ITS "QUALITY" THAT MATTERS

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PREAMBLE

In industrial practice one comes across terms such as :- Quality Assessment, Quality Control, Quality Assurance, Total Quality Management, which are often for convenience enshrouded in such abbreviations as QA, QC, TQM etc.

In terms of serious industrial usage it is advantageous to know and understand what these terms mean? What then is the real meaning of the term "Quality"? Is it a function of the price of the article or the prestigious nature of the company that produces it? For example an SLR digital camera is a quality product based on a production pattern that has been evolved by considerable research. Is it therefore superior to a simple camera that is relatively far less expensive? It is, in respect of its versatility and the functions it can perform, which the latter may not be able to do. But both are quality products with different target customer groups. The one is for the serious professional photographers. The other targets the simple enthusiast who wishes to record events with the least possible complexities. The important point is that they are both products of "Quality", - the outcome of rigorous research and development prior to entering the market. However they are designed for different purposes and to serve two different target groups, both of which are of importance to the producers. Accordingly the following definition of Quality arises.

" A product that conforms to quality standards is one that is unequivocally fit for its intended use."

Quality control (QC) is the process, which is designed to ensure that a given product meets the predetermined specifications that are necessary for its intended use. This process of QC includes appropriate sampling as well as established testing methodology.

Quality assurance (QA) has a more expansive implication. It covers surveillance of all factors that may influence the quality of a given product. TQM or Total Quality Management, is to ensure that there is control and management over the entire continuum of operations that go to produce the product, which would have predetermined specifications and a circumscribed intended use.

COMPONENTS OF TOTAL QUALITY MANAGEMENT

Every sizable production outfit must ensure that the components of Total Quality Management are in place. These components are the following :- (With special reference to the herbal Pharmaceutical Industry)

(a) RELIABLE DOCUMENTATION

There is a requirement for ensuring that documents on matters of policies, procedures, instructions, and obligations are in place. The contents of such documentation must be regularly explained to all relevant personnel. They should be available in languages understood by all relevant personnel.

Some readily available off-the-shelf quality systems that may be conveniently applied to a situation are the following : -

ISO 9001	-	Quality Management System
ISO 14001	-	Environmental Management System
MRP II Class A	-	Manufacturing Resource Planning
GMP	-	Rules and Guidance for Pharmaceutical Manufacturers and Distributors

Unfortunately there are no universally accepted Rules and Guidance for the Phytopharmaceutical Industry.

In Link Natural Products Pvt. Ltd. For example the following documentation is available to anyone, which conforms to ISO 9001 Quality Management System Requirements:-

1. A System manual
2. A Process manual

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The System manual of Link Natural Products describes the company, as well as the following:

- Quality policies
- Environment policies
- Organization structure
- Quality management system
- Environmental management system
- Responsibility matrices
- Process interaction matrix
- Documentation system
- Management responsibilities
- Planning
- Resource management
- Product realization
- Quality management procedures and
- Environmental management system procedures

In the Process manual the following core processes are illustrated in flow charts.

- Customer related core process
- Product development core process
- Purchasing core process
- Storage and handling core process
- Material preparation core process
- Manufacturing core process
- Engineering core process
- Product verification core process

In addition work instructions for each step in the manufacturing procedures are described in the Sinhala language as well. The following additional features are also included in the manual.

- Operational control instructions,
- Emergency preparedness and response procedures,
- Safety instructions,
- Sanitary instructions

(b) VALIDATION

The prescribed goal of a manufacturing process is to produce a given product which invariably conforms to the predetermined standard. Ensurement of the above is what is known as validation. (see LNP Digest Volume 1 No 2 pg 17-18)
The individual in charge of validation in a company must be familiar with the respective process parameters that constitute the Scientifically Optimized Process Protocols (SOPP), that are employed in the production of the various products.

This constitutes, in the Herbal Pharmaceutical Industry, such parameters as the following :-

- Extent of drying and cominution of raw material
- The extraction parameters (temperature, solvent, time etc)
- Speed of stirring
- Method of mixing ingredients
- pH and other relevant physical factors

Just as the SOPP has been designed by extensive R & D so must the Validation Protocol (VP). This must include:

- Outline of SOPP
- Critical individual process parameters
- Specifications against which the parameters are tested.
- Define the testing required to establish the process as valid

(c) INSTRUMENT CALIBRATION

A processing plant in the phytopharmaceutical industry comprises of a complex array of equipment to accommodate a number of individual processes.
eg: drying, sieving, cominution, extraction, distillation, etc.

These are associated with several measuring instruments. It is crucial to process validation that these instruments are regularly tested and calibrated.
The individual responsible for this task must have an intimate knowledge of the processes involved and all their parameters as well as knowledge of instrumentation. If such a person is not available, calibration will have to be assisted by a qualified instrument technician. Most often lack of a suitable electronics technician is a serious obstacle. This requirement may be met adequately if it is foreseen in the acquisition of instrumentation hardware.

(d) QUALITY AUDIT

One of the final components of Total Quality Management is the Quality Audit. This is quite simply, checking if the TQM system is operating in the manner for which it was designed.
This presupposes the existence of a definite TQM system, which is documented. In addition the industry has also adopted ISO 9000 quality system, that would provide an additional framework of reference.

CONCLUSION

In conclusion, it may be stated that "Quality" is the secure foundation on which an industry can thrive and prosper, Quality ensures customer confidence in the industrial concern and the products generated by it.