# Biol/Chem 4900/4912

**Forensic Internship**

**Lecture 5**

# Quality Assurance/ Quality Control

**Quality Assurance**

**A set of activities that ensures that development and/or maintenance processes are adequate in order for a system to meet its objectives.**

**Quality Control**

**A set of activities designed to evaluate the developed product.**

# Quality Assurance/ Quality Control

**Quality Assurance Examples**

- Develop and validate methods for analyzing and producing products to ensure they meet specifications and document those methods in standard operating procedures (SOPs) and production records
- Audit quality control, production and sales functions, and other records to ensure compliance with SOPs
- Assist quality control staff with troubleshooting and resolving unusual problems
- Develop quality metrics and assess trends for product or process implications
- Develop and implement improvements to existing sample and data analysis techniques
- Critically evaluate current processes and continually identify ways to save time and money without sacrificing product quality
- Investigate product, and process deviations, identify root cause, and develop corrective and preventative actions

# Quality Assurance/ Quality Control

**Quality Control Examples**

- Set up, troubleshoot, and maintain equipment, including calibration logs and training records
- Prepare samples in accordance with standard operating procedures
- Conduct analytical tests on starting materials, ingredients in-process samples and finished products, following specific protocols
- Provide timely and high-quality data reports that document test results
- Recheck out-of-specification results, using alternative methods if necessary
- Test products for long-term stability or stability under various conditions
- Interface, maintain, and populate a Laboratory Information Management System

# Quality Assurance/ Quality Control

**Why QA/QC matters**

- **Large percentage of a nations GNP (>5%)**
- **Need reliable data for political debates and agencies (i.e, global warming, fracking, contaminated water, forensic evidence)**
  - **Wrong forensic analysis – wrongful conviction**
  - **Undetected water contamination (Flint, Michigan, files false reports)**
  - **Local pharmaceutical laboratories (raided FBI)**

Chemist must choose the correct analytical method or instrument to solve a problem.

In order to do this, the chemist must understand a wide variety of methods and instruments and the limitations of each one.

To correctly select the method or instrument, the problem must be clearly defined.

1. What accuracy is required?
2. How much sample is available?
3. What is the concentration range of the analyte?
4. What components of the sample will cause interference?
5. What are the physical and chemical properties of the sample matrix?
6. How many samples are to be analyzed?

# Quality Assurance/ Quality Control

**Measurements made in one laboratory must be repeatable in another laboratory.**

**How do we accomplish this?**

- **Need standards or Certified Reference Materials (CRMs).**
- **Need known calibration procedures**
- **Need common agreed upon procedures**

# Quality Assurance/ Quality Control

**Standards have been developed by a variety of national, international, and businesses.**

**Standards can refer to physical components or operating processes.**

**Physical:**

- **An Fe solution standard for AAS**
- **$LaB_6$ powder for XRD**
- **A calibrated 1 gr weight for a balance**

# Quality Assurance/ Quality Control

**Standards have been developed by a variety of national, international, and businesses.**

**Standards can refer to physical components or operating processes.**

**Process:**

- **International Standard, ISO 90001:2000**
  - **Quality Management Systems - Requirements**
- **Good Laboratory Practice (GLP)**
- **Am National Accreditation Board (ANAB)(ASCLD)**

# Quality Assurance/ Quality Control

**International Standard, ISO 90001:2000**

**Gives the requirements for a quality management system**

**Organization for Economic Co-operation and Development (OECD)**

**Developed GLP principles to promote development of quality test data**

# Quality Assurance/ Quality Control

**Quality assurance of analytical measurements results in a system comprising 5 independent elements.**

- **Assurance of measuring traceability of the obtained results**
- **Evaluation of uncertainty of the results**
- **Use of certified reference materials**
- **Participation in various interlaboratory comparisons**
- **Validation of the applied analytical procedures**

# Quality Assurance/ Quality Control

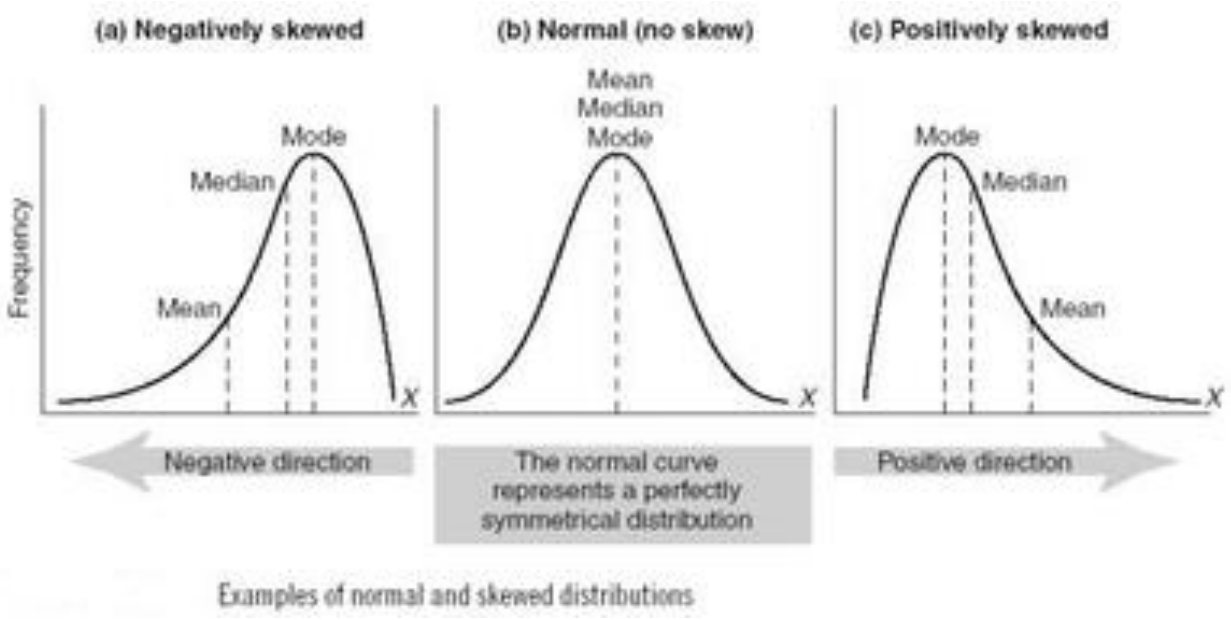
**To excel at QA/QC must understand and use statistical analysis.**

- **Correct equations must be used for the particular circumstance**
- **Review basic statistical analysis**

# Statistics

**Distribution of measurements**

- **Normal distribution (Gaussian distribution)**
  - **Characterized by an expected value, a median, and a variance**




Examples of normal and skewed distributions

# Statistics

**Since we never have the entire distribution but a sample of the population, statistical parameters are used to describe the sample, these parameters are divided into basic groups:**

- **Measure of location**
- **Measure of statistical dispersion**
- **Measure of asymmetry**

# Statistics

## Measure of location

- One value to represent the values of the population
- Can be mean, mode, median, etc

# Measure of dispersion

- To determine differences between individual observations and mean value
- Can be range, variance, standard deviation, average deviation, coefficient of variance, etc

# Statistics

## Measure of asymmetry

- An absolute value expressed as the difference between an arithmetic mean and a mode.
- Different instrumentation methods may have own unique approach, i.e., XRD (pearson VII), XPS, chromatography

**TABLE 1-3 Numerical Criteria for Selecting Analytical Methods**

| Criterion | Figure of Merit |
|---|---|
| 1. Precision | Absolute standard deviation, relative standard deviation, coefficient of variation, variance |
| 2. Bias | Absolute systematic error, relative systematic error |
| 3. Sensitivity | Calibration sensitivity, analytical sensitivity |
| 4. Detection limit | Blank plus three times standard deviation of a blank |
| 5. Concentration range | Concentration limit of quantitation (LOQ) to concentration limit of linearity (LOL) |
| 6. Selectivity | Coefficient of selectivity |

# Precision

**TABLE 1-5** Figures of Merit for Precision of Analytical Methods

| Terms | Definition* |
|---|---|
| Absolute standard deviation, $s$ | $s = \sqrt{\dfrac{\sum_{i=1}^{N}(x_i - \bar{x})^2}{N-1}}$ |
| Relative standard deviation (RSD) | $\text{RSD} = \dfrac{s}{\bar{x}}$ |
| Standard deviation of the mean, $s_m$ | $s_m = s/\sqrt{N}$ |
| Coefficient of variation, CV | $\text{CV} = \dfrac{s}{x} \times 100\%$ |
| Variance | $s^2$ |

*$x_i$ = numerical value of the $i$th measurement.

$\bar{x}$ = mean of $N$ measurements = $\dfrac{\sum_{i=1}^{N} x_i}{N}$

# Bias

**Bias = $\mu - x_t$**

**$\mu$ - population mean**

**$x_t$ - true concentration**

# Bias

**Sample – finite number of experimental observations (all the replicate).**

**The sample is a fraction of the infinite number of observations possible. (i.e. 50 measurements).**

**This infinite number of observations (measurements) is called the population or universe of data.**

# Sensitivity

**Instruments or methods ability to discriminate between small differences in analyte concentration.**

# Selectivity

**Degree to which the method is free from interference by other species contained in the sample matrix.**

# Detection Limit

**Minimum concentration or mass of analyte that can be detected at a known confidence level.**

# Dynamic Range

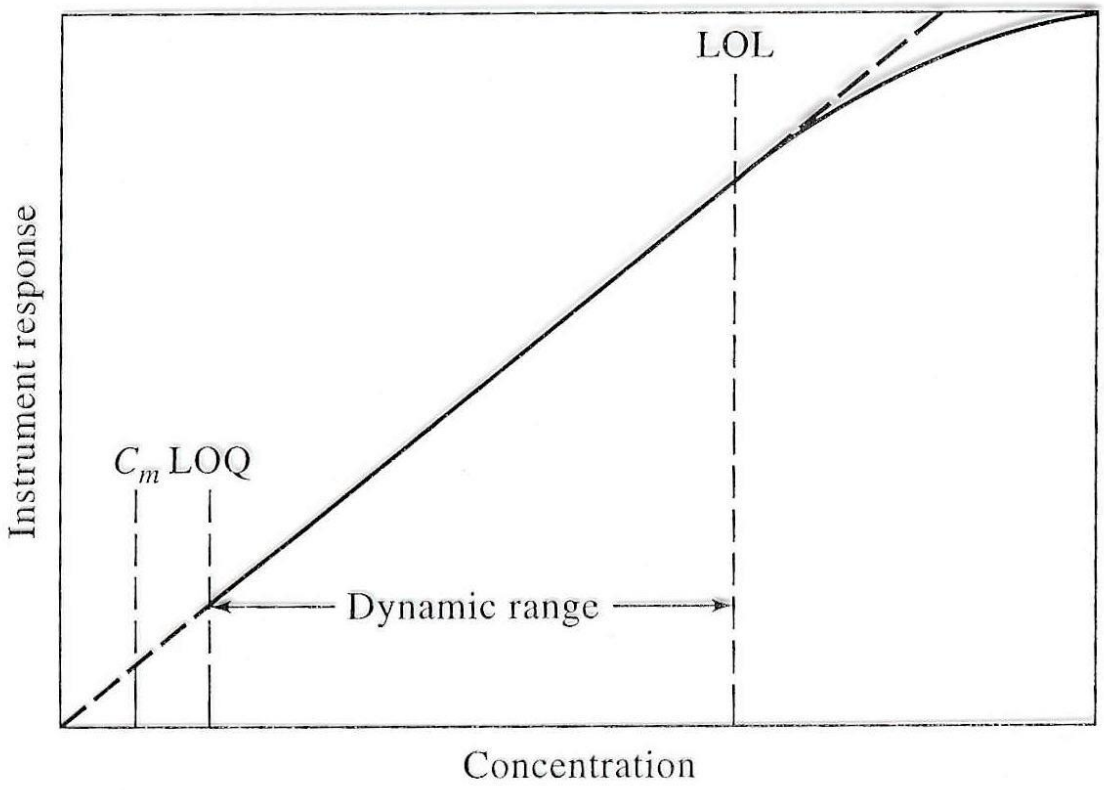



**Figure 1-7** Useful range of an analytical method. LOQ = limit of quantitative measurement; LOL = limit of linear response.

# Assignment

- Review Statistics
- Homework 4 & 5
- Homework 6 - Stats
- Read: QA/QC topic Ch. 1 and 2 of Prichard