

Quality Assurance at the University of Barcelona: The Quality Research Service

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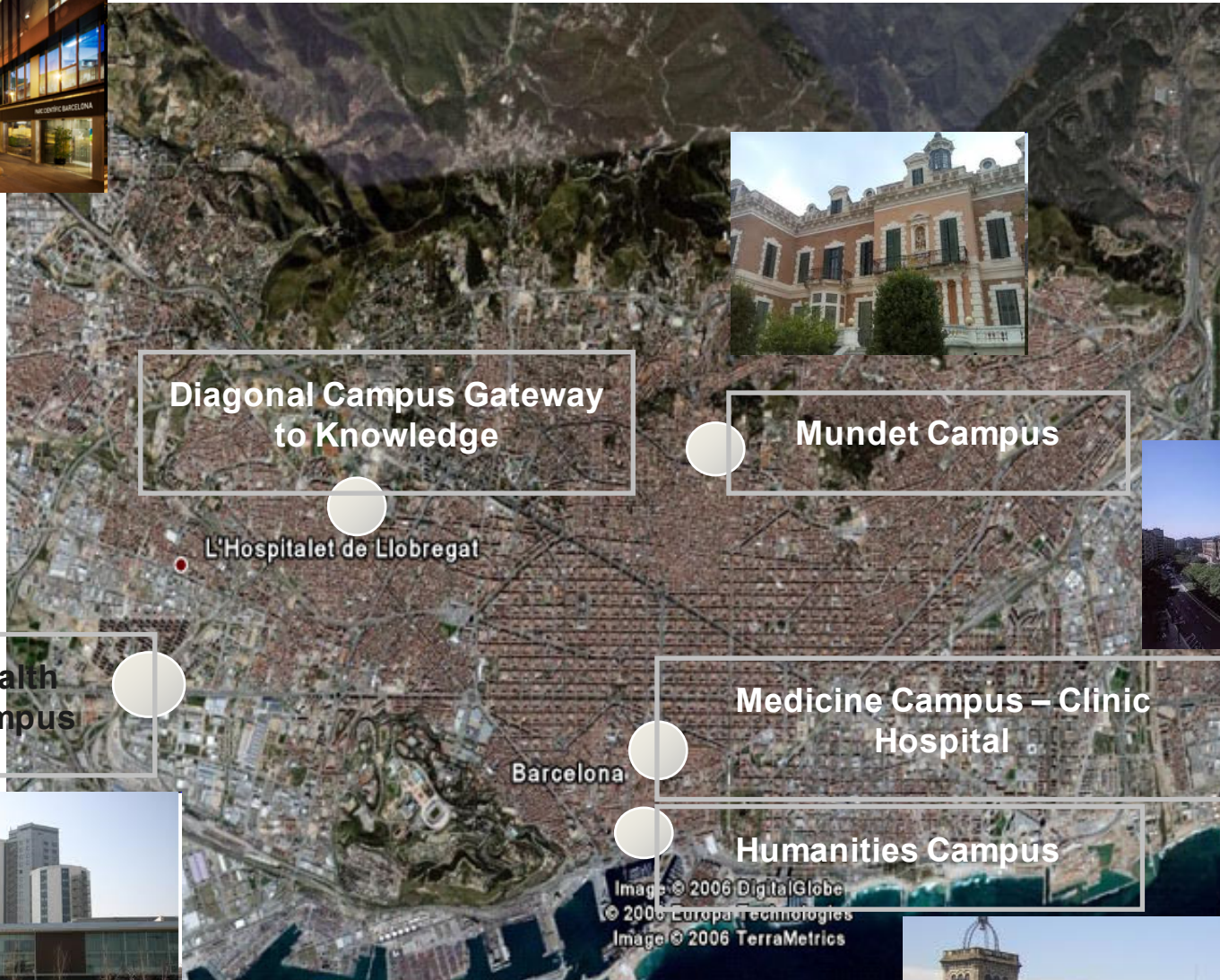
Schedule

- General view of the University of Barcelona (UB)
- When and why did we start?
- From the Quality Assurance Unit to the Quality Research Service
- Promoting Research Integrity: The Code of Good Research Practice
- How do we work?
- Closing remarks

The University of Barcelona (UB)

- UB is the **biggest** public institution of higher education in **Catalonia** and one of the biggest in Spain.
- It occupies a **competitive position** at national, European and worldwide levels in the **most important ranking tables** designed on a range of variables within different geographical areas.

The UB in the city of Barcelona



Some general figures



UNIVERSITAT DE
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**65,600
students**

**19 Faculties
and University
schools**

**5,300
teaching and
research staff**

**73 bachelor's
144 master's
48 doctoral programs**

**2,200 administrative
and services staff**

1
9
8
4
6
9
5
1
2
1

UB in Research and Technology Transfer

**680 Doctoral
theses
submitted**

**301
research
groups**



**21 research
institutes
and centers**

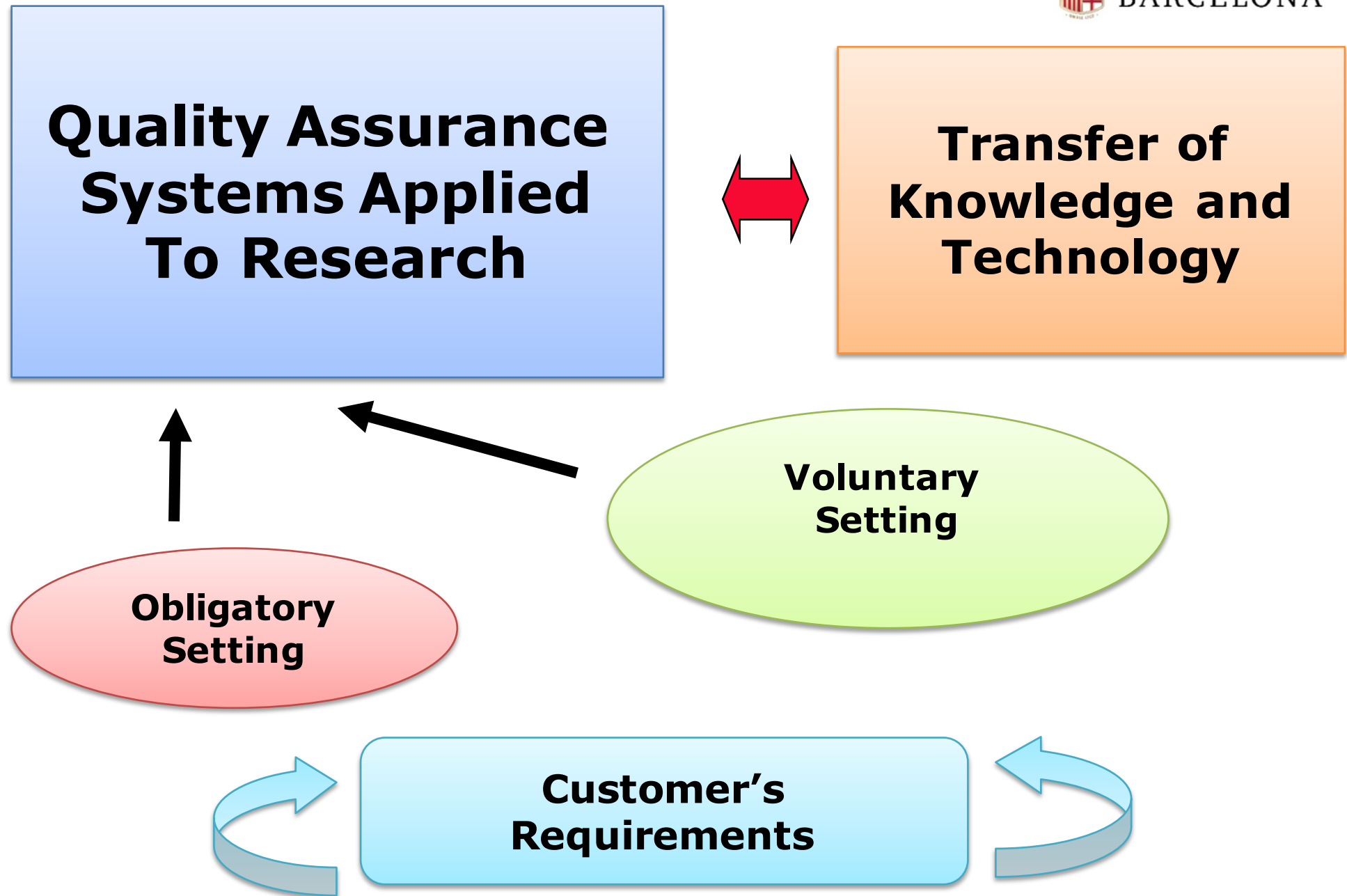
**663 active
research
projects**

**5,180 scientific
publications**

Figures corresponding to 2014



When and why did we start?



When researchers had to face to quality systems

- Did not know exactly which system fitted the customer's expectations or needs more.
- Were not familiar with the specific requirements of quality systems.
- Did not have enough technical staff to perform the additional activities needed when a quality system was implemented.

In **1994** the UB created a **Quality Assurance Unit (QAU)** in order to:

- Provide **support to research groups** that had specific needs in terms of quality assurance requirements.
- Implement a **quality assurance system** in the Scientific and Technological Centers (CCiTUB), a core facility that provide **support for research** at the university, other public institutions and private companies.

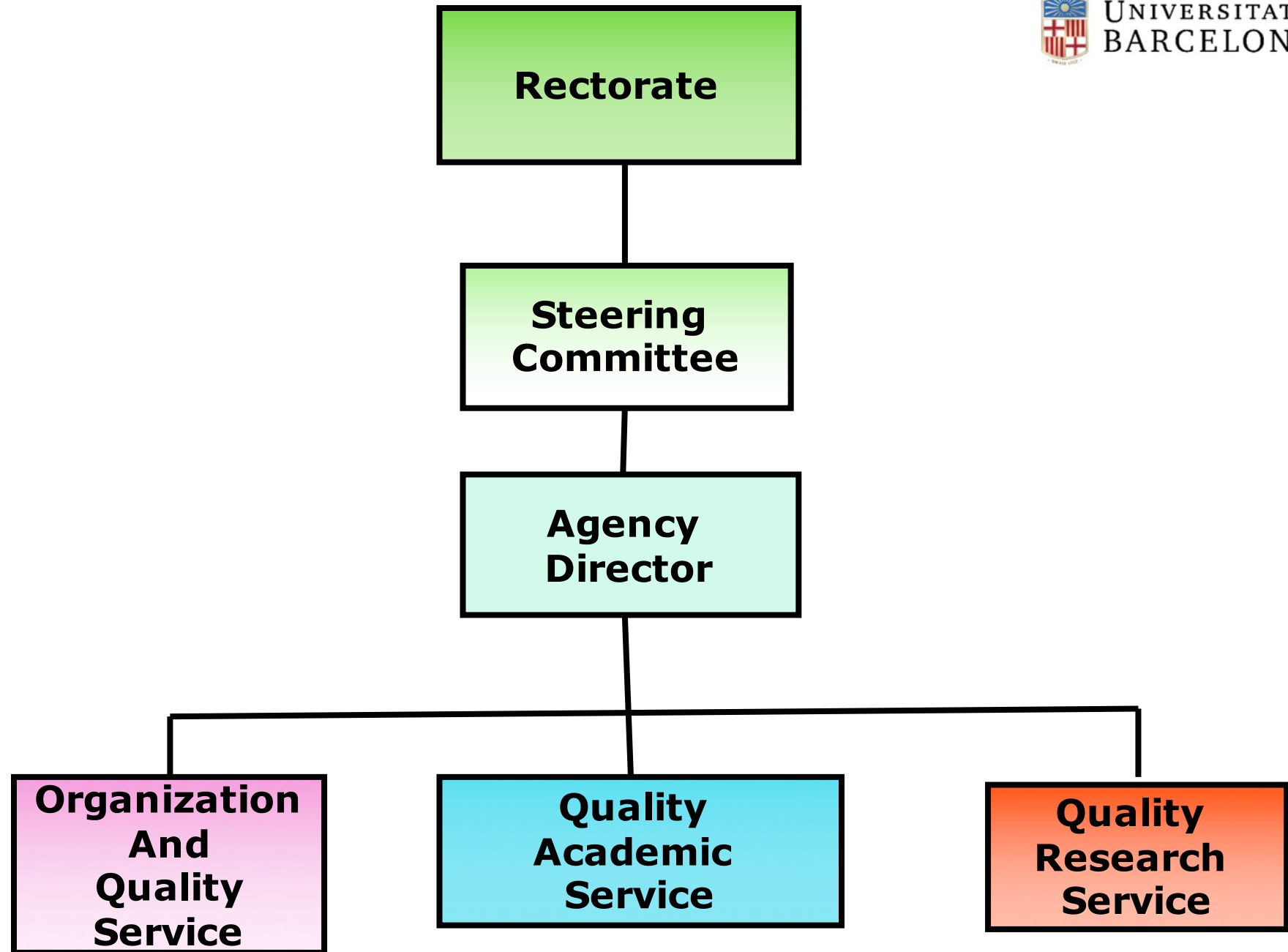
- The QAU was situated within the structure of CCiTUB as a new unit
- Advantages:
 - Integration into a structure well known to researchers.
 - Quality assurance was offered as any other kind of services offered to researchers.
 - It made it easier to develop the dual purpose of QAU: as a support for the research groups and as a quality unit at the CCiTUB.

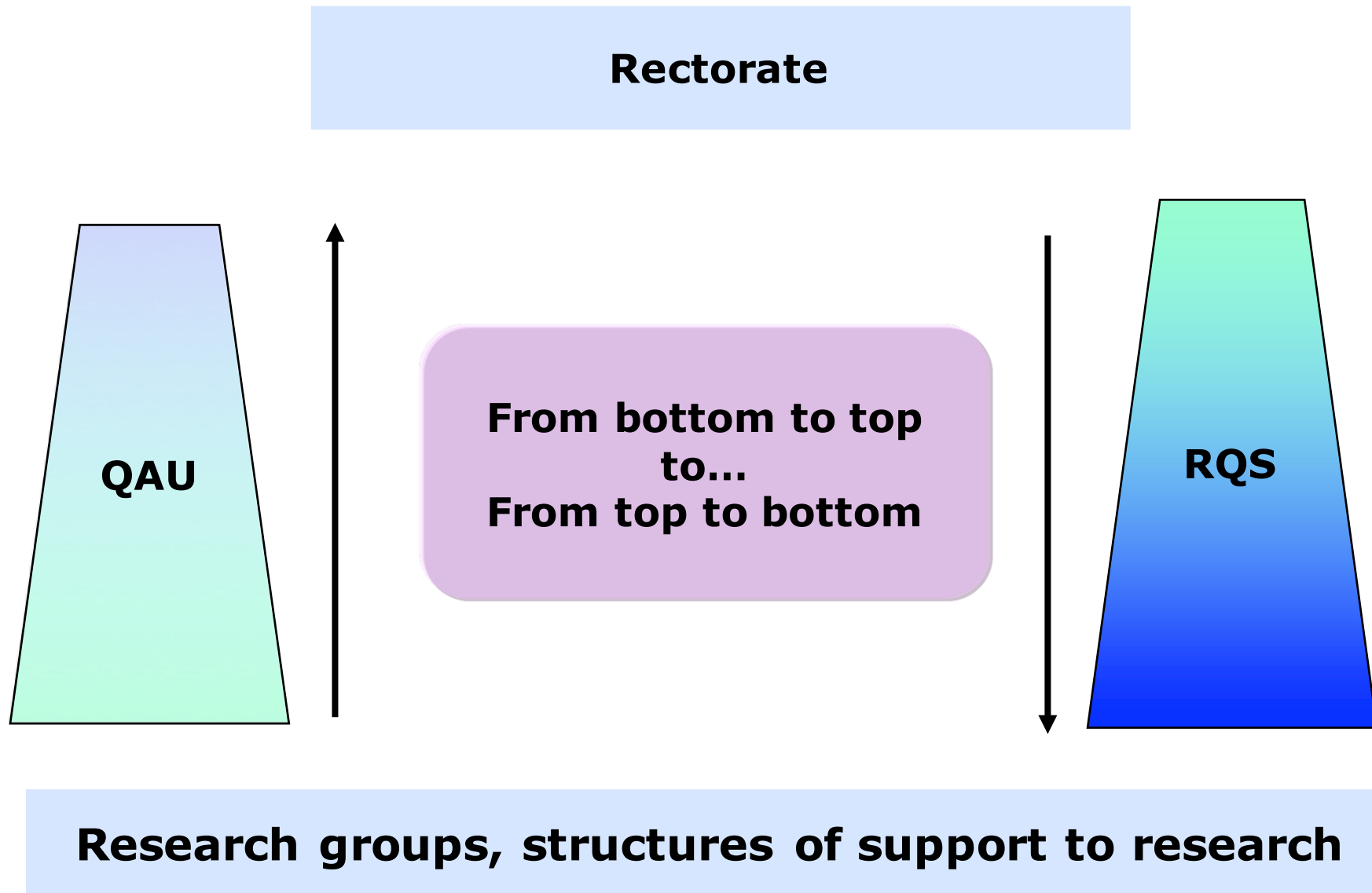


From the Quality Assurance Unit to the Quality Research Service

Agency for Quality Assurance

- **In 2007 the UB created the Agency for Quality Assurance.**
- **Its main objective is to give support to government bodies, centers, institutes, departments, administrative units and other university entities in all the processes of planning, evaluation and quality improvement at the University.**





The present mission of QRS

To provide support in all the processes of implementation, formal acknowledgement and maintenance of quality systems implemented in research groups and structures to support research at UB.

Strategy of quality implementation in research

- Implementation of **quality assurance systems** in activities related to **applied research for private companies** and in the structures of **support for research**.
- All **other** research activities covered by the **Code of Good Research Practices**.

Quality systems in which we are involved

- **OECD GLP**: studies about viral safety, bioequivalence, toxicology and ecotoxicology of human and veterinary drugs.
- **ISO 9001**: research and support for research.
- **ISO 17025**: analysis of environmental radioactivity.
- **EU and FDA GMP**: quality control of active principal ingredients (APIs).

Our certifications/accreditations



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- **ISO 9001 Certification:**



- » Scientific and Technological Centers (CCiT)
- » Center of Research in Metabolism (CEREMET)



- » Service of Development of Medicines (SDM)



- **ISO 17025 Accreditation:**



Environmental Radiology Laboratory (LRA)



- **GLP Certification:**



- » Enteric Virus Group (GVE)



- » Unit of Experimental Toxicology and Ecotoxicology (UTOX-PCB), Barcelona Science Park (PCB)





Activities performed by QRS (I)

- Give advice in selecting the quality system.
- Give support in the process of implementation.
- Conduct audits/inspections.
- Support to external inspections/audits.
- Training of laboratory personnel in quality assurance systems.
- Formal review and controlled distribution of Standard Operating Procedures (SOPs).
- Custody of certified standards for apparatus calibration.

**ISO
17025**

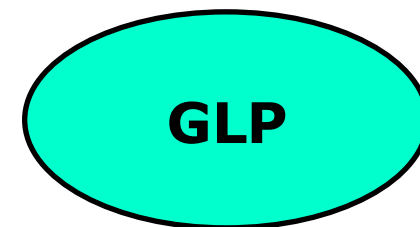
GMP

ISO 9001

GLP

Activities performed by QRS (II)

- **Quality assurance unit of GLP compliant laboratories: verification of protocol, study inspections, final report review, facilities and process-based inspections.**
- **Archive of the GLP documentation generated in the laboratories and in the QAU.**



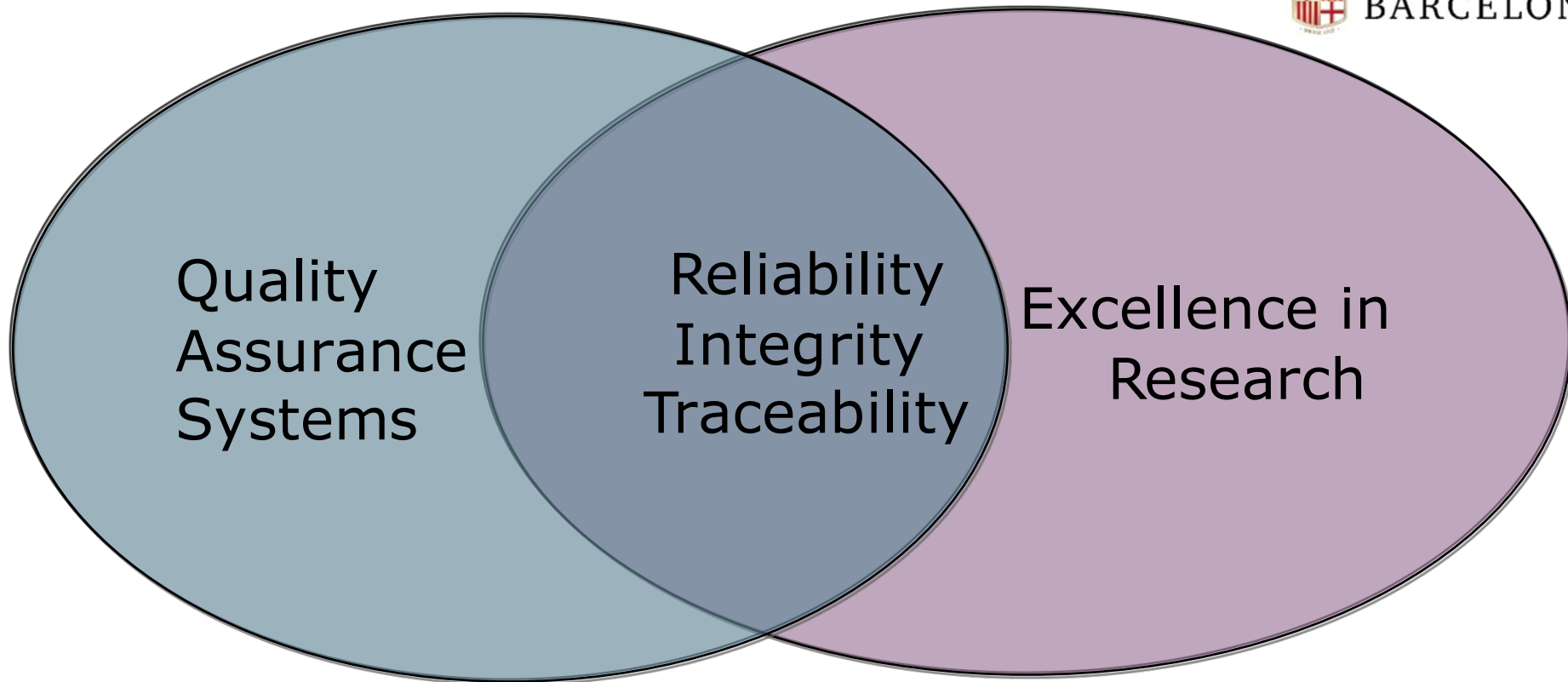
Promoting Research Integrity: The Code of Good Research Practice

Accurate

Reproducible

Scientific
results

Traceable



Quality in research: simply "good science"?

Code of Good Research Practices



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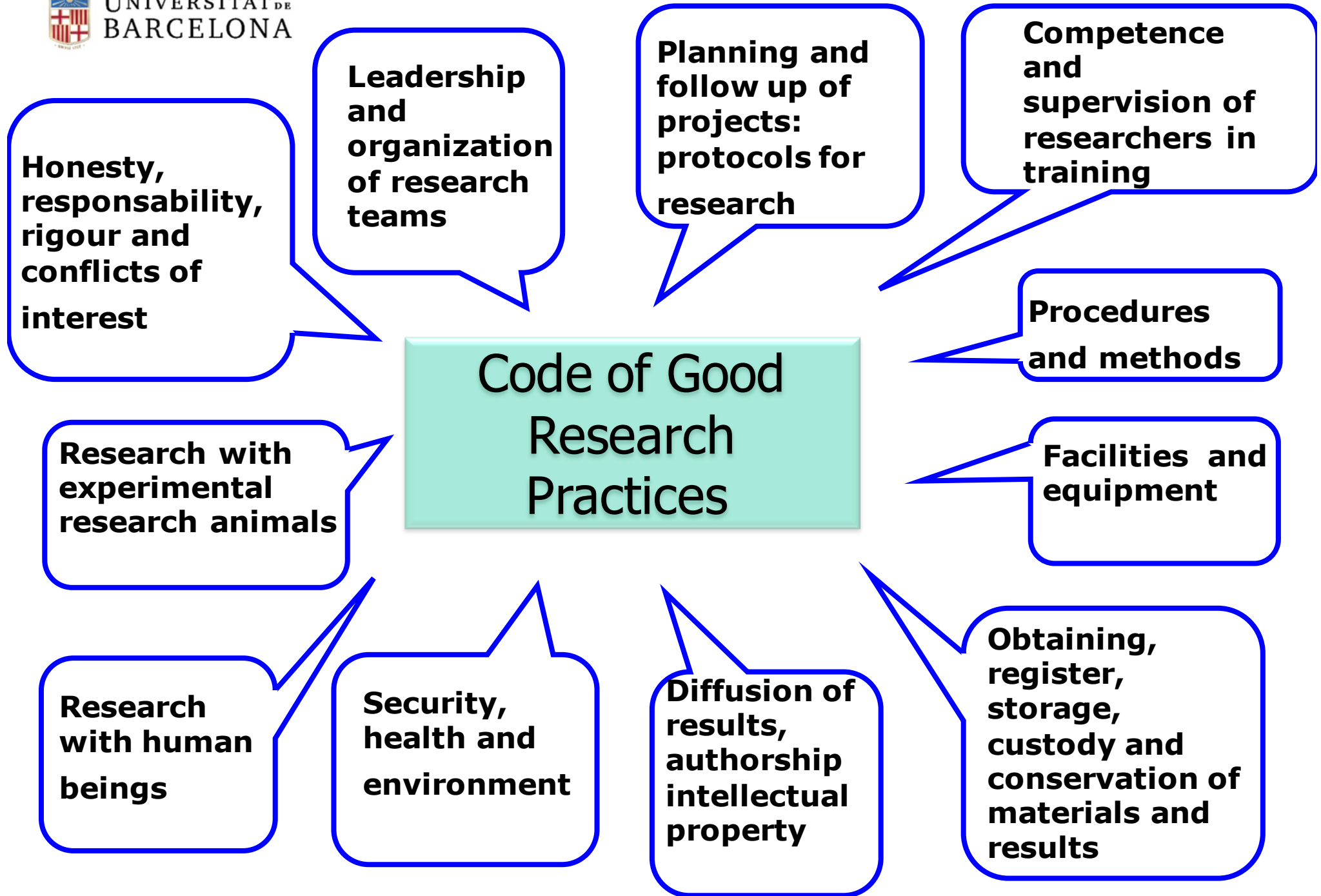
Objectives and scope

The *Code of good research practices* establishes guidelines on how to carry out research activities.

Its objectives are to:

- improve the quality of research in all fields;
- set up mechanisms for ensuring honesty, responsibility and rigour in research;
- ensure that researchers-in-training acquire good scientific practices.

This document is applicable to all the members of the UB Group who carry out research activities of any kind.



- The created document, that was initially designed for assuring the quality of the results of research, finally included also some guidelines about integrity in research



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How do we work?



Each group has a key person responsible for quality

- Acts as a link between the laboratory manager and the QRS.
- Sends the new SOPs to QRS for revision and controlled distribution, receives the controlled copies of new SOPs and withdraws the obsolete versions.
- Borrows the standards to QRS for calibration of apparatus.
- Assures that corrective and preventive actions are implemented after audits/inspections.

QRS in GLP compliant laboratories

- Facilities inspections are planned annually.
- Laboratory manager maintains Master Schedule and reports to QRS about new studies.
- There is a specific budget for each study: the cost of QAU and archive for the first 5 years is assumed by the sponsor.

QRS in the other quality assurance systems

- The schedule for internal audits is planned by the research group and performed by personnel appointed by QRS.
- In the case of CCI TUB:
 - The head of QRS is the person responsible for quality.
 - The calibration of general use apparatus (balances, pipettes, thermometers and incubators) is performed by QRS staff.

Distribution of SOPs

- All SOPs are based on the same template (SOP of SOPs) and controlled under the same system with the logical benefits of standardization involved.
- The system is controlled by QRS staff by means of a database. At present we are controlling more than 2,000 SOPs.
- All SOPs have to be revised every 3 years and a new edition has to be approved and distributed every 6 years.

Custody of standards for apparatus calibration (I)



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**QRS has some standards for calibration
of common use apparatus:
balances, thermometers,
spectrophotometers, incubators.**



QRS is responsible for maintenance and calibration in appropriate calibration laboratory, in order to assure traceability of measures to International System of Units.



Custody of standards for apparatus calibration (II)

- QRS provides instructions for use, makes recommendations about the calibration of each type of apparatus and teaches about how to use the standards.
- Each laboratory is responsible for the calibration of their apparatus (frequency, activities to perform, criteria for acceptance of results).
- Researchers and technicians can borrow the standards from QRS and are responsible for their proper use.

Closing remarks

Closing remarks (I)

- The QRS can provide the support researchers may need to implement a quality system.
- The system can be tailored to the needs and expectations of researchers.
- Some of the tools we offer are helpful to improve the quality of research.

Closing remarks (II)

The organizational structure built in the University of Barcelona, with the Quality Research Service, allows compliance with different quality standards, but with only one Quality Assurance Unit.

Thank you!

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