



Club Founder
Dr. Mahmoud Bahgat



International Factories Club

**QUALITY CONTROL ROLE
& ISO 17025 ACCREDITATION**

**Online zoom
10 pm KSA Egy - 11 pm UAE**



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SATURDAY 26th OCT. 2024



Co-Founder & Host:
Dr. Ahmed Rafat





Dr. Mohamed Shawky

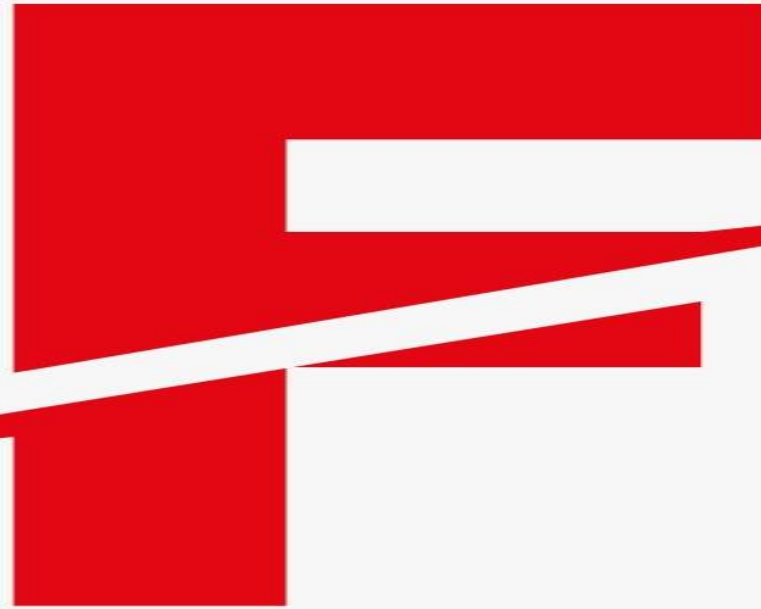
Education:

- B.Sc. of Pharmacy, Faculty of Pharmacy, Ain Shams University, Very Good, May 2001.
- M.B.A. From . AASTMT - 2022
- MQM [master in Quality Management 2017, Six sigma black belt – CQM – Internal quality Auditing certificates

Experience:

- 02/2022 – Now: Technical Manager in Western Pharmaceutical
- 01/2021 – 02/2022: Plant Manager of Dulex Lab Food and Supplement Industrial
- 06/2016 – 01/2021: Plant Manager of Uniswab Pharmaceuticals
- 06/2014 – 06/2016: Quality control Manager for Western Pharmaceuticals
- 06/2006 – 06/2014: Quality control Assistant Manager in western Pharmaceutical

International



Factories Club

Sharpen your skills



QUALITY CONTROL ROLE & ISO 17025 ACCREDITATION

By: Dr. Mohamed Shawky



QUALITY CONTROL ROLE



What is Quality Control [QC]?

Quality control, or QC, is the process that businesses use to ensure that a product or service adheres to a predefined set of quality standards or meets the requirements of customers or clients.

Which inspects and/or testing products before, during and after the manufacturing Process with any related items to ensure that products align with company standards

Quality Control vs. Quality Assurance

While some people use the terms "quality control" and "quality assurance" interchangeably and the processes share some related activities, there are different definitions for each. [Quality assurance](#), or QA, focuses on providing confidence that the product or service meets the company's quality requirements, and it includes all the activities that the company has implemented to provide such confidence. Quality control, however, refers to the inspection aspect of quality management, specifically the techniques and activities used to meet the quality requirements.

Why is Quality Control Needed?

1. Customer Satisfaction: Quality Control is indispensable for ensuring that the final products or services meet or exceed customer expectations. By maintaining high quality, organizations can enhance customer satisfaction, build trust, and foster long-term relationships. Satisfied customers are more likely to be repeat buyers and advocates for the brand.

2. Compliance with Standards: Quality Control is needed to ensure that products or services adhere to industry-specific standards and regulations. Meeting these standards not only reflects a commitment to quality but also helps in avoiding legal issues and regulatory penalties, ensuring ethical business practices.

Why is Quality Control Needed?

3. Risk Mitigation: Another crucial is the role of Quality Control in risk reduction. It helps in identifying and rectifying defects early in the production process, minimizing the probability of costly recalls, product failures, and customer complaints. This, in turn, safeguards the reputation of the company.

4. Cost Control: Quality Control is essential for controlling costs associated with defects and errors. By detecting and addressing issues early on, organizations can avoid expensive rework, minimize waste, and optimize resource utilization, contributing to overall operational efficiency.

5. Continuous Improvement: Quality Control is necessary to instill a culture of continuous improvement within an organization. Through the identification of areas for enhancement in processes and products, Quality Control promotes ongoing learning and adaptation, fostering innovation and competitiveness.

Why is Quality Control Important?

- 1. Brand Reputation:** Maintaining a high level of quality through Quality Control practices contributes significantly to building and sustaining a positive brand reputation. Consistency in delivering reliable products or services enhances consumer trust, leading to brand loyalty and positive word-of-mouth.
- 2. Customer Loyalty:** Quality Control is important for fostering customer loyalty. When customers experience consistent quality, they are more likely to remain loyal to a brand. Loyalty, in turn, results in repeat business and increased customer lifetime value.
- 3. Competitive Advantage:** Quality Control provides a distinct competitive advantage in the market. Organizations that prioritize and achieve superior quality stand out from their competitors, attracting discerning customers who are willing to pay a premium for reliability and excellence.

Why is Quality Control Important?

4. Risk Mitigation: Quality Control is essential for risk mitigation. By identifying and addressing potential issues before they escalate, organizations can prevent reputational damage, legal complications, and financial losses. A robust Quality Control system acts as a safety net against uncertainties.

5. Continuous Improvement: Quality Control contributes to a culture of continuous improvement by systematically analyzing processes and outputs. This ongoing evaluation and refinement result in increased efficiency, reduced waste, and the ability to adapt to changing market conditions.

Quality Control Process

- 1. Define Standards:** Establishing clear and detailed quality standards is the initial step in the Quality Control (QC) process. These standards serve as benchmarks against which products or services are mostly evaluated. Defining precise criteria ensures a common understanding within the organization and provides a basis for consistent quality assessment.
- 2. Plan Quality Control Activities:** Once standards are in place, a comprehensive plan is developed to outline the specific QC activities that need to be conducted. This plan includes the frequency of inspections, testing protocols, and the responsibilities of various team members. Planning ensures that QC efforts are systematic, thorough, and aligned with organizational goals.
- 3. Execute Quality Control Activities:** The planned QC activities are implemented during the production process. This involves inspections, tests, and measurements conducted according to the predetermined plan. Regular and systematic execution of these activities helps in identifying deviations from established standards and ensures that quality is monitored throughout the entire production cycle.

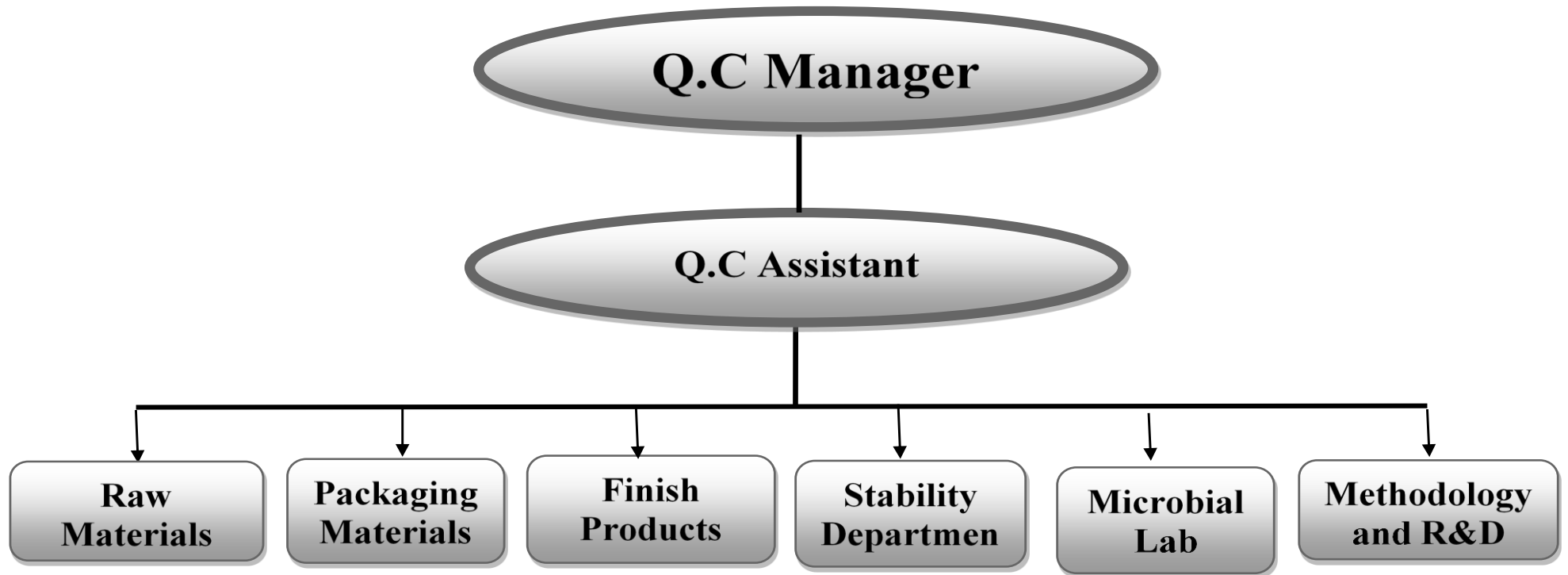


Quality Control Process

4. Evaluate Results: Data collected from inspections and tests are thoroughly evaluated to determine whether the products or services meet the defined quality standards. This evaluation may involve statistical analysis, trend identification, and comparison against benchmarks. Understanding the results allows for informed decision-making regarding the acceptability of the output.

5. Take Corrective Action: Based on the evaluation, any identified deviations or non-conformities trigger corrective actions. These actions can range from immediate adjustments in the production process to long-term process improvements. The goal is not only to address current issues but also to prevent their recurrence in future productions.

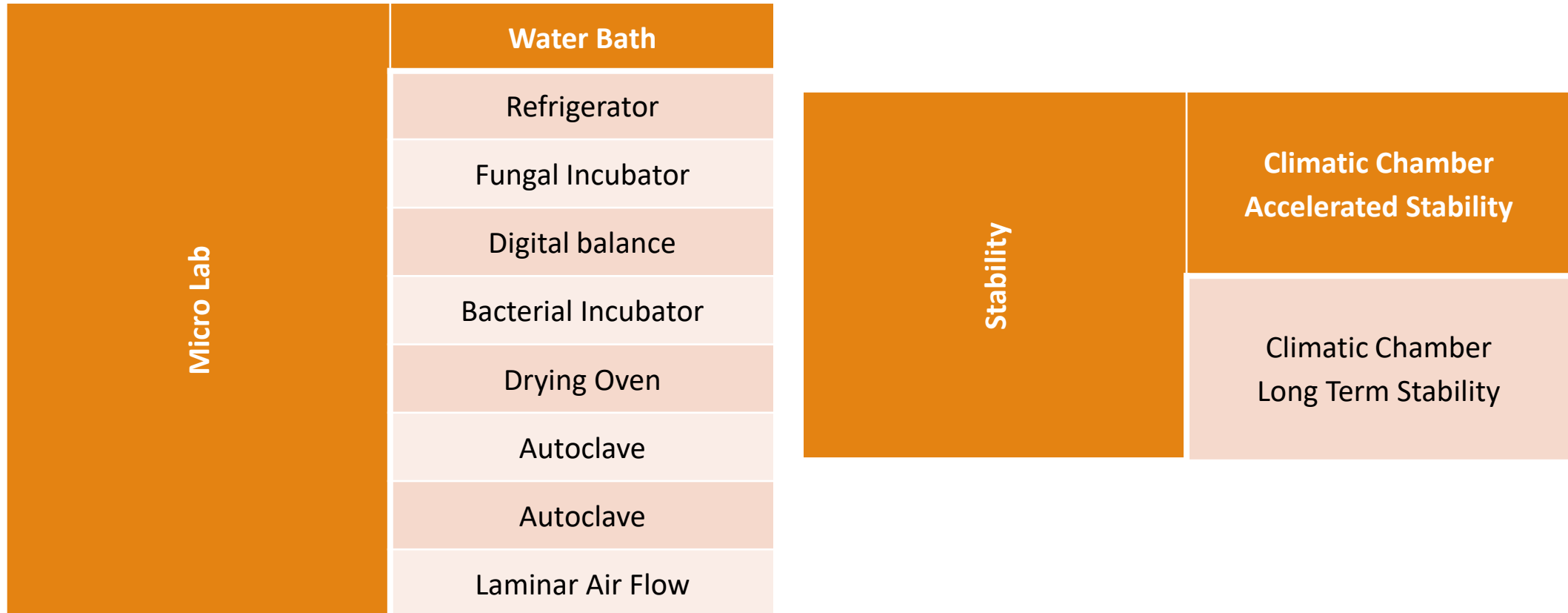
Quality Control Organogram



Quality Control Instruments

Q.C Lab	Equipment		Equipment
Instrumental Lab	HPLC	Chemical lab	Karl Fisher
	UV-VIS T80		Drying Oven
	Dissolution Tester		Water Bath
	Disintegration Tester		Muffle Furnace
	Viscometer		Conduct meter
	Hardness Tester		PH meter
	Friability Tester		Sonicator
			Hot Plate& Stirrer
			Vortex
			Fuming cabinet
			Digital balance

Quality Control Instruments



ISO 17025 ACCREDITATION

ISO/IEC 17025:2017

General requirements for the competence of testing and calibration laboratories

What is ISO/IEC 17025?

ISO/IEC 17025 is the international standard for testing and calibration laboratories. It sets out requirements for the competence, impartiality, and consistent operation of laboratories, ensuring the accuracy and reliability of their testing and calibration results

Why is ISO/IEC 17025 important?

This standard is vital for laboratories as it enhances the **credibility of their testing and calibration work**, fostering trust among clients and regulatory authorities. Compliance with ISO/IEC 17025 demonstrates a laboratory's **commitment to quality, technical proficiency, and scientific rigor**.

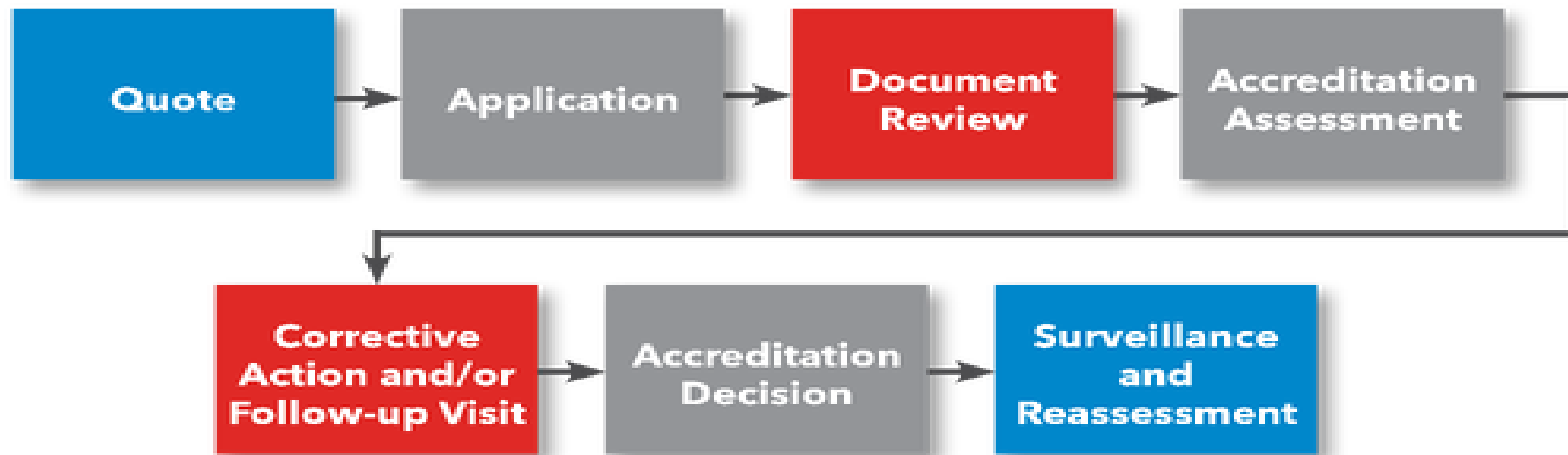
Benefits of ISO/IEC 17025

- * Establishes a global benchmark for **laboratory quality and reliability**
- * Enhances **confidence in test and calibration results**, both domestically and internationally
- * Facilitates **cooperation between laboratories and other bodies** by generating wider acceptance of results
- * **Reduces the need for retesting**, saving time and resources

Structure of ISO/IEC 17025

- | | |
|----------------------------|-----------------------------------|
| 1. Scope | 6. Resource requirements |
| 2. Normative references | 7. Process requirements |
| 3. Terms and definitions | 8. Management requirements |
| 4. General requirements | Annex A Metrological traceability |
| 5. Structural requirements | Annex B Management system |

Steps to ISO/IEC 17025 Testing Laboratory Accreditation



Steps to ISO/IEC 17025 Testing Laboratory Accreditation

- Quote
- Application
- Document Review
- Accreditation Assessment
- Corrective Action
- Accreditation Decision
- Surveillance and Reassessment