ALL INDIA COUNCIL FOR TECHNICAL EDUCATION (AICTE) Sponsored

Quality improvement programme

JSS College of Pharmacy, Ooty

on

"PHARMACEUTICAL REGULATORY AFFAIRS – INDUSTRY PERSPECTIVE & RECENT ADVANCES IN PHARMACEUTICAL QUALITY ASSURANCE"

01st to15th March 2016

Programme Summery Report

Department of Pharmaceutical Regulatory Affairs and Department of quality assurance jointly organized Quality improvement program on "Pharmaceutical Regulatory Affairs – Industrial perspective & recent advances in Pharmaceutical Quality assurance"in JSS college of Pharmacy, Ootacamund, Tamil Nadu.

The program was conducted on 1st March 2016 to 15th March 2016, in this program there are twenty eight (55) participants participated in and around south India.

In this program we focused Regulatory requirements for import & marketing of Drugs &Pharmaceuticals, cosmetics & Medical Devices. And also focused the drug approval process in emerged countries like USA, Europe & India.

GMP is that part of Quality assurance which ensures that the products are consistently manufactured and controlled to the Quality standards appropriate to their intended use. A set of principles and procedures which, when followed by manufacturers for therapeutic goods, helps ensure that the products manufactured will have the required quality.

The program divided two parts one is lecture from industrial experts and hand on training given by industrial experts and our faculty. Finally distribute the certificates for the participants.

Title: Pharmaceutical Patenting In India

Speaker: Dr. S. P. Subramaniyan, Assistant controller of Patents & Designs, Chennai.

Intellectual property (IP) is referred to creations of the mind such as inventions, literary and artistic works, and symbols, names, images, and designs used in trade. IP is broadly divided into two categories which is Industrial property and Copyright. Industrial property includes patents, trademarks, industrial designs, and geographic indications. Copyright is a bundle of right which includes literary and artistic works such as novels, poems and plays, musical works, cinematographic works, artistic works such as drawings, paintings, photographs; sculptures; architectural designs; algorithms and software. Copyright is also providing protection to performers, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs.

Patent is a statutory and monopoly right is granted by the Government for an invention for a limited period of time to the innovator in lieu of full disclosure of his invention which excludes others from making, using, selling, and importing the patented product or process for producing that product. Patent is an intangible property that can be exploited unlike other property. It can be simultaneously used throughout the world. Invention relating either a product or process that is new, involving inventive step and capable of industrial application can be patented, provided which shall not fall into the categories of inventions that are non- patentable under section 3 and 4 of the Act.

At the time of Independence, both product and process patent regime for drugs was prevailed in India which was governed by the Patents and Designs Act, 1911. It was designed in such way to benefit foreigners than Indians. As a result, there was no growth in scientific research and industrialization in the country and curbed the innovativeness and inventiveness of Indians.

To review the working of 1911 Act, a committee was constituted under the chairmanship of Justice (Dr.) BakshiTek Chand, a retired judge of the Lahore High Court in 1949. The Committee submitted the final report in1950 making recommendations for prevention of misuse or abuse of patent rights in India with special emphasis to food and medicine and surgical and curative devices which need to be made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee. The Act was

amended to provide compulsory license in respect of food and medicines, insecticide, germicide orfungicide, and a process for producing substance or any invention relating to surgical orcurative devices.

Another committee have been appointed under the chairmanship of Justice N. RajagopalaAyyangarin 1957, to further amend the patent law which meets the requirement of the country. The committee observed that the grant of patents to Indians and foreigners was roughly in the ratio of 1:9 during the period 1930-37 and the same was remained even number of institutions for post-graduate training and several national laboratories were established to encourage a rapid growth of scientific education immediately after independence.

The committee recommended to retain the patent system and excluded product patents for substances intended for use and capable of being used as food or as medicine or drug. The term of the patent was also brought down from 14 years to five 5 years from the date of sealing of the patent or 7 years from the date of patent whichever was earlier. India was dependent on imports for many essential bulk drugs and the prices of the drugs also very high till early 1970s. After enactment of Patents Act, 1970 many Indian companies started manufacturing bulk drugs in large scale. Indian generic companies have steadily become the “pharmacy of the developing world”.

Product patent is being granted for new chemical entity (NCE) from 1st January 2005 so as to comply with the international agreements WTO and TRIPS. Term of the patent is increased to 20 years from the date of filing. Following subject matters relating to drugs are acceptable in India;

(1) New Chemical Entity (drug per se)

(2) Process or method of preparing a drug

(3) Composition

(4) Combination

Herbal medicines are gaining momentum not only in India but also around the globe. Pharmacology is playing an important role for the development of herbal medicines. Even though indications for many traditional herbs are known in the art, safety and efficacy, dose and dosage regimen for the active ingredients separated from a plant, novel combination of plant materials or extracts are need to be studied using pharmacological

techniques for human consumption. For filing patent application either for synthetic or natural product, detailed clinical trial reports of pharmacological studies such as pharmacokinetic and pharmacodynamic results are not at mandatory, but there shall be convincing proof for the activity of said products or improved effect over the known substance or combination(s). Preliminary in vitro or in vivo test results are sufficient to protect the invention by filing a patent application. Any research work which is carried out with lot of efforts shall be evaluated for filing a patent before initiating for publication. It is observed that the contribution of Indian academic patenting is very low compare with the other developed and developing nations. Growth of the nation is depending upon industrial growth which in turn depends on strength of Intellectual property.

Application for patent can be filed either by true and first inventor or his assignee, either alone or jointly with any other person with Indian Patent Office either with complete specification or with provisional specification along with prescribed fee in person or through online filing system on the website of Patent Office i.e. www.ipindia.nic.in.

Applicant can file either provisional or complete specification. If provisional is filed, a complete specification shall be filed within 12 months from the date of filing of such a provisional. The provisional specification shall be deemed to have been abandoned where there is no complete filed after provisional specification. International application or conventional application shall be filed with the World Intellectual Property Organisation (WIPO) or in the countries interested (member countries of Paris Convention), if the applicant wanted to exploit his invention in other countries simultaneously. A permission need to be obtained from the Controller of Patents where applicant desires to file a patent application other than India. Request for Examination shall be filed within 48 months from the date of filing for processing the application for grant. The subject matter of the invention examined and the patent is granted if the invention fulfil various provision of the Act.

Title: Data Integrity in Pharmaceutical Industry

Speaker: Mr. JaganJayabalan, Associate Director, Kemwell Bio Pharmac(Pvt) limited, Bengaluru

Pharmaceutical industry is one of the dynamic industries in India. Globalization of pharmaceutical industry has made the companies to opt for mergers and acquisitions,

which in turn demands the industry to maintain highest quality. Frequent audits done by various global regulatory bodies like USFDS, UKMHRA, and Indian FDA has become order of the day. Each consumer expects that the drug they consume should be of highest quality and relieve them from the disease. For achieving these highest quality, global regulatory bodies has enacted lot of laws in the form Good Manufacturing Practices.

Data integrity – a term often used in the pharmaceutical industry in recent years has been a significant problem and is closely watched by all the global regulatory bodies. In recent years, there has been a steep increase in the number and types of data integrity issues that have been cited in regulatory inspections by both USA and European (especially MHRA) investigators. Integrity of data is the foundation, upon which we take all the important decisions on quality, safety and efficacy of the drug products.

US FDA's clear message to industry is "Do whatever is in the document and document whatever you do". In fact, data integrity issues have been increasing to become one of the most important GMP issues. This increase has led to the FDA establishing the types of issues that should be considered red flags triggering a more intensive investigation. They are also concerned with the impact of the data integrity problems on the firm and the products it manufactures. One of the areas prone to data integrity issues is the pharmaceutical laboratory.

Occasionally people tend to intentionally falsify the data. This is unfortunate, but, thankfully a rarity.

Following steps shall be taken by pharmaceutical companies to ensure data integrity:

a. Embed data integrity verification activities into internal audit process

b. Training the employees and create awareness among the employees about data integrity

In conclusion, FDA regulated laboratories are under stringent scrutiny. Data integrity enforcements are increasing due to increasing violations in recent years. Ensuring data integrity is critical in pre and post marketing approval activities.

Title: Quality Assurance in Clinical Research Organization

Speaker: Mr. Ashok P, AGM-QA, Par Bio sciences Pvt. Limited, Chennai.

Quality Assurance (QA) is an independent department that promotes excellence by ensuring adherence to all the process. Auditors' focus on quality has been lead to great

extend by years of multidisciplinary clinical research training, from extensive education on topics from software validation to Good Clinical Practices (GCP) to FDA requirements and other regulatory requirements. Every client is been benefited by experienced QA personnel in disciplines including health care practice, regulatory process, clinical data management and software validation.

Quality Assurance facilitates continuous improvement through internal audits, policy and procedure creation, and support of corrective and preventive actions from external audit findings.

In general QA team is guided by GCP, federal regulations, and sponsor specifications. Each internal QA team relies on the depth of industry experience and broad practical focus of the QA department.

GCP compliance including overall and study-specific compliance. Various types of audits include:

- Software and computer system validation documentation Audit
- Annual audit of Vendor and subcontractor qualification audits
- Continued maintenance of a system with written standard operating procedures
- Identification of areas for continuous quality improvement and ensuring the implementation of these improvements by conducting CAPA meetings with the respective departments.
- Communication with management about the Quality issues or problems and taking necessary plan to complete the identified discrepancy.

Conclusion:

An effective quality control followed by quality assurance program means a range of possible risks may be identified and prevented. To ensure quality is inherent in every stage of the process, the Shewhart model is often considered the best guide. Popularized by the father of quality control, Dr. Edward Deming, Plan, do, check, acts are the essential elements for quality assurance in clinical studies across the universe.

Title: Theory and Instrumentation of Flash Chromatography and Preparative column chromatography

Speaker: Ms. Poornima, Excecutive, Application support, Spinco Biotech Pvt Limited

Chromatography is a separation technique applied in various fields like pharmaceutical industry, environmental department, agro-chemical industry, etc. Any process in these fields flows as identification, isolation, characterization and scale up. Identification is done by analytical chromatography, whereas isolation and scale up are performed through preparative and flash chromatographic techniques respectively. Advancement in chromatographic technique led to rapid purification of compounds. The compound, thus isolated in pure form is essential for its characterization through the sophisticated instrument – NMR. This lecture explicates the theory, instrumentation, applications, differences, advantages and simple guidelines for translating thin layer chromatography and high performance liquid chromatography results into either isocratic or gradient flash chromatography and preparative chromatography.

Title: Modern Pharmaceutical Quality System

Speaker: Mr. Narendira Kumar, Head QA - Formulations (Orchid Healthcare), Chennai.

Risk taking is an important part of any business endeavor. Entrepreneurs and investors take risks every time they fund a start-up. Business executives take risks every day as they make decisions about which products, services, ideas and people to advance within an organization. Risk taking can be enormously profitable. But in the pharmaceutical industry, excessive risk taking can have devastating results; product delays, recalls, and enforcement actions by the Food and Drug Administration (FDA) have led to the demise of many small- to mid-size pharmaceutical manufacturers. Most importantly, consumer safety can be compromised by excessive risk taking. In the pharmaceutical industry, risk must be tempered by caution. And the mechanism for tempering risk is a robust pharmaceutical quality system based on the latest FDA guidance.

Quality cannot be an afterthought. Implementing an effective quality system involves up-front costs. An effective quality system should be in place at the earliest stages of product research and development. While the pursuit of quality can be a costly line item on a financial statement or business plan, failure to implement an effective quality system can have even more costly effects on the bottom line.

Based on the latest guidance from the FDA, an effective pharmaceutical quality system should help ensure compliance with cGMPs by focusing on:

Quality management

Quality assurance

Evaluation analysis and quality risk management tools

Preventive action

Risk management

Continuous improvement

This latest guidance does not replace previous FDA regulations, which require every pharmaceutical quality system to include Standard Operating Practices (SOPs), adequate personnel and training systems, and an adequate system for recordkeeping. The new guidance is simply aimed at addressing advances in manufacturing technologies, quality systems and risk management approaches that have been developed since 1978. The latest guidance is also aimed at harmonizing the cGMPs with other widely used quality management systems, including the FDA's own medical device quality system regulations. Developing a modern, quality system approach can provide the necessary framework for implementing continuous improvement and risk management efforts in the drug manufacturing process.

While a culture of quality should permeate the entire organization, management plays a very important role in the successful functioning, design, implementation and management of a modern quality system. Not only should management align the quality system plan with the company's strategic plan, it must demonstrate strong support for quality systems. It's essential for senior leaders of pharmaceutical manufacturers to encourage internal communication about quality issues and support the production, quality and manufacturing activities needed to produce quality products.

But what does a modern pharmaceutical quality system look like? Imagine the hub and spokes of a wheel. The quality system itself is at the center (the hub), but it is connected to five other manufacturing systems (the spokes). When you include the quality system as a subsystem at the center of it all, the six subsystems of a modern pharmaceutical quality system are the:

Quality System

Production System

Facilities and Equipment System

Laboratory Controls System

Materials System

Packaging and Labeling System

The quality subsystem at the center provides the foundation for the five manufacturing subsystems and helps them achieve compliance. Each subsystem has an impact on the others and they all have to work together to consistently produce a quality product. But it's important to understand that none of the individual subsystems equate to a functional group in an organization or manufacturing facility. For example, the Materials System does not simply apply to warehouse personnel. This subsystem includes the warehouse personnel who receive, store and handle components and raw materials and distribute final products, but it also includes the purchasers who buy components from qualified vendors, the manufacturing workers who request and receive components and transfer final products to the warehouse, the quality assurance specialists responsible for component and lot release, and the quality control employees who sample and test components and products.

Title: A Quality Assurance Approach on Impurity Profiling

Speaker: Dr. M. R. Jeyaprakash, J. S. S. College of Pharmacy, Ooty

The prime concern of analytical chemistry is the qualitative and quantitative analysis of chemical entities. Analytical chemistry provides an information about the relative amount of one or more of these components. Qualitative analysis of impurity (IM) is concerned with the description of chemical composition in terms of elements, compounds, or structural units, whereas quantitative IM analysis is concerned with the measurement of amount. High Performance Liquid Chromatography (HPLC) employed commonly for the analysis. Though HPLC separation based on the differing affinities or partition property of a mixture of solutes between two phases our fellow budding analytical chemist faces lot of obscurity in impurity analysis method development, because of problem in the usual stages of method development likely drug and IM profile collection, preliminary studies in solubility, assortment of reference standard, mobile phase, stationary phase, elution methods, sample selection, sample handling, storage of sample, detector selection, data analysis so on. Even though we are familiar with the method development in drug analysis, the stages of abstraction significantly increasing in the IM

analysis. Impurity profiling is an one more task in the quality assurance. Now a days regulatory bodies are very stringent to accept the API or dosage forms in presence of impurities. The present presentation enumerates certain ideas to develop an ideal and precise method to estimate the IM and related substances. The explanation eventually covers the regulatory needs and practical problem in the Impurity profiling process.

Title: Analytical Method Validation and Parameters

Speaker: Dr. S. N. Meyyanathan, J. S. S. College of Pharmacy, Ooty

Analytical method validation is a vital activity in the discovery of drugs and pharmaceuticals. Method validation can be considered as a process of defining the analytical requirements and confirming that the method under consideration has performance capabilities with what the application requires. In general there is often a need to transfer methodology from one laboratory to another to include it in official compendia. In such exercisers the use of a method by large number of people in various laboratories all across the world and on instruments manufactured by different manufacturers occurs causing a greater probability of decreased reproducibility and reliability. Therefore in order to minimize these differences there are various standard validation parameters.

VALIDATION PARAMETERS:

SPECIFICITY: It is the ability to measure desired analyte in a complex mixture.

ACCURACY: It is the agreement between measured and real value.

PRECISION: It is the agreement between a series of measurements.

LINEARITY: It is the proportionality of measured value to concentration.

RANGE: It is the concentration interval where method is precise, accurate and linear.

DETECTION LIMIT: It is the lowest amount of analyte that can be detected.

QUANTITATION LIMIT: It is the lowest amount of analyte that can be measured or quantified.

ROBUSTNESS: Ability to remain unaffected by small changes in parameters.

RUGGEDNESS: Reproducibility under normal but variable laboratory conditions.

Title: CPCSEA Standard operating procedure (SOP) for IAEC

Speaker: Dr. R.Vadivelan, J. S. S. College of Pharmacy, Ooty

Experimentation on animals in research and education is covered by provisions of the Prevention of Cruelty to Animals Act, 1960 and Breeding of and Experiments on Animals (Control & Supervision) Rules of 1998, 2001 and 2006 framed under the Act. These are enforced by the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), a statutory body under the Prevention of Cruelty to Animals Act, 1960.

The objective of the SOP is to contribute to the effective functioning of the Institutional Animal ethics Committee (IAEC) so that quality and consistent ethical review mechanism for research on animals is put in place for all proposals dealt by the Committee as prescribed by the CPCSEA under PCA Act and Breeding and Experimentation Rules 1998. Principles are adopted for scientific experiments on animals; relevant changes in rules and guidance for specific situations evolved by the consultative group accepted by CPCSEA.The CPCSEA guidelines are framed on specific aspects regarding the use of animals in scientific experiments to maintain the quality and are to prevent infliction of unnecessary pain or suffering on animals. They are as follows

- Need to avoid/minimize pain and suffering inflicted on experimental animals
- Proper care, handling and use of experimental animals
- Agricultural production research
- Powers of IAEC
- Inspection of animal house facilities

Title: The quality of pharmaceuticals using hyphenated Analytical technique

Speaker: Mr. B.Babu, J. S. S. College of Pharmacy, Ooty

Introduction of electrospray mass spectrometry, the coupling of liquid chromatography and mass spectrometry has become a common technique in most analytical laboratories in the world has opened the new way to the analysis of herbal medicines. Several valuable review articles dealing with LC–MS and its application in the analysis of botanical extracts have been published. In last decades, the increasing usage of LC–MS in the analysis of herbal medicines is quite obvious. Several good reviews have been published for the analysis of the bioactive chemical compounds in plants and herbal medicines, in which the hyphenated technique used most. Moreover, combined HPLC–

DAD–MS techniques take advantage of chromatography as a separation method and both DAD and MS as an identification method. DAD and MS can provide on-line UV and MS information for each individual peak in a chromatogram. With the help of this hyphenation, in most cases, one could identify the chromatographic peaks directly on-line by comparison with literature data or with standard compounds, which made the LC–DAD–MS becomes a powerful approach. With the help of this hyphenation, in most cases, one could identify the chromatographic peaks directly on-line by comparison with literature data or with standard compounds, which made the LC–DAD–MS becomes a powerful approach for the rapid identification of phytochemical constituents in botanical extracts, and it can be used to avoid the time-consuming isolation of all compounds to be identified. Liquid chromatography-mass spectrometry (LC-MS) is an analytical chemistry technique that combines the physical separation capabilities of liquid chromatography with the mass analysis capabilities of mass spectrometry. LC-MS is a powerful technique used for many applications which has very high sensitivity and selectivity. Generally its application is oriented towards the specific detection and potential identification of chemicals in a complex mixture.

Title: Atomic Absorption Spectroscopy (AAS)-Applications in Pharmaceutical Quality Assurance

Speaker: Dr.N.Krishnaveni, J. S. S. College of Pharmacy, Ooty

Atomic absorption spectroscopy is an analytical technique that measures the concentration of elements. The atomic absorption spectrometry uses absorption of light of intrinsic wavelengths by atoms. All atoms are classified into those having low energies and those having high energies. The state having low energies is called the ground state and the state having high energies is called the excited state. The atom in the ground state absorbs external energies and is put in the excited state.

When light of certain intensity is given to many atoms in the ground state, part of this light is absorbed by atoms. The absorption rate is determined by the atomic density.

The principle mentioned above can be applied to light absorption of “Free atoms”. A “Free atom” means an atom not combined with other atoms. However, elements in the sample to be analyzed are not in the Free State, and are combined with other elements invariably to make a so-called molecule. For example, sodium in sea water mainly combines with

chlorine to form a NaCl (Sodium chloride) molecule. Absorption cannot be done on samples in the molecule state, because molecules do not absorb light. The combination must be cut off by some means to free the atoms. This is called atomization. The most popular method of atomization is dissociation by heat – samples are heated to a high temperature so that molecules are converted into free atoms. This method is classified into the flame method, in which a chemical flame is used as the heat source; and a flameless method, in which a very small electric furnace is used.

SAMPLE PREPARATION TECHNIQUE:

- Wet digestion method
- Dry carbonisation and incineration
- Microwave assisted digestion
- Ultra sound assisted digestion

SAMPLE ATOMIZATION TECHNIQUE:

Atomization is the most critical step in atomic absorption spectroscopy. Two common methods of sample atomization are followed

- Flame atomization
- Electro thermal atomization

APPLICATIONS:

It is used mainly for quantitative analysis rather than qualitative analysis. Quantification can be carried out even at ppb and ppm levels. AAS is more commonly applied for analysis of heavy metals and trace inorganic minerals especially in pharmaceuticals, food products, industrial effluents, water, mining and herbal drug products. Its application towards clinical side is extended in the estimation of lead, sodium, potassium, calcium, lithium and magnesium in biological samples.

Title: Chiral Analytical Techniques In Present Scenario

Speaker: Dr. B. Gowramma, J. S. S. College of Pharmacy, Ooty

The separation of chiral compounds has been of great interest because the majority of bioorganic molecules are chiral. Living organisms, for example, are composed of chiral biomolecules such as amino acids, sugars, proteins and nucleic acids. In nature these biomolecules exist in only one of the two possible enantiomeric forms, e.g., amino acids in

the L-form and sugars in the D-form. Because of chirality, living organisms show different biological responses to one of a pair of enantiomers in drugs, pesticides, or waste compounds, etc. Chirality is a major concern in the modern pharmaceutical industry.3-4 This interest can be attributed largely to a heightened awareness that enantiomers of a racemic drug may have different pharmacological activities, as well as different pharmacokinetic and pharmacodynamic effects. The body being amazingly chiral selective, will interact with each racemic drug differently and metabolize each enantiomer by a separate pathway to produce different pharmacological activity. Thus, one isomer may produce the desired therapeutic activities, while the other may be inactive or, in worst cases, produce unwanted effects.

Nevertheless, to avoid the possible undesirable effects of a chiral drug, it is imperative that only the pure, therapeutically active form be prepared and marketed. Hence there is a great need to develop the technology for analysis and separation of racemic drugs. Current methods of enantiomeric analysis include such non-chromatographic techniques as polarimetry, nuclear magnetic resonance, isotopic dilution, calorimetry, and enzyme techniques. The disadvantages of these techniques are the need for pure samples, and no separation of enantiomers are involved. Chiral HPLC has proven to be one of the best methods for the direct separation and analysis of enatiomers. It is more versatile than chiral GC because it can separate a wide variety of nonvolatile compounds. Current chiral HPLC methods are either direct, which utilizes chiral stationary phases (CSPs) and chiral additives in the mobile phase, or indirect, which involves derivatization of samples. Direct chiral separations using CSPs are more widely used and are more predictable, in mechanistic terms, than those using chiral additives in the mobile phase.

Title: Quality control and quality assurance and ethics

Speaker: Mr.J.S.K.Nagarajan, J. S. S. College of Pharmacy, Ooty

Quality Assurance (QA) refers to the process used to create the deliverables, and can be performed by a manager, client, or even a third-party reviewer. Examples of quality assurance include process checklists, project audits and methodology and standards development.

Quality Control (QC) refers to quality related activities associated with the creation of project deliverables. Quality control is used to verify that deliverables are of acceptable

quality and that they are complete and correct. Examples of quality control activities include inspection, deliverable peer reviews and the testing process.

Quality Assurance is process oriented and focuses on defect prevention, while quality control is product oriented and focuses on defect identification.

Quality control is about adherence to requirements. Quality assurance is generic and does not concern the specific requirements of the product being developed.

Quality assurance activities are determined before production work begins and these activities are performed while the product is being developed. In contrast, Quality control activities are performed after the product is developed.

QC VS QA

Definition	QA is a set of activities for ensuring quality in the processes by which products are developed.	QC is a set of activities for ensuring quality in products. The activities focus on identifying defects in the actual products produced.
Focus on	QA aims to prevent defects with a focus on the process used to make the product. It is a proactive quality process.	QC aims to identify (and correct) defects in the finished product. Quality control, therefore, is a reactive process.
Goal	The goal of QA is to improve development and test processes so that defects do not arise when the product is being developed.	The goal of QC is to identify defects after a product is developed and before it's released.
How	Establish a good quality management system and the assessment of its adequacy. Periodic conformance audits of the operations of the system.	Finding & eliminating sources of quality problems through tools & equipment so that customer's requirements are continually met.
What	Prevention of quality problems through planned and systematic activities including documentation.	The activities or techniques used to achieve and maintain the product quality, process and

		service.
Responsibility	Everyone on the team involved in developing the product is responsible for quality assurance.	Quality control is usually the responsibility of a specific team that tests the product for defects.
Example	Verification is an example of QA	Validation/Software Testing is an example of QC
Statistical Techniques	Statistical Tools & Techniques can be applied in both QA & QC. When they are applied to processes (process inputs & operational parameters), they are called Statistical Process Control (SPC); & it becomes the part of QA.	When statistical tools & techniques are applied to finished products (process outputs), they are called as Statistical Quality Control (SQC) & comes under QC.
As a tool	QA is a managerial tool	QC is a corrective tool
Orientation	QA is process oriented	QC is product oriented

ETHICS

Rushworth Kidder states that "standard definitions of ethics have typically included such phrases as 'the science of the ideal human character' or 'the science of moral duty'".[1] The word "ethics" in English refers to several things.

It can refer to philosophical ethics or moral philosophy—a project that attempts to use reason in order to answer various kinds of ethical questions. As the English philosopher Bernard Williams writes, attempting to explain moral philosophy: "What makes an inquiry a philosophical one is reflective generality and a style of argument that claims to be rationally persuasive." And Williams describes the content of this area of inquiry as addressing the very broad question, "how one should live" Ethics can also refer to a common human ability to think about ethical problems that is not particular to philosophy. As bioethicist Larry Churchill has written: "Ethics, understood as the capacity to think critically about moral values and direct our actions in terms of such values, is a generic

human capacity. "Ethics can also be used to describe a particular person's own idiosyncratic principles or habits. For example: "Joe has strange ethics."

The English word ethics is derived from an Ancient Greek word êthikos, which means "relating to one's character." The Ancient Greek adjective êthikos is itself derived from another Greek word, the noun êthos meaning "character, disposition.