## INSTRUMENTATION

### Validation

- This is a process necessary for any analytical laboratory
- Data produced by "faulty" instruments may give the appearance of valid data
- The frequency for calibration, re-validation and testing depends on the instruments and extent of its use in the laboratory.

## SAMPLE TRACKING

Must maintain the unmistakable connection between set of analytical data and the specimen or samples from where they obtained. The original source of specimen or samples must be recorded and connected with set of analytical data. The sample or specimen should be adequately mixed or added the preservative used. This should be informed to analyst

## ANALYST CERTIFICATION

An acceptable proof of satisfactory training and competence with specific laboratory procedures must be established for each analyst. The qualification can come from education, experience or additional training, but it should be documented. The staff should be adequate. A review of all job descriptions, annually or in the event of any reorganization helps the facility management to ensure that their organization is coherent

## REPORTING

There are two basic types of report that might be produced when reporting results from analytical work

1. Analytical report; a formal report which may be issued on completion of work detailed in analytical plan.

2. Analytic results: Documents containing just the results, which is usually issued rapidly on completion of sample analysis on a given day

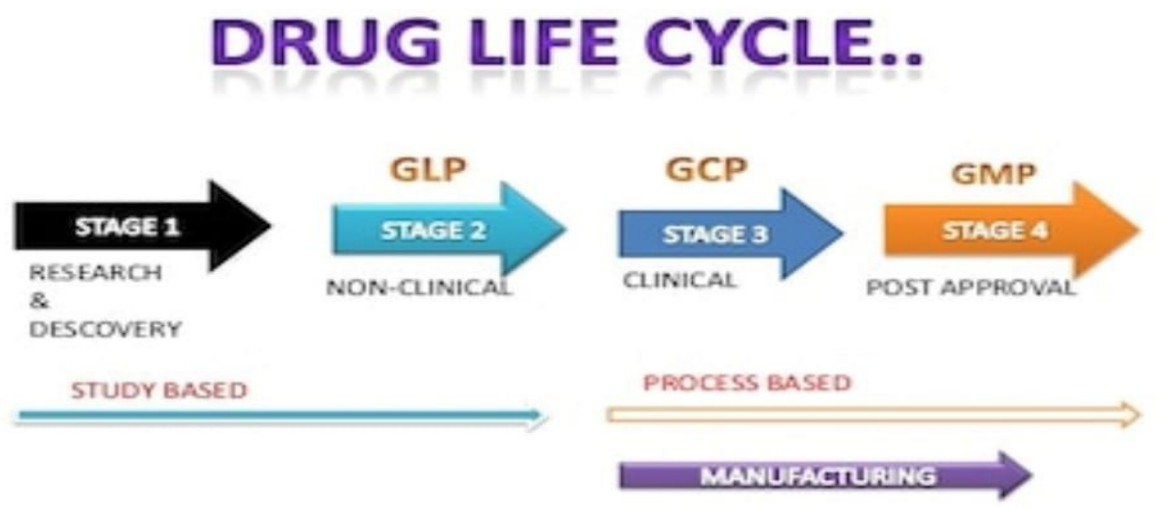
Documentation and Maintenance of Records

1. **Maintenance of all records provide documentation**

- Which may be required in the event of legal challenges due to repercussions of decisions based on the original analytical results

- General guidelines followed in regulated laboratories is to maintain records for at least five years.

• Length of time over which laboratory records should be maintained will vary with the situation




**2 Haematology Quality Assessmemt**

Laboratories must have an established quality assessment program as mandated by subpart K-Quality systems for non-wired testing of the clinical laboratory improvement amendments of 1988 (CLIA 88). A common approach to the development of a quality assessment program is to divide it into three components

(1) Pre-examination which deals with all aspects affecting the test outcome occurring prior to the testing procedure.

(2) Examination which incorporates all aspects affecting the testing procedure itself

(3) Post examination which deals with aspects affecting the test outcome occurring after the testing procedure0073

**Cytology**

Cytology deals with three types of fluids-

1) Fluid cytology

(2) Gynaec cytology

(3) Fine Needle Aspiration Cytology (FNAC).

Patient should be well informed about the procedure to be performed. If the patient is female, a female attender/staff should be accompanied with patient. Room should be well ventilated. Ancillary investigation like x-ray, sonography and MRI scan should be accompanied.

**Procedures –**

The sample received at cytology section should be well identified by noting Name, Age/Sex, Inpatient No. or Outpatient No. along with history and clinical diagnosis. The staining procedures are Papanecolou (PAP stain) or May - Granold – Giemsa (MGG) stain. The conventional PAP stain is better than rapid PAP stain. Nucleus and cytoplasmic morphology is clearer in PAP than MGG staining procedure.

2) Gynaec cytology- The test request form should include following – patient Name, Age, Sex, Inpatient No./Outpatient No., Date of specimen collection – Source of material submitted - cervical, endocervical, vaginal or other gynaecologic or nongynaecologic sites. Patient preparation - patient abstains from sexual intercourse for 48hrs prior to examination. Patient abstains from using vaginal medications, vaginal contraceptives or douches. The optimal time for PAP test is mid-cycle. Menses may interfere with test interpretation.

3) Details about gynaec specimens – Last menstrual period, pertinent clinical information – Routine examination, pregnancy, postpartum, hormone therapy, oral contraceptives, post-hysterectomy, post-menopausal or pelvic irradiation. The vaginal smear should be level the site from where the smear is obtained. The smear is fixed in ether-alcohol for 30mins followed by PAP staining procedure. Fine Needle Aspiration Cytology (FNAC) Fine Needle Aspiration Cytology (FNAC) has revolutionized the diagnostic modalities.

**Advantages**

It is cheaper than any other surgical procedure. It can be done on OPD basis. It requires minimal instruments. Disadvantages –

1) Uncooperative patient.

2) Bleeding diathesis may lead to complications like hematoma formation. If the swelling is not accessible during routine procedures, it can be done by Ultrasound guided FNAC. Patient should be well explained and the written consent to be taken before procedure. The requisition form should contain Patient’s Name, Age/Sex,

Inpatient/Outpatient Number, and Permanent Address along with Phone Number. Relevant clinical history should be given along with clinical diagnostics. Local examination of the tumor to be furnished any relevant investigations can be given. Once FNAC has been done, slides were prepared by putting one drop of aspirate on a clean, dry and dust free microscopic slide with the help of another slide and the smear were prepared. The slides with smear are fixed in either alcohol and fixed slides are used for Papanicolaou staining procedures and air dried smear are used for May-GrunwaldGiemsa staining procedures. The slides are mounted in DPX. The cytotechnician should always screen for whether material is there or not and then mount. The slides thus prepared are preserved for 3-5 years.

**MICROBIOLOGY** There is a certain element of risk in anything you do, but the potential risks in a microbiology course are greater.Person who work in a Microbiology Lab may handle infectious agents in additional to other hazards, such as chemicals and radioactive materials. There have been many documented cases of lab personnel acquiring diseases due to their work. The microbiology laboratory is a unique environment that requires special practices and containment facilities in order to properly protect persons working with micro-organisms. Safety in the laboratory is the primary concern. The three main elements of safe containment of micro-organisms are

(1) Good laboratory practices and technique,

(2) Safety equipment

(3) Facility design

**Biochemistry**

Biochemistry is an Interdisciplinary Science that integrates systematically the principles of mathematics, physics and chemistry to attempt to explain the distinctive characteristic of life processes in terms of structure function correlations. In recent years the fusion of biochemistry, cell biology and microbiology to form molecular biology has lead to spectacular advances in the understanding and control of biological processes in medicine, agriculture, pharmaceutics and the food and drink industry. Analysis means literally getting to the bottom of things, i.e. taking pieces. Hazards arise from three main basic causes: from dangerous chemicals, from infected specimens sent for analysis and from faulty apparatus and instruments

**HAZARDS FROM DANGEROUS CHEMICALS**

Injury from chemicals results from:

1. Direct contact: a. with the skin, e.g. when pouring reagents or from breakage of containers.

b. With lips or mouth when pipetting, mouth pipetting should be forbidden.

c. With the esophagus and stomach if inadvertently swallowed.

2. Damage to the lungs from inhaling vapours or less likely fine powders.

3. Toxic effects of substances absorbed from the lungs, alimentary tract or skin on other tissues such as bone marrow, liver or kidney.

**Corrosive Chemicals**

Chemical burns of the skin can be caused by strong acids or alkalis, e.g. nitric, sulphuric and hydrochloric acid, sodium and potassium hydroxide and phenol (Solid or strong solutions). Take great care when opening bottles containing strong acids or ammonia, particularly when previously unopened or if the stopper sticks. This is best done in a fume cupboard.