

# Workshops on quality management, accreditation and managing the human side of change in genetic testing laboratories

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EuroGentest, Network for test development, harmonization, validation and standardization  
Genetic testing in Europe – EU FP6-512148

Second Version



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## 1 Introduction

### 1.1 Background

The demand and provision of genetic testing within medicine is clearly increasing in all European countries, thanks to the completion of the Human Genome Project and other scientific and technical advances. Moreover, a genetic test is usually carried out only once in a lifetime and can impact on the life of other family members. It is therefore essential to assure the quality of the different elements of genetic testing, including laboratory testing, interpretation and reporting, and genetic counselling.

In this context, data from several organizations (Cystic Fibrosis Network<sup>1</sup>, European Molecular Genetics Quality Network<sup>2</sup>, European Science and Technology Observatory Network<sup>3,4</sup>, Organisation for Economic Co-operation and Development<sup>5,6</sup>) have revealed the need for improving quality and harmonization in genetic testing services within Europe. The quality of genetic testing could be increased by setting standards, providing training, promoting laboratory accreditation, participation in External Quality Assessment (EQA) schemes and the use of reference materials<sup>7</sup>.

The EuroGentest Network of Excellence (NoE) was created to address these challenges<sup>a</sup>.

### 1.2 Aims

EuroGentest<sup>8,9</sup> aims to harmonize and improve the overall quality of genetic testing services in Europe. A part of the project (Unit 1) aims to measurably improve the quality of management and provision of genetic laboratory services, and for laboratory accreditation to be considered as the standard.

In a focus on training and continuous education of personnel, key parameters in improving quality, a series of workshops has been organized with the aim of aiding laboratories in their processes of developing quality management systems (QMS) and working towards accreditation. Furthermore, the provision of international workshops also contributes to the harmonization of QMS and approaches to accreditation of genetic testing services throughout Europe.

### 1.3 Approach

The workshops brought together people from laboratories that are either already accredited or in the process of developing a QMS and working towards accreditation. The same group of participants was invited each time, including laboratory directors, scientists, technicians and quality managers, from cytogenetic, biochemical and molecular genetic laboratories in whole Europe.

The first workshop had broad aims and addressed implementing and living with quality systems, comparing the different standards for accreditation in Europe<sup>b</sup> and sharing experiences by examining cases of concrete situations related to quality processes in laboratories.

This workshop revealed a need for and an interest in IT support for QMS in medical laboratories, which logically became the main topic of the second workshop.

During the third workshop another crucial but difficult topic, internal audit, was tackled. A mixture of video clips and role-playing gave the participants an overview of all aspects of auditing from preparing and reporting the audit to communication and behaviour skills of the auditor.

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a EuroGentest Network of Excellence, an EU-funded project. EU Contract no: FP6-512148. Website: [www.eurogentest.org](http://www.eurogentest.org)

b Accreditation is a recognition that a lab works according to a good quality management system and is technically competent. Standards for accreditation in Europe: ISO 15189, ISO 17025, CCKL and CPA

Besides dealing with concrete aspects of quality systems, a fourth type of workshop, on managing the human and behavioral side of change, was organized. The fact of natural resistance in the team could be inherent to the implementation of a quality system in the laboratory.

The workshops in general are designed to be very interactive, with a maximum of time for targeted group discussions and occasional presentations on specific topics. To facilitate the active involvement of everybody, the number of participants is kept low, with a maximum of about 30 people.

The workshops are organized and animated by a team consisting of a director of an accredited laboratory (MAM), a laboratory quality manager who conducts accreditation audits for the Belgian Organisation for Accreditation (BELAC) and who is a member of ISO Technical Committee 212 (ED), a EuroGentest scientist (SB), and collaborators of EuroGentest partner 'Management, Consulting & Research' (MCR) Leuven, specialists in the "human side of change processes" (MG, AW).

This report describes the outcomes and summarizes the discussions of the pilot workshops, organized since 2005.

## 2 Workshop on accreditation - Leiden

*April 14-15, 2005, held at the Centre for Human and Clinical Genetics LUMC, Leiden, The Netherlands*

### 2.1 Focus and approach

The initial workshop consisted of a debate on quality systems and breakout sessions. The workshop was complemented by visits to the Molecular Genetics and Cytogenetics laboratories in Leiden, which were amongst the first genetics laboratories in Europe to be accredited<sup>c</sup>. Structured questionnaires were used to help participants formulate their opinions, positive and negative, during the workshops. These questionnaires started with an individual reflection, followed by discussion in small groups and ending with a whole group debate to reach final conclusions.

### 2.2 Outcome

The first task for the participants was to answer some questions individually, for example on their motivation to come to work every day, on the (dis)advantages of accreditation and implementing a quality system and their idea of a uniform quality system in European genetic testing laboratories.

Working in a genetic testing laboratory is a challenging job for technicians as well as for quality managers and laboratory directors, because of the dynamic field, the social and scientific aspects and the fact that “you can make a difference”. Besides a positive motivation, sometimes the frustration of all the paperwork, lack of space, time and budget and unmotivated colleagues is present.

Despite everybody sees the advantages of implementing a QMS and working under accreditation, some fears were brought to the surface. It is clear that a good QMS leads to a better organization of laboratory workflow, more traceability, better results and national recognition. On the other hand, people are afraid of changing their existing system or of losing flexibility, especially if quality systems should be harmonized within Europe. The fear of increased workload and lack of staff and personnel motivation restrains laboratories from starting to implement a quality management system.

A realistic suggestion formulated by the participants was to stimulate and improve communication between all staff grades and to appreciate the work of everybody. The importance of quality and the consequences of making a mistake should be emphasized.

The second part of the workshop included breakout sessions, in which small groups of about six participants get a case study accompanied by questions (box 1). The case studies addressed situations that could arise in any laboratory and formed a basis for broader discussions on topics including non-conformities, reporting, lab results, document control, auditing, equipment, personnel training etc. Moreover, participants shared experiences, learned from each other and got new ideas to put into practice.

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<sup>c</sup> Molecular Genetics is accredited by RvA ([www.rva.nl](http://www.rva.nl)) since 1998 and the Cytogenetics laboratory is accredited by CCKL and RvA since 2000, according to ISO 17025 and ISO 15189.

The mixture of experienced and less-experienced people, and of technicians and laboratory directors, gave an extra dimension to the debates. All people could contribute with their point of view.

#### BOX 1 - CASE STUDY

Johan is preparing a PCR reaction for hereditary haemochromatosis. He fills in the worksheet of the lab and determines the necessary amounts of reagents. He enters the set-up room for the PCR reaction, puts the laminar flow on and takes his reagents out of the freezer. The temperature of the freezer is above the allowed range: he measures  $-15^{\circ}\text{C}$ , whereas the accepted range is between  $-30^{\circ}\text{C}$  and  $-20^{\circ}\text{C}$ .



- a) How should Johan react, in your quality system, when the temperature is higher than allowed? How do you follow corrective/preventive actions?
- b) How are the thermometers calibrated in your lab?
- c) How many times is the temperature logged in your lab? How are the “acceptable ranges” determined for fridges, freezers etc?
- d) How long are worksheets stored in your lab? What should be included on a worksheet for PCR? Draft a template for the ideal worksheet.

During the workshop, special attention was paid to the current available accreditation standards used within Europe. The International Organization for Standardization (ISO)<sup>10</sup> has developed an international guideline for testing laboratories in general (ISO 17025), and one in particular for medical laboratories (ISO 15189). Some countries prefer a “local” guideline<sup>d</sup> such as CCKL<sup>11</sup> in The Netherlands and CPA<sup>12</sup> in the UK. Participants were trained to compare and use these standards in actual practice. An overview of the different quality standards for genetic testing laboratories in European countries is outlined in box 2.

#### BOX 2 – ACCREDITATION STANDARDS

##### **ISO 17025 ‘General requirements for the competence of testing and calibration laboratories’**

This international standard contains all the requirements that **testing and calibration laboratories** have to meet if they wish to demonstrate that they operate a quality system, are technically competent and are able to generate technically valid results. Accreditation bodies that recognize the competence of testing and calibration laboratories use this international standard as a basis for their accreditation.

##### **ISO 15189 ‘Medical laboratories – Particular requirements for quality and competence’**

This international standard provides requirements for competence and quality that are particular to **medical laboratories**. Medical laboratory services have to meet the needs of all patients and the clinical personnel responsible for the care of those patients.

##### **CCKL ‘Praktijkrichtlijn voor een kwaliteitssysteem voor laboratoria in de gezondheidszorg’**

This Dutch guideline is based on the ISO 15189 standard and applies to **medical laboratories**.

##### **CPA ‘Standards for the medical laboratory’**

The CPA standard is the national guideline for accreditation of **medical laboratories** in the United Kingdom.

<sup>d</sup> CCKL: Coördinatie Commissie ter bevordering van de Kwaliteitsbeheersing op het gebied van Laboratoriumonderzoek in de Gezondheidszorg in The Netherlands.

CPA: Clinical Pathology Accreditation in UK.

## 2.3 Discussion

It was remarkable that all the participants agreed on the positive side of accreditation and implementing a quality management system, but at the same time they shared the same fear of changing approaches or of convincing and motivating colleagues to change.

It is inherent to human beings to have negative attitudes and perceptions towards change. To get people behind the new idea of implementing a QMS, they need to realize and understand that the change will really happen, before they completely accept it. People typically perceive change processes in different phases; the learning cycle of Kolb<sup>13</sup>, adapted by MCR, is used to explain and teach approaches for change processes in laboratories (box 3).

The most important element is to include everybody in the laboratory and to give responsibilities to all. If they can start helping - for example in collecting and re-writing procedures - the rest will follow. Managing the human side of change will be discussed in chapter 5 in more detail.

### BOX 3 – CHANGE PROCESSES



- 1) People need to experience that the situation can not be maintained. Make people realize that the current situation is not suitable anymore. Involvement and responsibility of everybody is important.
- 2) People need to have time to observe and reflect.
- 3) People will form ideas and theories. Do not explain what the most relevant option is (implement quality system, accreditation), but let them come with solutions.
- 4) People will test these ideas to see whether they are viable. The results of these experiences can then form the basis of reflection, new ideas etc. When people experience by themselves, they go along with change. Let people start with easy tasks. Give positive feedback. Finally new things become routine.

As mentioned above, some countries use different accreditation standards, but their aims are all the same: implementing and assuring good quality in testing laboratories, for the benefit of patients. However, ISO 15189 is now the preferred standard for accreditation of genetic testing laboratories<sup>14-16</sup>. Repeated comments during the group discussions revealed that everybody had the “same goal”, the “same questions” and the “same problems”. Although formal requirements may vary between standards, it was evident that the commonality of approaches between laboratories will make a significant degree of harmonization a feasible and relatively natural outcome.

### 3 Workshop on IT support for quality management - Leuven

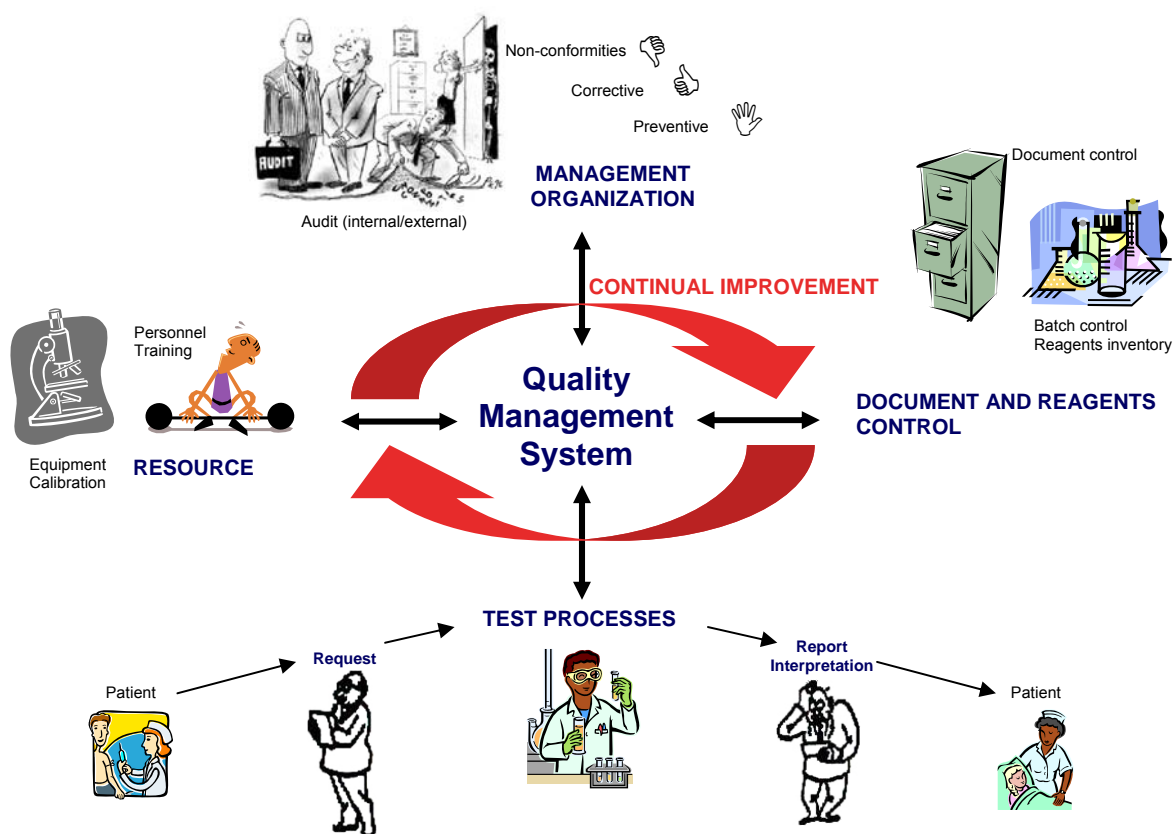
September 15-16, 2005, held at the Catholic University of Leuven, Campus Arenberg III, Leuven, Belgium

#### 3.1 Focus and approach

Based on feedback from the first workshop, the decision was made to address software packages to support quality management systems. The successful format of mixing lectures and interactive sessions was maintained.

A quality management system should at least include document control, auditing, training of personnel, follow-up of corrective and preventive actions, maintenance and calibration of equipment and reagent and batch control (figure 1). All these aspects can be included in a software package, to optimally support the quality system. Laboratory Information Management Systems (LIMS), which only include tracking and monitoring of laboratory data, were not included in the scope of the workshop.

FIGURE 1 – ASPECTS OF A QUALITY MANAGEMENT SYSTEM



During the first part of the workshop, three companies presented their software solutions. Afterwards, all participants had the chance to work hands-on with the software, alternating with brief question-and-answer sessions. On day two, further time was available for working with the software, and presentations were given by three further companies. To exchange and analyse experiences best, a full group debate was held, after individual analysis and sub-group discussions. A number of advantages and disadvantages of implementing a software package became clear, and a group consensus was reached for a list of criteria for selecting a software system. A significant finding and a subject of animated discussion, were the relative advantages of managing the QMS in a database-

centred or a document-centred fashion. The conclusion was essentially that both approaches can work and the choice is a matter of preference.

### 3.2 Outcome

A thorough internet search<sup>e</sup> was performed to identify QMS software on the market. EuroGentest has no intention to sell or to give preference to any package, and consequently the list in box 4 is only a random selection and could be a starting-point in the selection of a proper software programme that fits a particular laboratory's workflow. It will help to give an idea what IT support could include, or rather what the different approaches and possibilities are to support a quality management system. The software companies marked, contributed to the workshop either by a presentation alone (\*) or by a presentation and providing installed demo versions (\*\*), permitting the participants to evaluate and test the software. These companies were also asked to provide details of the different modules in their software, the technical requirements, the possibility to link with other programmes (e.g. hospital information systems), support, maintenance, training and prices. This comparison revealed huge differences between the available software solutions.

BOX 4 – QMS SOFTWARE SYSTEMS IDENTIFIED BY INTERNET SEARCHING  
(this list is provided “as is” - EuroGentest does not sell or give preference to any package)

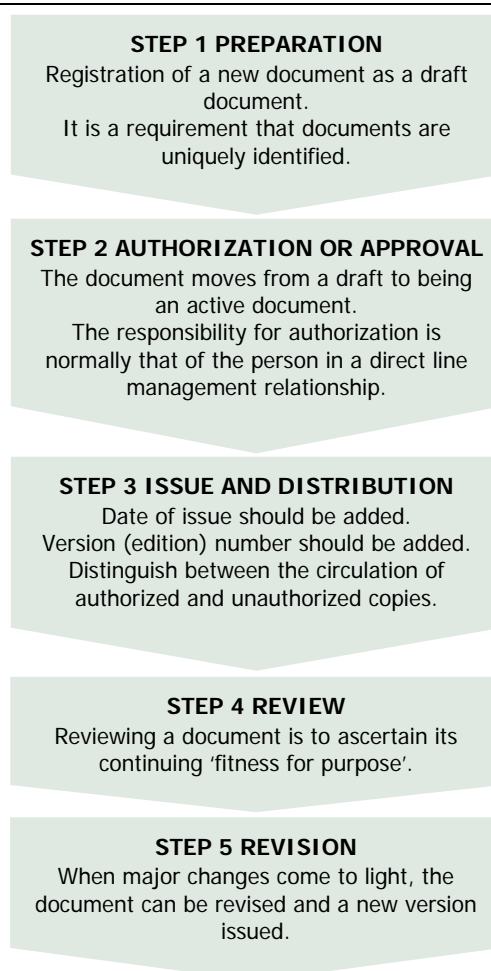
|  |   |
|--|---|
| <b>Amadeus Solutions - eQRP (France)</b><br><a href="http://www.amadeussolutions.com/">http://www.amadeussolutions.com/</a>        | <b>MasterControl - Integrated Quality Suite (US)</b><br><a href="http://www.mastercontrol.com/">http://www.mastercontrol.com/</a>         |
| <b>Autoscribe - Matrix LIMS (UK)</b><br><a href="http://www.autoscribe.co.uk/">http://www.autoscribe.co.uk/</a>                    | <b>Noweco - JKT9000 (Germany)</b><br><a href="http://www.noweco.com/">http://www.noweco.com/</a>  |
| <b>Bitos - Mithras (Belgium) **</b><br><a href="http://www.bitos.com/">http://www.bitos.com/</a>                                   | <b>Pilgrim Software - SmartSolve (The Netherlands) *</b><br><a href="http://www.pilgrimsoftware.com/">http://www.pilgrimsoftware.com/</a> |
| <b>bizzApps - Quality Manager (The Netherlands)</b><br><a href="http://www.bizzapps.com/">http://www.bizzapps.com/</a>             | <b>PQ Systems - Quality Workbench Professional (UK)</b><br><a href="http://www.pqsystems.com/">http://www.pqsystems.com/</a>              |
| <b>Gael Quality - Q-Pulse (UK) **</b><br><a href="http://www.gaelquality.com/">http://www.gaelquality.com/</a>                     | <b>Quality On-Line - Quality On-Line (The Netherlands)</b><br><a href="http://www.qualityonline.com/">http://www.qualityonline.com/</a>   |
| <b>Genial Genetic Solutions - iPassport (UK) **</b><br><a href="http://www.genialgenetics.com/">http://www.genialgenetics.com/</a> | <b>Qualsys - EQMS (UK) *</b><br><a href="http://www.qualsys.co.uk/">http://www.qualsys.co.uk/</a>   |
| <b>Interax Group - Paradigm II (US)</b><br><a href="http://www.interaxgrp.com/">http://www.interaxgrp.com/</a>                     | <b>SoftTech Health - SoftTech Lab QMS (US)</b><br><a href="http://www.softtechhealth.com/">http://www.softtechhealth.com/</a>             |
| <b>LabWare - LabWare LIMS (UK)</b><br><a href="http://www.labware.com/">http://www.labware.com/</a>                                | <b>Software Compliance - ISOXPRT (US)</b><br><a href="http://www.softwarecompliance.com/">http://www.softwarecompliance.com/</a>          |
| <b>Lysoft - Quallys laboratoire (Switzerland) *</b><br><a href="http://www.quallys.ch/">http://www.quallys.ch/</a>                 | <b>Sparta Systems - TrackWise (Israel) *</b><br><a href="http://www.sparta-systems.com/">http://www.sparta-systems.com/</a>               |

The test sessions on the computers were focused with concrete questions, exercises and road maps developed by EuroGentest and the companies. Through the exercises and the discussions, participants developed their understanding of the different elements of a quality system, for example document control (see figure 2, based on David Burnett, A practical guide to accreditation in laboratory

<sup>e</sup> Using combinations of the following key words: compliance, quality, management, software, ISO, laboratory, audit, document control

medicine, p71-72<sup>17</sup>). So participants not only had an overview of how IT can support their QMS, but were also introduced to different ways of organizing quality systems.

FIGURE 2 – DOCUMENTATION CONTROL



The motivation to change to a software-based quality management system could include issues like saving time due to reduced paperwork, better traceability, simplified follow-up of audits and corrective actions, and programmable notifications. Furthermore, a central data store, accessible from everywhere, makes work more efficient and well-organized. On the other hand, besides the initial cost, it will take significant time and effort to implement the system and to win everybody over to its advantages.

A necessary starting point when selecting a system is compiling a requirements list of what is needed to fit with the own laboratory workflow. Define what is essential for your laboratory, based on what you have already in place, the size of the laboratory, IT experience, long-term expectations and existing data. During the workshop, such a list of criteria was drawn up during group discussions (see box 5), which can provide a starting point or guidance for each laboratory.

## BOX 5 – CRITERIA WHICH SHOULD BE TAKEN INTO ACCOUNT WHEN SELECTING A SYSTEM

|                      |  |
|----------------------|--|
| <b>User-friendly</b> | <p>Familiar interface</p> <p>Restricted access so that only relevant information is shown</p> <p>Intuitive and simple</p> <p>Logical structure</p> <p>Multiple languages possible</p> <p>Designed for labs → results recording from routine EQA</p> <p>It has to appeal to the lowest common denominator</p> <p>Easy to implement all the data you already have</p> <p>Does it require exclusive training of all staff?</p>  |
| <b>Complete</b>      | <p>Follow up of documents, audits, non-conformities, corrective and preventive actions, complaints, training, equipment, reagents, suppliers ...</p> <p>Extra: statistic information, printing possibilities of labels, graphics</p> <p>Make a combination of modules and buy extra modules when lab is ready for it.</p> <p>Customization, a flexible system built for purpose</p> <p>Co-develop a system (expensive! / maintenance?)</p> <p>The system should fit with the laboratory requirements and integrate with the current processes, databases etc.</p>  |
| <b>Support</b>       | <p>All aspects: product updates, new versions, maintenance</p> <p>Populate it with all the data</p> <p>Helpful/efficient after sales service</p> <p>Confidentiality (confidence that the company will be there in 5 years)</p> <p>Support from local IT-department</p> <ul style="list-style-type: none"> <li>└ involve from the beginning</li> </ul> <p>Support from people in your own lab with a strong training or experience</p> <p>User groups of people using the same software</p> <ul style="list-style-type: none"> <li>└ consensus in the group</li> <li>└ afterwards coming to the company to try to implement it</li> </ul> <p>Customer forums: feedback, questions</p> |
| <b>Costs</b>         | <p>Especially for small labs</p> <p>Initial costs + hidden costs (new hardware, training, update, manual, extra license...)</p> <p>Long-term cost: what if new requirements emerge?</p>  |
| <b>Systems</b>       | <p>Database-based (database centric): advice for the future</p> <p>Document-based (index centric): ok for small labs</p> <p>Possibility to link with other existing systems and databases: e.g. Patient database</p> <p>Robust and reliable</p> <p>Is the system validated?</p>  |

### 3.3 Discussion

During the discussions it became clear that everybody was strongly in favour of implementing a software package to support their quality system. Some barriers were identified, including convincing the management, or extra workload and costs; suggestions were formulated to overcome these problems.

The principles of managing change processes can be applied. Start by involving all relevant people from the beginning, including technicians, secretaries and the IT personnel, as well as the quality manager and laboratory director. Listen to their ideas and distribute responsibilities to increase

motivation. When people have the impression that they contribute to the decision-making, they will be more open to implement and to put effort into the new system.

Take your time to educate yourself via colleagues, internet and demo versions. Visiting a laboratory that uses a system could help convince personnel of the value of changing. To reduce the excess workload, invest in training and work in a phase-to-phase approach, implementing and optimizing one module before you start implementing others; to reduce or spread the costs, purchasing of modules can be phased.

General consensus was reached on criteria which should be taken into consideration before choosing a software system. When comparing currently available software with these criteria, it was evident that all packages had interesting aspects, but that none yet really fulfilled all the ideal criteria for quality management in genetics laboratories.

Based on the feedback afterwards, it was clear that every participant took something out of this workshop, despite the difference in experience with software packages. Existing users had the opportunity to discover which features their software has (or not), in comparison with other packages; new ideas were obtained for optimizing their own system. Non-users became aware of the usefulness of software for their QMS, and now have an idea how to choose and implement a system.

In addition to the benefit for participants, the companies present – who could participate freely in all sessions – collected information and feedback. They were able to talk to users or potential clients and hear their concerns and wishes. Based on the criticism and comments they received, promising new versions were released by Gael Quality and Genial Genetics Solutions.

Some of the participants are now in the process of selecting a system; some have already acquired a software package that was shown at the workshop.

## 4 Workshop on internal audit - Oxford

June 22-23, 2006, held at the Oxford Spires Four Pillars Hotel, Oxford, United Kingdom

### 4.1 Focus and approach

The first workshop of 2006 was dedicated to internal auditing. The aim was to train participants to efficiently and effectively direct and/or participate in a laboratory audit in the spirit of peer review and education. Participants were motivated to exchange ideas and learn from each other and the experts, through general presentations, role-play, video clips and group discussions.

### 4.2 Outcome

A general presentation, alternated with practical exercises, touched upon all the different aspects of auditing, categorized in the “why, what, who and how” of internal audit (box 6).

#### BOX 6 – WHY, WHAT, WHO AND HOW OF INTERNAL AUDITING

##### Why?

An accredited laboratory should carry out internal audits at regular intervals to ensure that its quality system is fully implemented in practice.

The main elements of the quality system should normally be subject to an internal audit once every twelve months<sup>10</sup>.

- Audits are an essential part of a quality system
- The process is not an inspection but a peer review
- The primary goal is working towards improvement

ISO 15189:2003 -> 4.14.2

ISO 17025:2005 -> 4.14.1

##### Who?

•Character: fair, intelligent, tenacious, logical, sensitive, analytical, calm, respectful, trustworthy and open-minded.

•Knowledgeable: his/her understanding of quality procedures should be current and accurate.

•General qualities: Communicative, competent to examine, question, evaluate and report, able to work within a team.

•Technical qualities: knowledge of methods, instruments, calibration, able to judge the competence of the lab, observation of the work performance of personnel.

•Responsibilities: communicate and explain, plan; perform and report the results, keep confidentiality, ensure co-operation within and support of the team.



##### What?

###### Horizontal audit

A detailed check of a particular aspect of the documentation and implementation of the quality management system or examination processes.

E.g. examine a number of reports to see whether appropriate interpretative comments and/or follow-up of abnormal results had been provided.

###### Vertical audit

A detailed check that all elements, associated with a chosen examination (test), are implemented.

E.g. Select a single request form and its associated sample (input) and follow it through every element of the process until the report (output) is produced<sup>16</sup>.

##### How?

- Keep it simple
- Stay on track and finish the job
- Do it in an effective and efficient way
- Perform the audit with regard to the requirements
- Do interviews, documentation checking, observations, and cross-checks
- Document and discuss findings
- Respect the feelings of all participants
- Resist the pressure to change the truth
- Avoid judgmental tones and body language
- Manage personal and interpersonal stress
- Evaluate evidence in a fair and impartial manner
- Do appropriate follow-up.

The exercises, including role-play, short video clips and group discussions, were divided into three categories: the execution of an audit, completed by communication and behaviour skills, the preparation beforehand and finally the reporting and follow-up afterwards.

Experienced auditors and people who never performed an audit before were mixed and divided into small groups, each of which received a case description of a realistic laboratory situation. The group had to enact the situation, in which both auditors and auditees were present. Based on the feelings and experiences of auditor and auditee during the role play, a list was compiled of what went well and what could be improved when doing an audit. Furthermore, small video fragments gave extra information how you should behave and handle situations during an audit. All the raised elements were discussed further.

It is important that the auditor starts with and mostly uses open questions, which are simple and straightforward. If necessary, subsequent questions may be asked to develop deeper answers, but 'why' questions should be avoided as they often trigger defensive reactions. It is preferable to start with 'how' questions, based on what can be seen. The use of words like 'maybe', 'a little bit', 'could', etc. may have miscellaneous effects. On the one hand, they make the message less direct or threatening; on the other, they may give the impression that the auditor is not sure about himself. The auditor should mention when something is not conforming to the procedure, so that the auditee already understands during the audit that not everything was perfect. At the end of an internal audit, the auditor should focus on solutions and improvement and should include suggestions as well as positive feedback.


The behaviour of an auditor, as well as his way of communicating, can be crucial for a successful audit. When the auditor begins, he should make the auditee feel at ease by being polite and not too formal. He should explain the planning and make clear that it is the system and not the person that is being audited; no "blame" will be attached to the person. It is essential to find the balance between confrontation and empathy. Although it is essential not to hide or minimize when something is wrong, the auditor should stay calm and must not raise his voice. A good auditor always stays objective and independent, and will adapt to the behaviour of the auditee. Finally, he has regular eye contact and does not interrupt the auditee, which additionally helps in monitoring the body language.

It is impossible to perform a good audit without thorough preparation. The audit plan should be flexible to permit changes, and should include the objectives and scope of the audit. Furthermore, the individuals who have direct responsibilities, should be identified and informed if a date and time is known, as well as the people who will be directly involved in the audit. The preparation should also include the identification of all reference documents (Standard Operating Procedures, standards etc.). Working documents, like checklists and observation forms, are helpful to facilitate the auditor's investigations and to document and report the results.

Taking accurate notes during the audit is essential. Based on these, the auditor will make a clear and structured audit report within a defined time limit. This report should include the major and minor non-conformities, as well as mentioning positive points. Following the report, an action plan must be

developed, identifying for each action the responsible person and a deadline. General elements, like the auditor's name, the date and the standard used should be present, in addition to specific details such as the Standard Operating Procedure (SOP) number, equipment number etc. An example of a report is shown in figure 3.

FIGURE 3 – EXAMPLE OF AN AUDIT REPORT

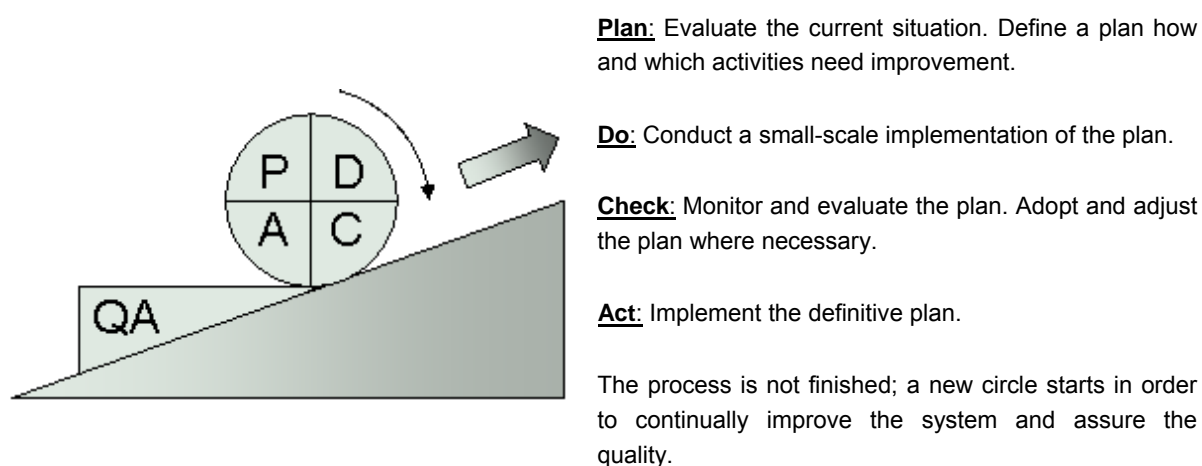
| Date   | Auditor(s)  | SOP   |   |              |          |  |
|--|---|---|---|--------------|----------|--|
| 1/06/2006  | Paul Delia  | PP00129 revision 2<br>LiPA compounds and test analysis  |   |              |          |  |
| Audit type   | Auditee   | Application date  |   |              |          |  |
| Vertical audit   | Kyle Neath  | 21/10/2005  |   |              |          |  |
| Standard   | Section advisor   | Section   |   |              |          |  |
| ISO 15189:2003   | /   | LiPA compounds test analysis room   |   |              |          |  |
| Description  | Item  | Class.  | Action  | Responsible  | Deadline |  |
| The audit took place in the LiPA compounds test analysis room, during routine working conditions. All necessary documents were readily available. The SOP was easy to follow, well documented. Good laboratory practice was observed throughout. Several non compliances were detected and these need to be addressed. |   |   |   |              |          |  |
| Document control 4.3   |   |   |   |              |          |  |
| 1. It was noted that there had been an amendment to the working document where the incubation time had been decreased from 30 to 20 minutes. There appeared to be no technical validation of this critical step. The change was made by pencil.  | 4.3.2   | B   | Amendments should be in pen and announced at the weekly meeting.                                | Sue Davids   | 10/06/06 |  |
| 2. A database system exists to follow-up changes.  | 4.3.2   | +   |   |              |          |  |
| Identification and control of non-conformities 4.9   |   |   |   |              |          |  |
| 1. Documentation of non-conformity concerning the storage of reagents was well documented, however, it was noted that a reagent had frozen during storage.   | 4.9.1   | +   |   |              |          |  |
| Personnel 5.1  |   |   |   |              |          |  |
| 1. Training records were not up to date, last record training states from 2004   | 5.1.2   | +   | All training files will be checked if they are up to date.                                      | Brian Alvey  | 01/07/06 |  |
| Laboratory equipment 5.3   |   |   |   |              |          |  |
| 1. Maintenance records for the main incubation machine was two weeks overdue for calibration due to Holiday of responsible person  | 5.3.2   | B   | A better follow-up of absences is necessary. Action plan will be set up at next weekly meeting. | Richard Torn | 15/08/06 |  |
| 2. Equipment is uniquely labelled and the status of calibration is indicated   | 5.3.3<br>5.3.9  | +<br>+  |   |              |          |  |
| Signature  | Following classification with the definition of the codes is used |   |   |              |          |  |
|   | A   | Major non-conformity which is a direct danger for the quality and means that the quality system is not conform the pre-defined accreditation criteria |   |              |          |  |
|  | B   | Non-conformity that could influence the reliability of the results and the effectiveness of the quality system on the long-term                       |   |              |          |  |
|  | +   | Recommendation, will be evaluated next time   |   |              |          |  |
|  | +   | Is implemented or operational conform with the standard   |   |              |          |  |

### 4.3 Discussion

A laboratory is committed to constantly evaluate its activities and to maintain and improve its quality. Performing internal audits is one tool to evaluate and improve a quality system and to detect non-conformities. Other possibilities are participating in external quality assessment (EQA) schemes or undergoing an external audit, conducted by an external independent organization such as a national accreditation body. An internal audit is conducted by the laboratory itself on different aspects of the laboratory<sup>15</sup>. The auditor could be confronted with some minor and major non-conformities during the audit. Consequently, an action plan needs to be set up to eliminate the non-conformity in the future. During the next internal audit, these elements could be checked again to evaluate if the action plan was effectively implemented.

This process refers to the Plan-Do-Check-Act (PDCA) circle, also known as the 'Deming wheel'<sup>18</sup>. It is a very simple concept which helps coordinate your quality improvement efforts: just as a circle has no end, the PDCA cycle repeatedly executes in pursuit of continual improvement. It emphasizes and demonstrates that improvement programs must start with careful planning, must result in effective action, and must move on again to careful planning in a continuous cycle (figure 4).

FIGURE 4 – DEMING WHEEL FOR CONTINUAL IMPROVEMENT



In conclusion, internal audits are designed and should be used to continually improve the quality system, and not to inspect the people working within the quality system. The involvement of the whole group is important to achieve successful improvement. A thorough knowledge of the quality standard and of the quality manual is essential when performing audits.

## 5 Workshop on managing the human side of change - Nice

February 7-8, 2008, held at the Novotel Nice Centre, Nice, France

### 5.1 Focus and approach

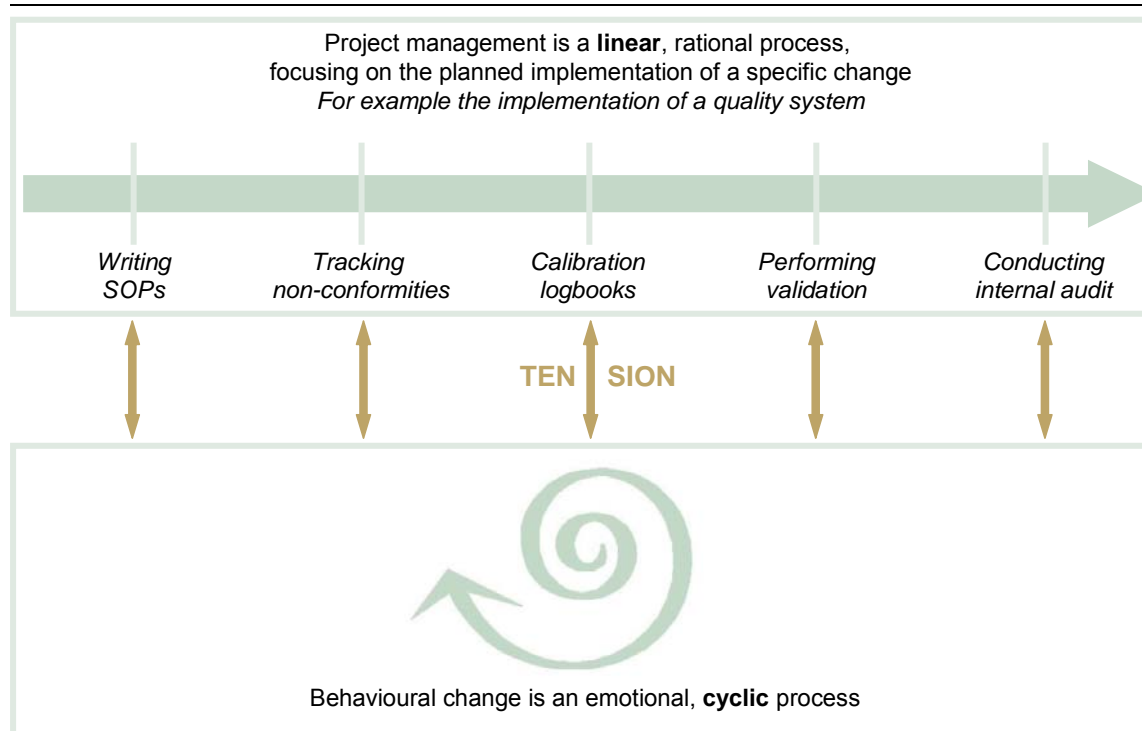
One of the biggest challenges in implementing a quality system in the laboratory lies in overcoming natural reluctance of team members, and convincing them of the value of quality assurance to justify the effort that will be required.

This workshop aimed to give insight in the human and behavioural aspects of change, including the different (psychological) phases in the whole process. Furthermore, techniques were presented to manage these aspects and to communicate during change processes. Case studies and role play provided illustration and practical training, to help to apply these insights in the own laboratory.

### 5.2 Outcome

Implementing a specific change in the laboratory is a **linear process**. For example, the head of the laboratory decides together with his staff members to implement a quality system. The different steps (writing SOPs, tracking non-conformities ...) and when they should be implemented is definable. This linear process is usually organised with the help of techniques like project management and is restricted in time. However, the reaction of the technicians in the laboratory, or what we call behavioural change, cannot be planned in time as it is a **cyclic process**. The technicians will need to go through a learning process during which they receive new information, experience certain emotions, try out new things etc. This process is individually different and can not be managed in the same linear way. Tension will emerge between those two processes and this will causes resistance during a change process (figure 5). This resistance cannot be avoided, but when managed well, it could increase effectiveness and efficiency of the change you would like to implement.

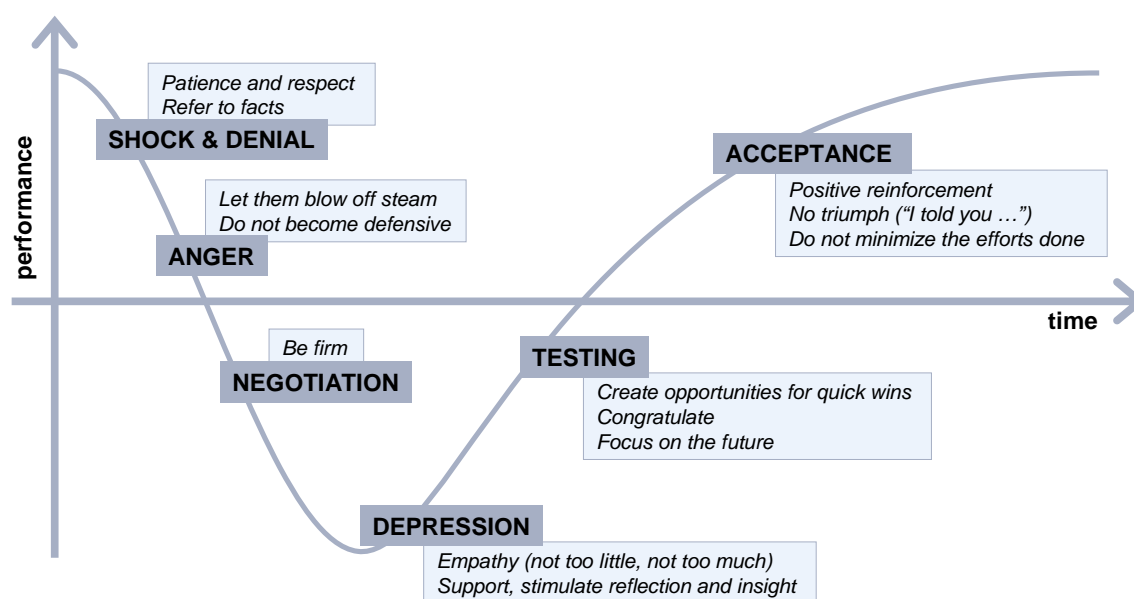
FIGURE 5 – CHANGE MANAGEMENT: TWO INTERFERING PROCESSES



The cyclic process mentioned above encloses different phases people may go through when confronted with change:

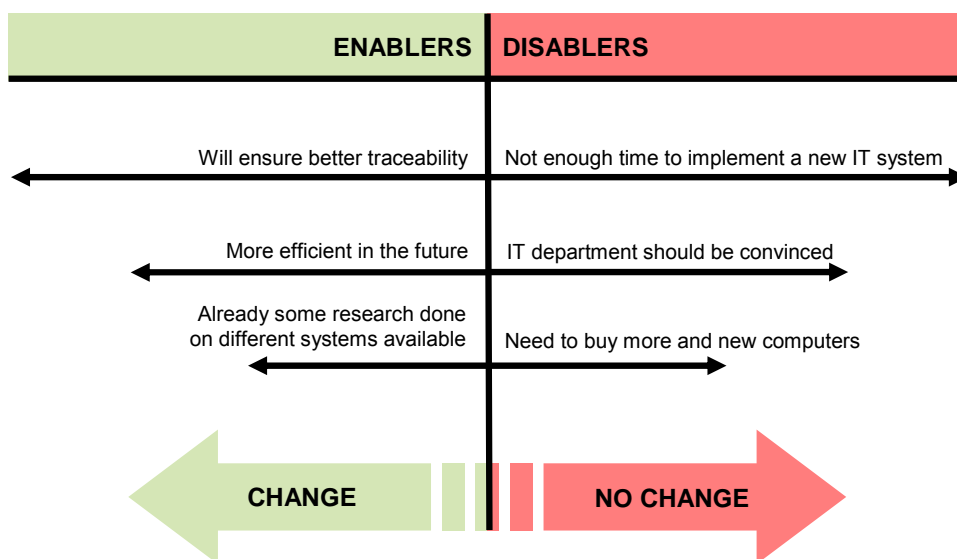
Initially, people deny the impending change and continue with their work. They progressively become aware that the change is significant and may begin to doubt and become angry. Consequently, people will negotiate and try to maintain the status quo. When it is accepted that change is inevitable, they may become depressed. After a period of inner struggle, people see new opportunities, start exploring them, and develop alternatives to go about with the changes. In the last phase they accept the situation and plans can be made to continue. Each individual will go through these phases, but at different speeds, resulting in the need for flexibility, in particular from the management. Figure 6 gives an overview of the different phases as well as how you should react accordingly when you are implementing change. First, patiently repeat the message and the facts to people in the 'shock and denial phase'. Secondly, give them the opportunity to blow off some steam and listen. If they start to negotiate, be firm, which can be followed by encouragement. Once people accept what is going to happen, do not minimize their efforts and be positive.

FIGURE 6 – PHASES PEOPLE GO THROUGH IN TIMES OF CHANGE



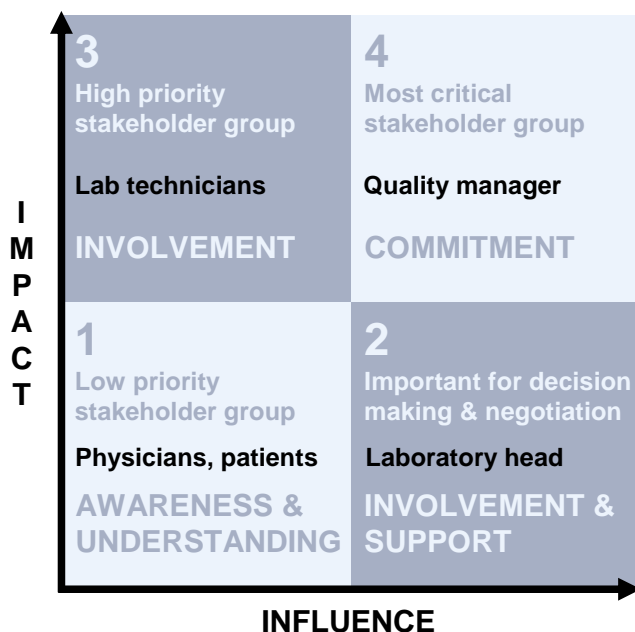
A useful tool to manage the human side of change is **force field analysis**, which helps you to go through the phases of change in a participative way with your team or department (group problem solving tool). It is based on the fact that every situation involves a balance between conflicting forces, called driving forces and restraining forces. Driving forces or enablers are actions, skills, equipment, procedures, people etc. that help to move towards the desired objectives, while restraining forces or disablers inhibit you from reaching the goals. Force field analysis is usefully done as a group exercise, involving identifying the different forces together. The forces can be prioritized and appropriate actions should be defined to minimize the disablers and to stimulate enablers so that change becomes possible. In figure 7 the force field analysis is applied on implementing an IT support system in the laboratory.

FIGURE 7 – FORCE FIELD ANALYSIS EXAMPLE: IMPLEMENTING AN IT SUPPORT SYSTEM



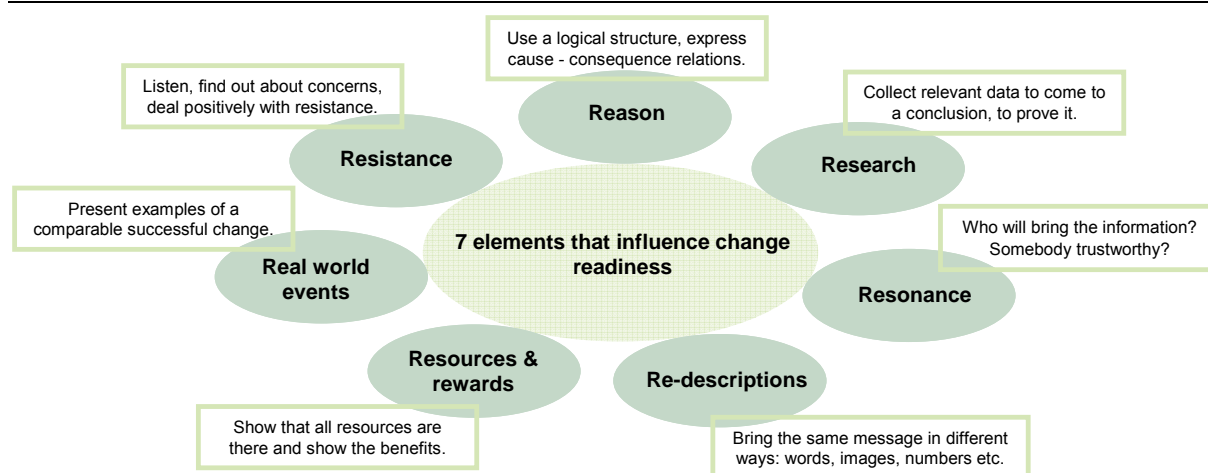
A second tool to improve insight in the change process is **stakeholder analysis**. Stakeholders are individuals who have a direct interest in the change process (positive or negative); they have the information, resources and expertise important for the success of the change process or they have the authority to influence the success. The inclusion of all relevant stakeholders in this analysis is essential for the success of the change process. Here is how it works. First create a list of all stakeholders (**stakeholder map**): e.g. laboratory technicians, quality manager, laboratory director, physicians and patients. Split all stakeholders up into clusters, based on influence and impact (cluster 1-4 in figure 8). This enables you to assign priorities within the stakeholders group (high, low, critical, important for decision making etc.). Finally, strategies should be developed to involve, inform or mobilize the different stakeholders (**stakeholder management plan**). For example the strategy for stakeholders that have a low influence, but high impact (cluster 3) should be oriented towards empowerment, which encloses involvement by giving limited power to decide.

FIGURE 8 – STAKEHOLDER ANALYSIS



In case of major change processes, it can be worthwhile to develop a structured **communication plan**. The stakeholder map acts then as a starting point to identify the people you have to communicate with. The communication plan should include these stakeholders, the message you want to communicate, the actions needed, how and when you will communicate your change process to the stakeholders and finally who will be responsible for the actions. In addition, individuals think in different ways, therefore they should be approached differently. Gardner identified seven levers (“7 RE’s”) that aid or thwart the process of mind change. These levers are: reason, research, resonance, re-descriptions, resources and rewards, real-world events and resistance<sup>19</sup> (figure 9). Consider these levers to bring about significant changes in perspective and behaviour in order to reach all collaborators and to improve your communication plan.

FIGURE 9 – 7 RE’s, H. GARDNER



The tension between the cyclic and linear process results mostly in resistance. This resistance is not problematic and if managed well, it could have a positive impact or even optimize the change process. When confronted with resistance you could make an appeal to the following four steps:

*1/ Listen and reward:*

That is a good question. It is indeed important to take that into account. I understand why you have difficulties with that.

*2/ Summarize to check if you understood your collaborator:*

If I understand well ... So you think that ...

*3/ Keep asking questions:*

Could you give some examples? What do you mean exactly?

*4/ React, depending on the time you have, the emotion of the collaborator or the difficulty of the question:*

- Park or move the issue: Is it ok that I make a note and come back to it later on?
- Give more explanation: When you think a collaborator does not understand everything, explain it again in a different way.
- Start the discussion: If you want to know how others think about it. If it is obvious you cannot continue before a certain point is discussed.
- Take away the objective / give in: Sometimes a small concession could raise a lot of goodwill of the collaborators.
- Hold on to your point: If unrealistic questions are asked, stay friendly, but firm.

### 5.3 Discussion

When implementing a change process you should be aware that individuals will go through a psychological process which causes resistance. Tools, such as a force field analysis and a stakeholder analysis, help to navigate more efficiently through the whole change process, to stimulate behavioural change and to involve all stakeholders. In addition, a good structured approach, by using for example a communication plan, will help to develop better strategies to overcome resistance. It is essential not to answer resistance with resistance. On the other hand, it is not just enough to listen and acknowledge. It might be a challenge for a manager to dare to deviate from the original change process when it is clear that the resistance revealed some precious indications to do so. It might be a contradiction to defend change while refusing to have an open attitude to change oneself.

## 6 Opinions of participants

### 6.1 Dr. Tony Herbert – Assistant Director & Quality Manager of Wessex Regional Genetics Laboratory, Salisbury, UK – CPA accredited laboratory

I have been fortunate to attend most of the Unit 1 EuroGentest workshops on Quality Management over the last two years. I first attended the workshop in Leiden as a newly appointed UK Quality Manager with these new duties occupying about 1/6th of my time. I was somewhat apprehensive about what would be expected of me and the amount of bureaucracy this job would entail, however, since quality management was seen as a mandatory requirement of an accredited laboratory and I had been instrumental in preparing for previous successful accreditation visits, the mantle of Quality Manager naturally fell to me. The role can be seen as either a chore or as an essential component of a properly organized service laboratory. I view it as the latter and have formed a committee with shared responsibilities to promulgate this ethos throughout the laboratory.

The joy of being involved in EuroGentest workshops comes from the realization that you are not alone; that there are quality managers in laboratories throughout Europe, all striving to improve standards in our individual laboratories. This role is new to all of us and much time can be saved by sharing ideas gained from experience.

The workshops start with an ice-breaker; usually a task designed to encourage delegates to interact with one another. These ice-breakers immediately put one at ease and set the tone for the rest of the meeting. Sessions are introduced and led by Unit co-ordinators and delegates are then arranged into small workgroups. This is the main attraction for me and the reason I keep returning to the workshops. The interactive nature of the workshops allows personal involvement and the opportunity to take part in make-believe 'real-life' scenarios, sometimes even visiting the host laboratory. The experience provides the opportunity to learn which strategies will work and which will not in real-life situations.

For example, on returning from the workshop on internal auditing, I re-designed our audit forms and audit strategy as a direct result of what I had learnt at the workshop. The workshop on Quality Management Software afforded the opportunity to identify what elements we thought were essential in a QM package and what features were desirable extras, making the life of the quality management team and the laboratory as easy as possible.

Having now attended different EuroGentest workshops, I still return to the laboratory with renewed enthusiasm and new ideas - and look forward to the next one!

### 6.2 Uta Malburg - Quality Manager of the Department of Human Genetics, University Würzburg, Germany – preparing for ISO accreditation

As professionally offered training courses often refer to quality management in general or to the more common certification standard ISO 9001, it is nearly impossible to find a workshop that concentrates on aspects of quality management which are relevant especially to medical or even genetic laboratories.

I attended several EuroGentest workshops because I wanted to take this special chance to exchange experiences with colleagues who have to solve the same problems and overcome the same obstacles in their (genetic) laboratories. Participants with less knowledge/experience from laboratories that are undergoing the accreditation process can learn from participants with more experience. Even people

who have worked in the field of quality management for a long time can profit from new ideas and solutions that are brought up during the workshops.

All workshops had quite a convenient size for a productive working and learning atmosphere and were prepared very professionally and thoroughly.

For me as a staff member of a non-accredited laboratory, the first workshop on accreditation in Leiden was very informative, particularly because of the visits to the Molecular Genetics and Cytogenetics laboratories. It was possible to explore the implementation of the theoretically discussed issues in practice on-site.

The discussion of the case studies with the other participants revealed that, even if there exist different accreditation standards over Europe, all have much the same requirements and aims. Nevertheless the practical implementation of these requirements is handled variously from laboratory to laboratory. So I left the workshop with several new ideas how to solve some tricky problems.

The workshop on IT support for quality management provided a useful survey of different IT systems that are on the market. It was very helpful that there were not only presentations of some software-solutions but also the possibility to test several programmes to find out the advantages and disadvantages of these tools for use in our laboratory. For specific questions the participants had the chance to talk to representatives of the software companies.

This workshop helped me to make the decision that for us as a rather small laboratory the implementation of IT support is not indicated at the moment, for different reasons. But if we come to the decision that we want to start working with an IT system, I now know which companies I can contact.

The workshop on internal audit delivered useful insight to the formal issues that have to be considered during the audit process. It was helpful for me to exercise the preparation of an audit plan and an audit report with non-conformities and action plan. I have an idea now how to proceed when planning and executing an internal audit.

## 7 Conclusions

Implementing a quality management system is a process with different phases starting from choosing an appropriate standard, delegating responsibilities and collecting information, through to writing down all standard operating procedures, offering training and performing validation and audits. This requires a lot of energy and time for laboratory personnel. However, all the invested time will return as an increased quality for the patient and confidence in the test results as well as a higher efficiency and traceability.

By bringing all kinds of genetic testing laboratories together, the training workshops offer a platform for accredited and non-accredited laboratories to meet colleagues experiencing the same and to discuss specific issues as there are not many other possibilities to do this. The common situation of all participants encourages them to start or continue implementing, harmonizing and improving quality systems within Europe, which is one of the major aims of EuroGentest.

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