# Internal Quality Audits

## Jacki Fee

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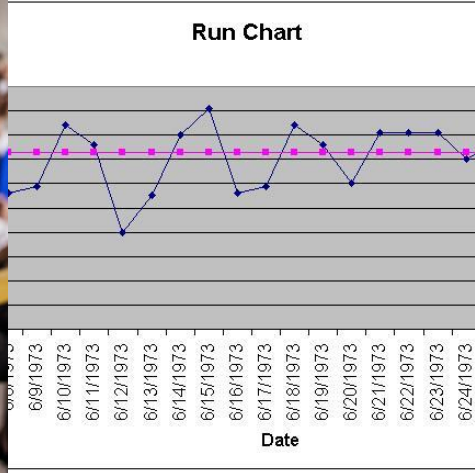
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# Quality Management Systems



**Design and Build**

**Deploy**

**Control and Measure**

**Review and Improve**

# Auditing

## Internal audit (first person)

- performed within an organization to measure its strengths and weaknesses against its own procedures or methods
- performed against external standards adopted by (voluntary) or imposed on (mandatory) the organization
- conducted by auditors who are employed by the organization being audited but who have no vested interest in the audit results of the area being audited.

## External audit (second person)

- performed on a supplier by a customer or by a contracted organization on behalf of a customer
- a contract is in place, and the goods or services are being, or will be, delivered
- more formal than first-party audits because audit results could influence the customer's purchasing decisions

## Professional Independent Audit (third person)

- performed by an audit organization independent of the customer-supplier relationship and is free of any conflict of interest
- independence of the audit organization is a key component of a third-party audit
- may result in certification, registration, recognition, an award, license approval, a citation, a fine, or a penalty issued by the third-party organization or an interested party.

# What is an Internal Quality Audit?

Internal audits assist in monitoring the system and checking that it is meeting conformance and standards.

The goal of an internal audit is to gather information about the effectiveness of the quality system.

An internal audit is performed by someone within the company.

# Three Types of Internal Audits

**Process Audit**

Conformances

Resources

Effectiveness

**Product Audit**

Specifications

Customer Requirements

Performance Standards

**System Audit**

Company policies

Contract Commitments

Compliance

# How to set up an internal audit?

Schedule audits

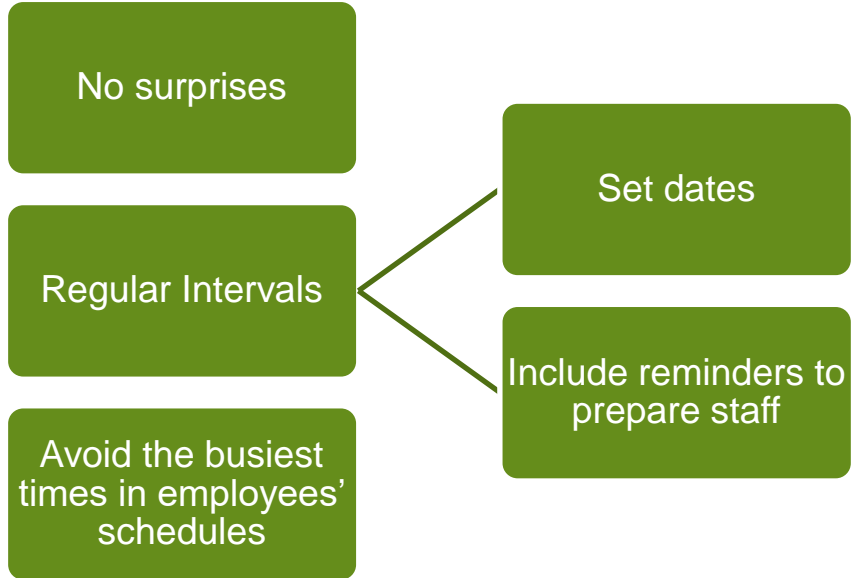Determine the scope

Plan the audit

Conduct the audit

Report audit findings

Develop goals and recommendations for improvement

# Schedule the Audit

No surprises

Regular Intervals

Set dates

Include reminders to prepare staff

Avoid the busiest times in employees' schedules

# Determine the scope

- The Quality Manager and team determine criteria for audit
- Focus on entire workflow and risk areas
- Keep criteria consistent
- Ensure flexibility

# Plan the audit

**1** → **2** → **3** → **4**

**1** Appoint an auditor

-Internal employee familiar with process

**2** Advise employees being audited

-What will be audited and how

**3** Identify tasks and processes

-Be transparent about content of audit

**4** Establish Audit Format

-Document review; task demos; interviews

PLAN

# Conduct the audit

Begin with a pre-audit meeting to communicate objectives

Eliminate fears; encourage suggestions for improvement

Allow enough time to fully complete the objectives

Wrap up and review

# Report the audit findings

- Auditor's report

- Track quality and performance

- Communicate to management and to entire team

- Highlight successes

- Show improvements from last audit

# Develop goals and recommendations for improvement

- Show staff internal audits matter by acting on findings

- Focus on one or two areas at a time

- Regularly assess impact of changes based on audit results

| Audit finding | Potential corrective actions |
|---|---|
| Lack of reagent bridging SOP | • Develop SOP for parallel testing to ensure that all reagents used in kits perform equivalently across rounds |
| Lack of/inconsistent assay training | • Develop SOP for training new employees and employees that have taken an extended absence<br>• Develop training matrix stating required SOPs |
| No internal competency testing | • Develop program to assess each operator's ability to perform an assay |

# Example



The fermentation lab will have an internal audit on Wednesday, October 19th at 10:00am (schedule)
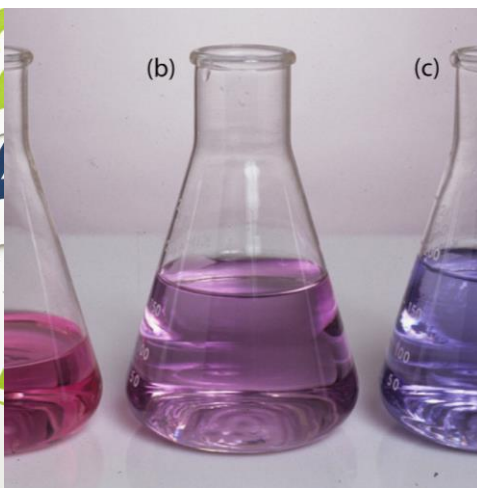
The audit will review and examine acidity titration technique and all calibration records. (scope)

The audit team will plan to review technicians on shift 10/19 completing an acidity titrations and will review the calibration records and LIMS entries. (plan & conduct)

Report all technician followed the SOP. exhibited good technique and entered daily information to LIMS.  The calibration records found 2 missing entries. (report)

# Example

## Goals and Recommendations

- Goal is 100% compliance with calibration records entry

- Recommend review with all technicians at shift exchange

- Gather feedback from crews to improve compliance with data entry

- Revisit at quarterly meeting and deliver improvement story prior to next scheduled audit

# Summary

Internal auditing is a part of a Quality Management System

Internal auditing should be performed on a regular cadence

Measure, control and analyze both strengths and weaknesses

Focus on one or two areas at a time

Act on findings, show improvements and celebrate successes