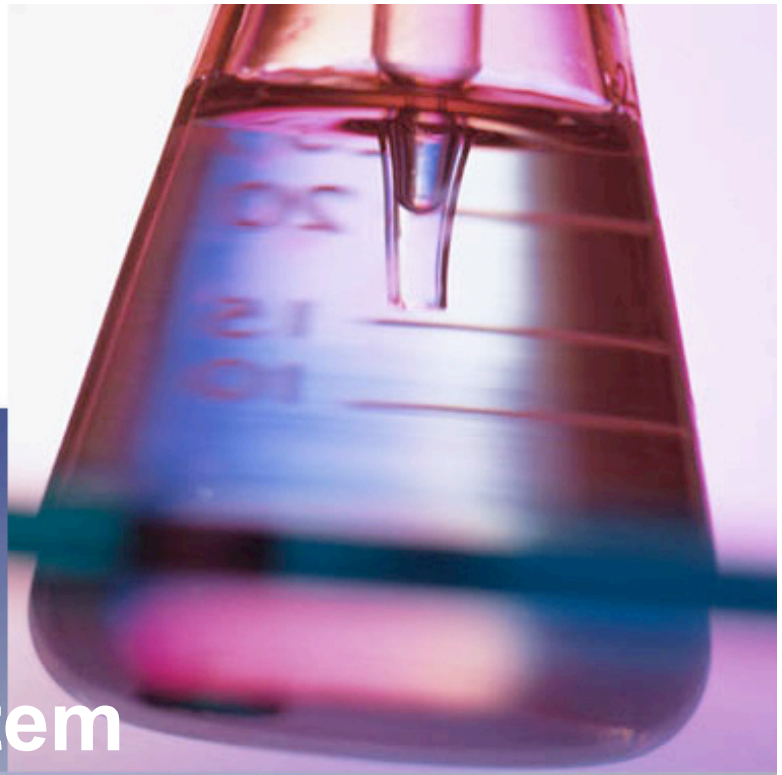
Implementation of CAREC Laboratory Quality Management System



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OBJECTIVES

1. Structure of ISO 15189
2. Structure of CAREC Laboratory QMS
3. Plan
4. Challenges
5. Progress
6. Next steps

4.0 Management Requirements

- 4.1 Organization and Management
- 4.2 Quality Management System (QMS)
- 4.3 Document Control
- 4.4 Review of Contracts
- 4.5 Examination by Referral Laboratories
- 4.6 External Service and Supplies
- 4.7 Advisory Services
- 4.8 Resolution of Complaints
- 4.9 Identification and Control of Nonconformities
- 4.10 Corrective Action
- 4.11 Preventive Action
- 4.12 Continual Improvement
- 4.13 Quality and Technical Records
- 4.14 Internal Audits
- 4.15 Management Review

5 Technical Requirements

- 5.1 Personnel
- 5.2 Accommodation and Environmental conditions
- 5.3 Laboratory Equipment
- 5.4 Pre-examination Procedures
- 5.5 Examination Procedures
- 5.6 Assuring quality of Examination Procedures
- 5.7 Post-examination Procedures
- 5.8 Reporting of Results

Structure of the QMS – 12 Quality System Essentials

- 01 - Organization
- 02 - Personnel
- 03 - Equipment
- 04 - Purchasing/Inventory
- 05 - Process Control - Pre Analytical
  - Analytical
  - Post Analytical
- 06 - Documents/Records
- 07 - Occurrence Management
- 08 - Internal Assessment
- 09 - Process Improvement
- 10 - Service and Satisfaction
- 11 - Information Management
- 12 - Facilities and Safety

Relationship of QSE to ISO 15189

Section in the Quality Manual	Section of ISO 15189:2007	
QSE 01 - Organization	**4.1**	Organization and management
	4.2	Quality management system
	4.15	Management review
	Annex C.1	General ethics
	Annex C.10	Financial arrangements
QSE 02 - Personnel	**5.1**	Personnel
QSE 03 - Equipment	**5.3**	Laboratory equipment
	Annex B.1	General
	Annex B.7	Hardware and software
	Annex B.8	System maintenance

Relationship of QSE to ISO 15189

Section in the Quality Manual	Section of ISO 15189:2007	
QSE 04 – Purchasing and Inventory	**4.4**	Review of requests and contracts
	4.5	Examination by referral laboratories
	4.6	External services and supplies
QSE 05 – Process Control	**5.4**	Pre-examination procedures
	5.5	Examination procedures
	5.6	Assuring the quality of examination procedures
	5.7	Post examination process
	5.8	Reporting of results
	Annex C.5	Examination, Reporting results
	Annex C.6	

Relationship of QSE to ISO 15189

Section in the Quality Manual	Section of ISO 15189:2007	
QSE 06 – Documents and Records	**4.3** **4.13** **Annex C.7**	Document control Quality and technical records Storage/retention of medical records
QSE 07 – Occurrence Management	**4.8** **4.9** **4.10**	Resolution of complaints Identification and control of nonconformities Corrective action
QSE 08 - Assessment	**4.11** **4.14**	Preventive action Internal audits

Relationship of QSE to ISO 15189

Section in the Quality Manual	Section of ISO 15189:2007	
QSE 09 – Process Improvement	**4.12**	Continual improvement
QSE 10 – Service and Satisfaction	**4.7**	Advisory services
	Annex C.2	General principles
QSE 11 – Information Management	**Annex B.4**	System security
	Annex B.5	Data entry and reports
	Annex B.6	Data retrieval and storage
	Annex C.3	Information
	Annex C.4	Consent
	Annex C.8	Access to laboratory records
	Annex C.9	Other purposes
QSE 12 - Facilities and Safety	**5.2**	Accommodation and environmental conditions
	Annex B.2	Environment

Plan

1. Get commitment from top management
2. Review current regulations
3. Communicate your intent to all staff
4. Create a quality unit and identify a responsible person
5. Perform a gap analysis
6. Develop an implementation plan
7. Set policies - Quality Policy (Commitment to Quality), - Mission/Vision
8. Review Quality Manual – a compendium of policies – originally an outline
9. Review the format for documents – SOPs – Technical and Administrative and Forms

Plan

10. Train staff in documentation

11. Map processes as they are now

12. Determine the gaps in processes and associated documentation

13. Plan, document the new processes and associated procedures
    - QC programme
    - Safety programme (implement biosafety regulations)
    - Management of equipment
    - Information management

14. Develop an audit mechanism and measure the effectiveness of processes and procedures

15. If problems are identified, modify the processes and return to Step 13 (Continuous Improvement)

16. Schedule an external audit

CHALLENGES

- Implement then document vs, document then implement
- Several changes in management in recent history
- Major revision in mode of operation in the lab as well as the Centre
- Competing job obligations
- Varied support from general staff
- Lack of understanding regarding requirements
- Lack of co-ordination between laboratory departments
- Lack of involvement from other divisions
    - HR
    - Procurement
    - Maintenance

PROGRESS

01 – Organization – 80% Completed
– Quality Manual completed – under review
- Several SOPs written e.g., Management Review – to be implemented

02 – Personnel – 80% Completed
- QM to meet with HR

03 – Equipment – 90% Completed
– QM works very closely with the General Service Operations co-ordinator who has the majority responsibility for this area
– Equipment SOPs to be completed

04 - Purchasing/Inventory – 90% Completed

05 - Process Control
- Pre Analytical - Completed – SOP to be reviewed
- Analytical – 80% Completed – SOP under review
- Post Analytical – Completed – SOP to be reviewed

PROGRESS

06 - Documents/Records – 80% Completed
- SOP format developed – Under review

07 - Occurrence Management – To be completed

08 - Internal Assessment
- SOPs – Internal audit and PT developed

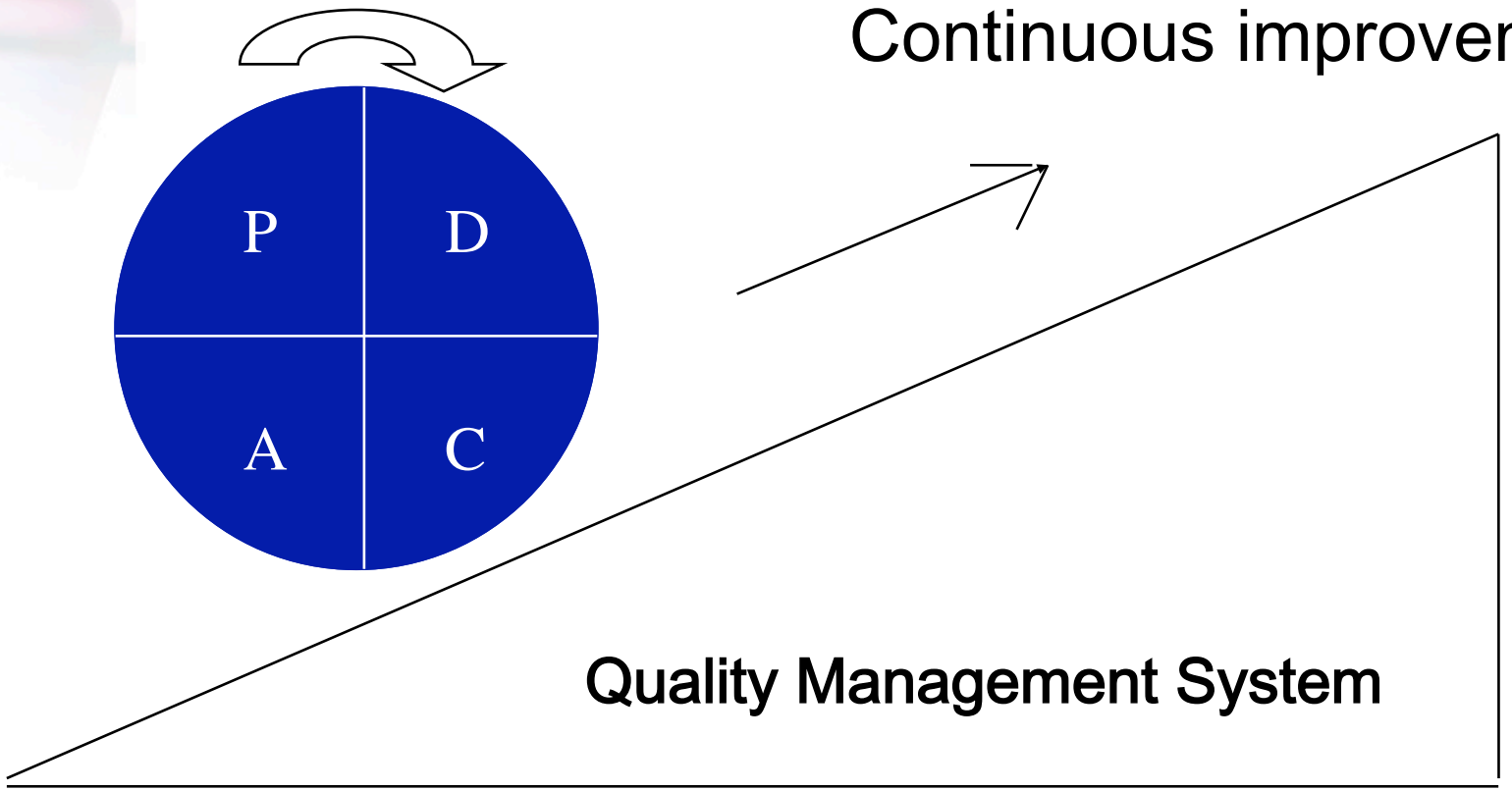
09 - Process Improvement – To be completed

10 - Service and Satisfaction – To be completed

11 - Information Management – To be completed

12 - Facilities and Safety – 80% completed
- Safety Manual complete and under review

QUALITY CIRCLE

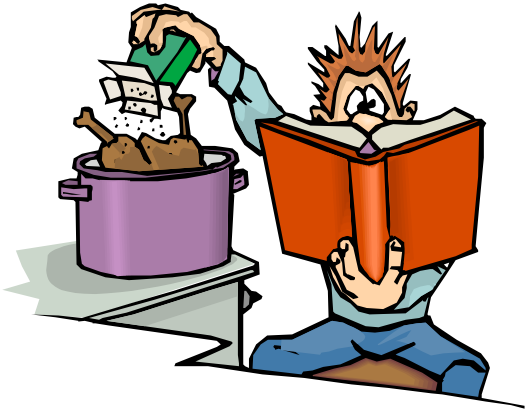


P = Plan, D = Do, C = Check, A = Act

Why QMS?

Many believe that "following the method" ensures accurate data.
HOWEVER a method is only one component of generating reliable results.

Consider - chefs, in two kitchens, using the same recipe . . .



Both cooks, however, may be following the same "method".

MAKE QUALITY THE MEANS TO THE END

Tabasco, May 2007

Thanks to Dr. Jean-Marc Gabastou