

# Training on quality management to support genetic testing laboratories in continuous improvement and progress towards accreditation

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## Starting point

### Share

- Genetic testing laboratories all face the same problems
- They have all found solutions in the past

### Learn

- What do the accreditation standards require for genetic testing?
- How have accredited, expert and smaller labs dealt with similar situations?
- How can we use other labs' experiences (and mistakes!)?

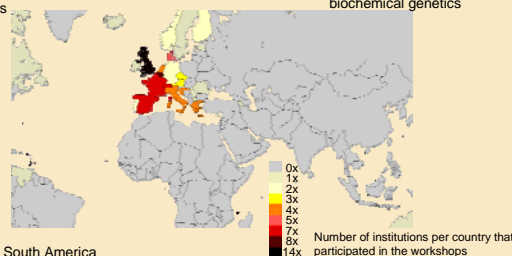
### Apply during workshops organized by EuroGentest

- Case studies and small-group discussion of common laboratory situations
- Role-playing and videos of internal audits
- Hands-on trials of quality management software

## Participants (data of past 9 workshops)

- 221 participants in total
- 35 of them participated more than once
- 167 unique participants
  - quality managers
  - laboratory directors
  - scientists
  - technicians
- 90 institutions
  - of which 22 accredited
  - molecular genetics
  - cytogenetics
  - biochemical genetics

- 74 cities
- 28 countries
  - Europe
  - Australia
  - North America and South America



## Topics



### Workshop on accreditation and quality management

- The aspects of a **quality system**, and **accreditation and related standards** were introduced and analysed.
- Common situations** encouraged the laboratories to start or continue implementing a quality system.



### Workshop on internal audit

- Participants were trained to efficiently and effectively **direct and/or participate in a laboratory audit**.
- A list of **essentials** was compiled for **preparing, executing and following up an internal audit**.



### Workshop on IT support for quality management systems

- Companies presented their software solutions** for supporting quality management systems.
- Participants had the chance to work **hands-on** with the software and a list of **criteria** was compiled for **selecting a software system**.

### Workshop on managing the human side of change

- Participants were provided with **insights on the 'human, behavioural' side of change**.
- Some tools to **manage the human side of change** were presented: **group problem solving, stakeholder map, communication plan**.

## Survey results and conclusions

Accreditation status in 2005 and 2007

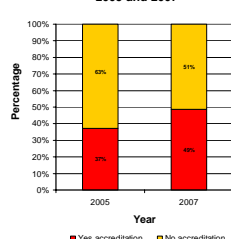


Figure 1

Presence of a quality manager in relation to accreditation status in 2005 and 2007

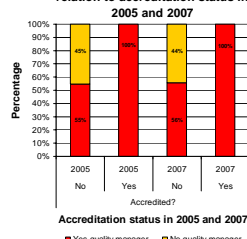


Figure 2

Number of people working in the laboratory in relation to the accreditation status in 2007



Figure 3

- 35 institutions** that participated in the workshops in 2005 were surveyed about their accreditation status and the implementation of key 'quality parameters' in the year 2005 and 2007.
- Over the years, the number of accredited labs increases: in 2005, 13 (37%) of the surveyed labs were accredited; in 2007, 17 (49%) of the surveyed labs were accredited (**Figure 1**).
- All surveyed labs that are accredited in 2005 and 2007 have a quality manager; About 50% of the labs that are not accredited in 2005 and 2007 have a quality manager (**Figure 2**).
- The non-accredited laboratories are mainly smaller labs: 60% of the non-accredited labs have less than 30 people employed (**Figure 3**).

Evolution of the implementation of key 'quality parameters' implemented in genetic testing labs

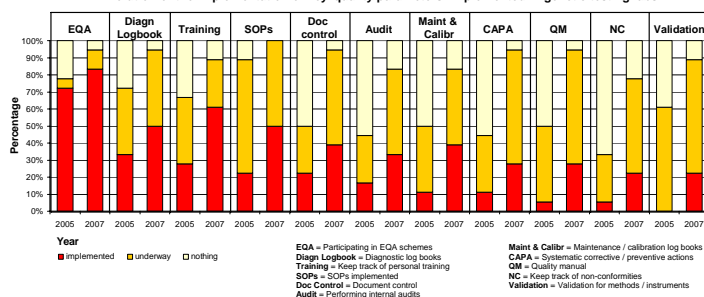


Figure 4

- The non-accredited laboratories in 2005 and 2007 (18) were surveyed about the progress of the implementation of 'quality parameters' in their laboratory in 2005 and 2007 (**Figure 4**).
- Participation in EQA is implemented by more than 83% of the surveyed laboratories in 2007.
- In 2007, all surveyed laboratories are in the process of implementing SOPs or have SOPs implemented in comparison to 89% in 2005.
- In 2005, no laboratory fully implemented the validation of methods or instruments.
- Quality assurance increases over the years.

## Future

Case studies on quality assurance and quality control issues in genetic testing laboratories, 2 hrs during the ESHG, 31 May '08.

If there are any free places, registration possible at the EuroGentest booth #220

Fulfilling the requirements of ISO 15189 for management review, internal quality control and external quality assessment, Berlin, 9-10 October '08.

Registration and more information: [www.eurogentest.org/unit1/workshops.xhtml](http://www.eurogentest.org/unit1/workshops.xhtml)

Validation of diagnostic tests in clinical molecular genetics, Prague, 8-9 January '09.

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