regulatory requirement for improving efficiency and maintaining product quality and safety.

Trainers and all staff should be encouraged to retrain using standardized manual to enable the consistent level of efficiency and productivity.

Companies should develop in-house training expertise for effective training. Training expertise should have the same importance as other expertise areas needed to operate a manufacturing facility.

External trainers should be practically knowledgeable about the topic of training, and organizational objectives for effective training.

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