

QUALITY MANUAL: MODEL ACCORDING EC4 ESSENTIAL CRITERIA

1. GENERAL INFORMATION

1.5. RESEARCH AND DEVELOPMENT

AUTHOR	VERSION	APPROVED BY	DATE	

CIRCULATION LIST:	NAME	POSITION

CODE) DOCUMENT: QMM01	(CHAPTER TITLE):	(INSTITUTION): EC4 UNIVERSITY HOSPITAL
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1. INTRODUCTION

The laboratory is recommended to take part regularly in research projects concerning development or evaluation of new methods and methodologies.

Larger laboratories should be involved in research

If applicable the hospital laboratory should give support to clinical research

The laboratory should give analytical and consulting support to clinical trials (1)

1.1. SCOPE

1.2. AIMS

To fulfil the requirements of the following clauses:

ISO 15189	ISO 9000: 2000	ISO 17025
5.1. Personnel.5.1.4.(m)	8. Measurement, analysis and improvement. 8.1. Planning 8. Measurement, analysis 8.2.3. Measurement and process monitoring 8.2.4. Measurement and product monitoring 8.4. Data analysis	5.4. Test and calibration methods including sampling. 5.4. Test and calibration methods including sampling 5.4.3. Laboratory-developed methods.

1.3. PUBLICATION CREDITS

EC4 WG

1.4. REFERENCES

1. Jansen RTP, Blaton V, Burnett D, Huismann W, Queraltó JM, Zérah S, Allman B. European Communities Confederation of Clinical Chemistry: Essential criteria for quality systems of medical laboratories. Eur J Clin Chem Clin Biochem 1997; 35(2): 123-132.
2. Jansen RTP, Bank CMC, Huisman W, Penders TJ. NVKC Model quality manual. 2nd rev. Ed. Utrecht: NVKC 1996.
3. ISO/TC 212/WG 1., Quality management in the clinical laboratory. Revised ISO/CD 15189, Quality management in the medical laboratory (December 1998), 5.1.4.
4. ISO, IEC. General requirements for the competence of calibration and testing and calibration laboratories. DIS 17025. Geneva: ISO, 1998; 5.4., 5.4.3.
5. ISO. DIS Quality management systems – Requirements. ISO 9000. Geneva: ISO, 2000; 8.1., 8.2.1., 8.2.1.4., 8.4.
6. Plebani M. Sistema qualità de accreditamento nel laboratorio clinico (II). Aspetti applicativi. Milano: Biomedica, 1999; 21-22.

1.4. RELATED DOCUMENTS

1.5.1. General Information. Research and Development. Trial Protocols File Index

1.5.2. General Information. Research and Development. Research and Development Annual Report

1.5. ABBREVIATIONS

1.6. RELATED DEFINITIONS

clinical/medical trial protocol: written procedure which contains all the details about an experimental procedure.

clinical/medical trials: any experimental action or process undertaken to discover something not yet known or to demonstrate something known.

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Medical Ethical Review Committee: Institution body which has the responsibility to review, authorised and monitor experimental projects,

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2. MEDICAL RESEARCH

2.1. GENERAL

Applied medical research in the fields of:

Pharmacogenetics
Diabetes
Molecular biology of colon and pancreas cancer
...

is conducted at the laboratory.

The laboratory's Clinical Chemists endeavour to publish at least one article a year in an international peer-reviewed journal of Clinical Chemistry, and one in a national journal.

The clinical chemists try to organise applied clinical trials with medicinal products at the institution.

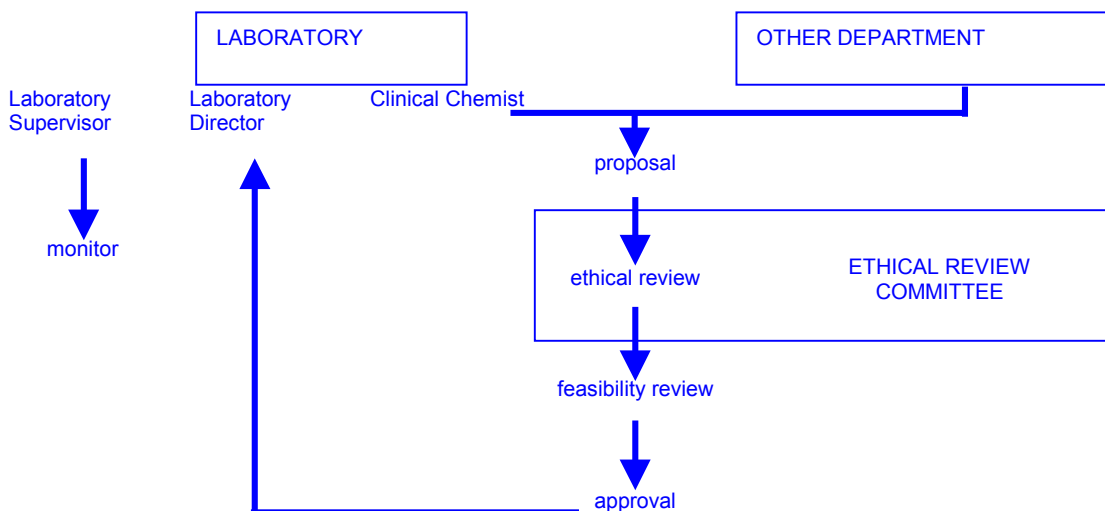
With a view to remaining abreast of developments within the discipline, the staff attend or follow carefully selected congresses, symposia and in-service training courses, particularly those organised under the auspices of the national Society for Clinical Chemistry, or the IFCC, the International Federation of Clinical Chemistry.

A register of scientific activities is maintained and updated (see 2.3.)

2.2. MEDICINAL PRODUCTS TRIALS

The clinical chemists decide whether the laboratory will participate in a medical product trial and what form such participation should take.

A research protocol is submitted to the *Medical Ethical Review Committee* before any medical product trial is conducted at the Institution.



If the *Medical Ethical Review Committee* approves a proposed trial, the directors discuss the organisational feasibility with the department involved. If it is decided that the trial is feasible, the Laboratory Director approves it.

Located in the Administration Area.

The Laboratory Supervisor monitors the status of trials in progress and ensures that the necessary documents (certification details, reference values, costs, etc.) are sent to the company on whose behalf the trial is being conducted

2.3. OTHER RESEARCH AND DEVELOPMENT

A 1.5.2. Research and Development Annual Report is prepared and updated annually by the Laboratory Director.

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This report is filed in the Administrative Area, and can be available to all the personnel.

The *1.5.2. Research and Development Annual Report* contains all the scientific production of the Laboratory: publications, communications, books, lectures, etc. In each item, it is specified:

- If it is a project lead by the Laboratory or by other department
- The responsible of the project
- The team
- The financial aspects

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