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Strategic Utilisation of R&D Personnel to Strengthen Quality Control Functions in Manufacturing Organization

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ABSTRACT

In many manufacturing organizations, meeting stringent project timelines is increasingly dependent on the availability of skilled personnel in the Quality Control (QC) function. However, the hiring of new manpower for QC poses a major constraint due to time, cost, and competency-related challenges. At present, QC departments in many organizations face **manpower shortages**, especially during peak project phases. Simultaneously, Research & Development (R&D) departments possess **technically skilled personnel with strong product and process knowledge**. However, their capabilities remain largely **underutilized outside R&D**, leading to siloed working structures and limited cross-functional collaboration.

The objective of this research is to evaluate and establish **a controlled strategy for the effective utilization of R&D personnel within the Quality Control (QC) environment** of a pharmaceutical manufacturing organization experiencing manpower constraints.

Following methods or frameworks like **Change management, Competency based framework, Kirkpatrick model and PDCA cycle** can be applied during the progress of the research. Here are the key risks associated with using R&D personnel in a QC environment under manpower constraints, along with practical mitigation strategies, tailored to pharmaceutical manufacturing. The associated risks are **Regulatory & Compliance Risk, Data Integrity Risk, Conflict of Interest, Operational Inefficiency, Skill & Knowledge Gaps, Quality Culture Risk**. These risks required to be mitigated through appropriate action plans like **understanding the human behaviour, rigorous training mechanism, qualification of personnel & continuous feedback** during the course of the project activities. R&D personnel can be effectively utilized in QC environment through **rigorous trainings, skill development, continuous monitoring and performance evaluation** through methodologies & frameworks (Change management, Competency based framework, Kirkpatrick model and PDCA cycle) and its application to achieve the desired results for benefit of the organization.

INTRODUCTION

The company senior professional are responsible to drive the culture within the organizations. It depends what the senior professionals would like to see their organizations in long terms, (Healthy culture or Toxic culture). The Mission, vision and values will always flow from top to bottom. Top Leadership in current organization is very positive to drive excellence and innovation. Looking back when the company starts, the company focus is more towards marketing, however with time the company focus on developing and innovation their own products as well in the market. The Hugh investment done in R&D and Quality departments builds a strong network of workforce, specialized instruments and equipment's has to meet the regulatory requirements & expectations. Most of the products has been developed by R&D team and ready for commercialization, however these products must be validated and tested for release through QC department. The R&D workforce is technical, innovative and have sufficient workforce to support the QC (Analytical Validation Laboratory) department activities, however to meet the stringent product timelines QC (AVL) department require more work force to meet the timelines.

It has been agreed by senior professionals to proceed ahead with the objective of utilising the R&D personnel in QC (AVL) environment. The success of the research will help in future to overcome the work force challenges and maintaining a robust environment wherein R&D personnel can be effectively utilised in QC environment using controlled strategy to meet the organization objectives without compromising the data integrity and quality issues.

LITERATURE SURVEY

Article Overview: "Quality Management in a Research and Development Environment"
Event: ISO World 2017: Business in the Internet of Things
Focus: Application of quality management approaches to R&D contexts.

The paper reviews how **quality management (QM) systems and principles** can be applied effectively in **research and development (R&D) environments**, which are usually unpredictable and require flexibility. It argues that: Traditional, rigid quality systems can hurt innovation in R&D.

Flexible models like **Total Quality Management (TQM)** and **Quality Characteristics (QCs)-linkage model** are better suited. Successful QM in R&D balances quality focus with autonomy and innovation. Overly structured quality interventions may decrease performance and creativity.

There are **real-world industry examples** where **R&D personnel are typically not utilized in Quality Control (QC) environments**, along with the organizational reasoning behind this separation.
Why R&D personnel are not utilized in QC (Pharma Industry):

- Regulatory frameworks such as U.S. Food and Drug Administration and European Medicines Agency require:
  - Clear separation between **development** and **commercial quality testing**
  - Documented independence of QC laboratories
- GMP principles demand **objectivity and independence** in release testing.
- R&D involvement in batch release testing may be viewed as a **conflict of interest**.

Other Industries like Automotive Manufacturing Industry:
Why R&D is not utilized in QC:

- Lean manufacturing separates **design engineering** from **production quality control**.
- QC focuses on process stability and defect reduction.
- R&D is considered cost-intensive and strategically reserved for innovation.
- R&D rarely performs daily shop-floor quality inspections.

This information has been collected based on contacts or relations built in pharmaceutical industry over more than 20 years of experience in pharma industry. None of the organizations has been directly utilizing the R&D personnel in QC environment for responsible QC activities. Based on the Literature survey it can be interpreted that utilization of R&D personnel in QC environment often impose a challenge for manufacturing organizations. Leading this challenge, as an opportunity, a structured approach and mechanism must be driven in order to break the myth that R&D people can't utilized in manufacturing organizations.

Overview Mechanism:
Structured approach can be subdivided into following stages:

- UNDERSTANDING THE HUMAN BEHAVIOUR (Open Hall meeting of Senior professionals)
- COMPETENCY GAP BETWEEN R&D AND QC (Identify GAPS w.r.t GMP requirements)
- TRAINING MECHANISM (Rigorous & Effective training mechanism, SMEs, Verbal assessment)
- QUALIFICATION OF PERSONNEL (Highly Motivated QC personnel deployed with R&D personnel)
- OUTPUT OR RESULTS (Sample Analysis, TAT or Output ratio, Feedback through surveys, Average score calculation based on parameters)
- SCOPE OF IMPROVEMENT (Deviation, Incidents, Feedback mechanism)
- FRAMEWORK APPLICATION (Change Management, Competency based framework, Kirkpatrick model, PDCA)
- CONTINUOUS IMPROVEMENT (Retraining, Feedback, CAPA)

RISKS AND MITIGATIONS

Here are the key risks associated with utilisation of R&D personnel in a QC environment under manpower constraints, along with practical mitigation strategies, tailored to pharmaceutical manufacturing:

1. Regulatory & Compliance Risk
Risk: R&D staff may lack full GMP/QC compliance experience, leading to audit observations or data integrity issues.
Mitigation: Provide GMP (ICH Q7 and Data integrity), Functional (Human Error) and SOP trainings; authorization of tasks; maintain documented competency assessments.

2. Data Integrity Risk
Risk: Unintentional deviations in documentation, ALCOA & ALCOA+ violations or poor QC practices.

Mitigation: Implement supervised execution, second-person verification, periodic data reviews, and clear segregation of duties.

3. Conflict of Interest
Risk: R&D personnel testing products they develop may introduce bias.
Mitigation: Define clear role boundaries; prevent R&D staff from testing their own development batches; ensure QA oversight.

4. Operational Inefficiency
Risk: R&D priorities may conflict with routine QC timelines, impacting productivity.
Mitigation: Define time-bound QC assignments with workload planning and clear escalation mechanisms.

5. Skill & Knowledge Gaps
Risk: Limited hands on experience with validated QC methods and instruments.
Mitigation: Structured cross functional training, Qualification of personnel, and mentorship by experienced QC analysts.

6. Quality Culture Risk
Risk: Perception of "shortcuts" due to manpower pressure.
Mitigation: Strong QA governance, management communication reinforcing quality-first mind-set and continuous monitoring through KPIs. As QC is running short of workforce, hence it is mitigated to introduce R&D workforce in QC environment to handle high priority time bound project activities.

7. Attrition Risk
Risk. What would be the associated risk If R&D personnel would resign or QC personnel would resign. Factors of Attrition and its Mitigation are:
Factor: Not satisfied with Management decision.
Mitigation: Consent taken, Clear communication.
Factor: Feeling of demotivation or unfavourtism
Mitigation: Quality culture, Motivational speeches.
Factor: Feeling of Job insecurity-
Mitigation: Agenda of cross utilization of employees should be communicated from Top to Low levels through channels of communication (Open hall Meetings, Conference room discussions).
Factor: Compatibility issues
Mitigation: Highly motivated employees, One to One discussion.
Factor: Good Job offer

Mitigation: Immediate transfer of role/responsibility, Applause & reward for responsible & positive attitude employees.
Factor: Hearsay or nuisance talks
Mitigation: Strict action through HR for employees doing such acts.

Structured flow of Training process

1. GAP Identification w.r.t GMP through questionnaire
2. User ID/JR/TNI approval in system
3. Training through SMEs or skilled Trainers
4. Verbal assessment related to SOPs
5. Qualification through skilled QC staff
6. Planned strategy for Product A & Product B analysis
7. Incident & Deviation handling

Methodologies or Frameworks applied in execution of Project activities

Change Management
Resistance from Employees at Mid-Level or Low Level > Resolved through Open Hall Discussions
Culture & Identity roles > Resolved through Collaborative study approach

Kirkpatrick Model (Effectiveness of Training)
Reaction is monitored through Feedback & Verbal assessment.
Learning is evaluated through verbal assessment & questionnaire evaluation.
Behavior is based on the evaluation done by QC employees based on certain parameters through surveys. Average score of R&D personnel ranges from 4.2 to 4.5, Above 4 score considered to be good as per industry norms.
Results: TAT Ratio of R&D vs QC is about 0.91

Competency Framework
Identify GAPS through Verbal assessment & Interviews
Implementation of effective Training through Feedback from trainees
Evaluating performance outcomes through TAT or output ratio

PDCA CYCLE-Continuous Improvement

Plan: Identify GAP & Plan for Training
Do: Classroom & Self reading sessions, Sample analysis
Check: Results & Analysis, Calculation of TAT or output ratio & Comparison with QC
Act: Analytical results, Incident & Deviation investigation through RCA & CAPA implementation. Continuous improvement through Training & Feedback mechanism

Outcomes & Results:

Key Aspects	Expectation	Achievement	Strategy
R&D Personnel utilization	Trained & Qualified	Success	SMEs & Skilled QC Analysts
Control for Testing for Release	Valid & Authentic results	Success	Cross utilization or Flip of Testing
TAT or Output or Productivity ratio (Days)	90-100% (0.9 to 1.0)	91% (0.88 to 0.94= 0.91)	Structured planning (Micro level)
Collaboration of R&D & QC employees	Average score should be between 4 to 5	4.2 to 4.5	Feedback or Survey conducted
QMS events (Incidents or Deviations)	Approach to Zero	1 each for Incident or Deviation	Why-Why analysis, Retraining & CAPA

Conclusions and Recommendations:

- The process of Training has been conducted in a structured manner. Training duration, real life examples used for better learning perspectives.
- Verbal assessment by Trainer or SMEs on each day after completion of SOPs for better understanding & clarity of trainees.
- Laboratory rounds (GAMBA walk) for some practical aspects of learning.
- Skilled QC analysts has been deployed with trainees (R&D personnel) for qualification activities.
- Strategic planning for making a group of two trainees each for product A & B activities.
- Cross or Flip off testing to avoid conflict of interest.
- Incident or deviation investigation through RCA & CAPA implementation.
- Feedback from the trainees for improvement & effective training mechanism.
- Survey of R&D personnel through QC employees based on Behaviour, Communication skills, Knowledge & Analytical expertise parameters.
- Frameworks applied (Change Management, Competency framework, Kirkpatrick model, PDCA)
- TAT or output ratio calculation and its comparison (Average TAT is 0.9)

Based on the outcome of the results obtained, utilisation of R&D personnel in QC (AVL) environment seems to be strategically optimum choice to handle stringent timeline projects without impacting GMP & DI guidelines, wherein manpower constraint shall not be a bottleneck to meet the project timelines keeping in mind that it should not become a routine practice for departments. Such scenarios shall be handled with controlled strategy through senior management approval.

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2. ICH Q9 – Quality Risk Management.
3. ICH Q10 – Pharmaceutical Quality System.
4. WHO Technical Report Series (TRS) – GMP for Pharmaceutical Products.
5. US FDA – Guidance for Industry: Data Integrity and Compliance with CGMP.
6. EU Guidelines for Good Manufacturing Practice, Volume 4.
7. MHRA – GxP Data Integrity Guidance and Definitions.

8. Internal Company SOPs related to Job description, Training of Personnel and Analyst Qualification.
9. Methodologies or Frameworks related to Quality Management system, Operations management or Human resource management

Glossary

1. QC or AVL (Quality Control or Analytical Validation Laboratory): Department responsible for validation, testing and release of COA for raw materials, intermediates, and finished products.
2. R&D (Research & Development): Function involved in product development, method development, and formulation studies
3. QA (Quality Assurance): Oversight function ensuring compliance with regulatory and quality systems.
4. GMP (Good Manufacturing Practices): Regulatory requirements ensuring product quality and patient safety
5. Data Integrity: Accuracy, completeness, and reliability of data throughout its lifecycle (ALCOA+ principles)
6. ALCOA: Attributable, Legible, Contemporaneous, Original, Accurate,
7. ALCOA Plus: Complete, Consistent, Enduring, and Available
8. KPIs: Key performance indicators
9. CAPA: Corrective & Preventive action
10. RCA: Root cause analysis
11. JR: Job responsibility
12. TNI: Training need identification
13. SME: Subject Matter Experts are expert in their own subject or field.
14. TAT: Turnaround time (Time taken by the employees from beginning to the completion of project)