Total Quality Management as a Tool to Achieve "Good Medical Laboratory Services"

Umfassendes Qualitätsmanagement: Ein Instrument zur Erzielung „guter labormedizinischer Dienstleistungen"

R. Haeckel[1,2]

Summary: Total quality management (TQM) is a concept to obtain good or even excellent "business results" or, in the case of a medical laboratory, to achieve good medical laboratory services (GMLS). The term GMLS is explained by a model proposed by a working group of the European Confederation of Laboratory Medicine (ECLM) based on a comprehensive TQM concept issued by the European Foundation for Quality Management. The ECLM model for GMLS includes competence for operative, normative and strategic management and good use of laboratory medicine (GULM) in the sense of evidence based medicine (GMLS = TQM + GULM). In hospitals, GMLS should be applied to all activities within the central laboratory and outside its boundaries e.g. by taking responsibility in point-of-care testing (POCT).

Keywords: Total Quality Management; Laboratories/standards; Laboratories/utilization; Europe.

Zusammenfassung: Umfassendes Qualitätsmanagement (total quality management, TQM) ist ein Konzept zur Erreichung eines guten oder sogar hervorragenden „Geschäftserfolges", im Fall der medizinischen Laboratorien gleichbedeutend mit „guten labormedizinischen Dienstleistungen" („good medical laboratory services", GMLS). Der Begriff GMLS wird erläutert durch ein von einer Working Group der European Confederation of Laboratory Medicine (ECLM) vorgeschlagenes Modell, dem ein allgemeines TQM-Konzept der European Foundation for Quality Management zugrunde liegt. Das ECLM Modell für GMLS umschließt operatives, normatives und strategisches Management sowie die adäquate Nutzung der Laboratoriumsmedizin („good use of laboratory medicine", GULM) im Sinne einer Evidenz-basierten Medizin (GMLS = TQM + GULM). Im Krankenhaus sollte GMLS alle Aktivitäten innerhalb des Zentrallaboratoriums und auch außerhalb liegende Bereiche , wie z.B. die Übernahme von Verantwortung beim Point-of-care Testing, umfassen.

Schlüsselwörter: Umfassendes Qualitätsmanagement; Laboratorien/Standards; Laboratorien/Nutzanwendung; Europa.

In recent years economical problems had priority in many hospital laboratories. Some were checked by consulting companies from outside or by in-house controlling mechanisms much more than other institutions of the hospital with similar service functions. As a consequence resources for quality assessment programs were reduced. It appeared, therefore, necessary to counteract this development by reinforcing quality aspects, however, by developing new strategies under the slogan "quality and money instead of quality versus money".

These new strategies will become the major concern for future laboratory management. The goal is "good laboratory practice" (GLP) which has to be defined for the purpose of laboratory medicine. As a strategy to achieve the goal, adoption of the total quality management (TQM) concept is proposed.

Definition of GMLS

A working group of the European Confederation of Laboratory Medicine (ECLM) has suggested to use the term "good services" instead of "good practice" [1]. Good services mean a high quality of services offered. Quality has been defined in the International Vocabulary of Metrology [2]: "totality of characteristics of an entity that bears on its ability to satisfy stated and implied needs". This definition has been later adopted in the EN/ISO standard 8402 [3].

Unfortunately this definition is rather vague because it leaves open what needs mean and to whom these requirements may apply. In laboratory medicine at least 3 parties have needs: the customers (patients or physicians ordering a test), the personnel and the owner or the hospital management. Further needs may be postulated from external authorities, students, re-

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Table 1 Concept of normative, strategic and operative management activities

Normative Management	Strategic Management	Operative Management
Vision	Staff management	Processes
Mission, goals	- motivation	Ecological aspects
Business politics	- development of expertise	Economical aspects
Business culture	- demarcation of responsibilities	Consulting with physicians on the optimal utilization of the laboratory (GULM) including sampling and transport of samples (input quality)
Business concepts	- communication lines	
Setting and promoting objectives	Management of resources	
	- investment decisions	
	- calculation and billing of costs	Involvement in POCT
	- budgeting and financial follow-up	Infection control
	- reflecting on in- and outsourcing concepts	
	- definition of test program	
	- test strategies	
	- QMS	

search groups depending on the field of activities in which a particular laboratory is involved.

The needs required by the customers probably cannot be defined by one single statement. An overall mission, however, is to provide the customer with the most effective and efficient answer(s) to particular diagnostic and monitoring questions concerning the health or disease status, usually based on examinations of an individual's sample.

The needs defined by the personnel concern e.g. safety, stress-free and agreeable working conditions, continuous training, and job security.

The needs defined by the owner or, in the case of a hospital, by the top management can be summarized as an optimal use of the resources provided and effective cooperation with the customers and other parties of the hospital.

If needs and missions have been defined a model of good quality can be developed for medical laboratories. Then quality criteria can be derived. This approach forms a quality pyramid, consisting of the 3 elements mission, model and criteria (or characteristics).

Many lists of criteria have been developed for the medical laboratory [1]. However, the basic model of a good laboratory from which these criteria are derived is not always made clear. Therefore, the ECLM group has developed a model in which several quality levels are distinguished according to a proposal of *Donabedian* [4]:

- Quality of structure: the availability and organization of human, physical and financial resources (staff, space, equipment, consumables, etc) required for the delivery of a product or service.
- Quality of process: all activities for the delivery of a product or service (examination including quality assurance, reporting, interpretation, consultation).
- Quality of (patient health) outcome: the outcome as defined by *Donabedian* means a change in a patient's current and future health status as a result of a particular intervention.

In the context of laboratory performance, outcome also depends on the choice of examinations (tests), strategies for diagnosis, prognosis or monitoring of disease and whether an appropriate effect on the health care outcome for individual patients can be achieved in the sense of good use of laboratory medicine.

Although in *Donabedian's* multidimensional quality concept, the quality of the top or overall management of the laboratory is a part of the "quality of structure", laboratory management could be a further, separate quality level, because it has an integrative responsibility for all 3 quality levels. Integrative management (tab. 1) should have a normative, strategic (or support) and an operative dimension [5, 6].

Whereas in the past, laboratory managers were mainly concerned with the operative dimension, in the future, the normative and strategic dimensions will become more relevant. The normative dimension should start from a vision with an integrative force in horizontal and vertical directions: the "goal of the journey" must be known to all staff members.

Public relations activities for improving the image of the laboratory become more important in competition strategies (self-marketing and self-promoting). For the survival of individual laboratories, cooperation with other laboratories or with other disciplines in the sense of a "laboratory without walls" may become necessary. Syncytial organizations should replace cellular structures which now exist to overcome overlapping existence of resources on local and regional scales [7].

Most reviews of future strategies in laboratory medicine published recently have stressed that consulting will become more important. This will require more

Non standardized abbreviations: EAL, European Cooperation for Accreditation of Laboratories; ECLM, European Confederation of Laboratory Medicine; EFI, European Foundation for Immunogenetics; EFQM, European Foundation for Quality Management ; EN, Europäische Norm; GMLS, good medical laboratory services; GULM, good use of laboratory medicine; ISO, International Organization for Standardization; POCT, point-of-care testing; QMS, quality management system; TQM, total quality management.

academic overheads, whereas everywhere academic positions are presently reduced. However, this consulting expertise will be crucial if customer satisfaction has to be taken seriously. Regional cooperation between laboratories to increase the consulting expertise is the most promising solution [8, 9] instead of supraregional concentration of laboratory services by industrialized "megalaboratories".

Focussing TQM on optimum solutions for the customer must not disregard the cost. In economic terms, effectiveness (i.e. the ratio of objectives actually achieved to the intended objectives) and efficiency (i.e. the performance related to the expenditure) have to be taken into account [10].

Economic duties of laboratory managers become more diversified and include:

- Decision making on capital investments.
- To consider costs and profit, establish "prices" (for in-house budgets and/or external clients; policy of reimbursement).
- The hospital management expects a most efficient use of the resources spent on laboratory services: low process costs and high efficacy of the testing strategy (optimizing the request rate by developing the request program and request behavior).
- Another major concern is to find a good balance between outsourcing and in-house testing.

A new generation of automated chemistry, hematology, immunoassay, coagulation, and microbiology analytical systems is now available that can provide rapid throughput and a wide repertoire of clinically relevant assays crossing traditional disciplinary boundaries. With this availability, efficiency, and diversity - coupled with increased emphasis on cost containment, intense competition between laboratories, and rapid ground and air transport capabilities - large volume testing is now conducted in consolidated, centralized laboratories that offer extensive, cost-effective, and efficient testing. Conversely, point-of-care analyzers and portable, single-purpose analyzers are available for use in the home; this movement toward decentralized testing has made it possible to reduce turn-around time and improve customer satisfaction [11].

This facet of management activities has become more important in the present situation of rapid technological change by removing the boundaries of time and space from many key aspects of our movement toward the so-called "placeless society" or the "age of everything everywhere" affects also the clinical laboratory resulting in a network of clinical laboratories and the unusual situation in which clinical testing is simultaneously becoming both centralized and decentralized [11].

A task force of the American Association of Clinical Chemistry [12] has defined 5 "core competencies" for laboratory managers (tab. 2). These core competencies could be split in managerial and professional capabilities [5, 6]. This differentiation, however, is not very useful because of many overlapping contents.

Because the management competencies are becoming so important for the entire laboratory as a medical discipline, it appears justified to introduce the quality of management as a fifth level of quality into the concept of multidimensionality of the term quality characterizing the comprehensive quality process in laboratory medicine.

The concept of TQM

Several concepts (tab. 3) have been developed to improve the business outcome in industrial processes, especially in Japan. One example is Kaizen.

Kaizen means to improve. Kaizen is a continuous improvement concept and a complex of several partial concepts. It seems that the Japanese author *Imai* [13] has collected many modern terms, has written them under an umbrella, and chosen the subtitle: key to the success of Japan in global competition. A basic element is human resource management, a culture of continuous improvement by including all staff members. This corporate culture is probably one key to Japan's success in competition. In this culture, more money is spent in the development of human resources, career planning and education.

Another concept is called benchmarking. Benchmarking is the method of comparing with others, lear-

Table 2 Core competencies for laboratory managers according to a task force of the American Association of Clinical Chemistry [12]

1. Fundamental skills: required for certification in clinical chemistry/laboratory medicine.
2. Chemical skills: consulting in test selection, test logic, and test interpretation, the appropriate use of laboratory tests, with a focus on improved patient outcomes.
3. Scientific and technical skills: lead in the introduction of new technologies (e.g., robotics), improving clinical laboratory science.
4. Management skills: developing strategic business skills ranging and gaining expertise in multidisciplinary team building, team problem solving and team leadership.
5. Professional development: engaging in career-long professional development through continuing education, participating in their professional society, sharing their knowledge, and maintaining their expertise.

ning from others. Therefore, benchmarking means to study the results of the best competitors and compare these results with the own performance. Benchmarking can also be extended to processes, and may be applied to in-house units. A benchmark, in geodesy, means a hallmark to measure height differences in the landscape. The aim for searching a benchmark is to establish a standard, a quality goal.

Zink [6] has defined benchmarking "searching for the best processes or results, which are relevant for the particular task in the own business unit. The aim is to learn from these processes and results and to improve the own performance". In this sense, benchmarking is an old technique of mankind. The Chinese general *Sun Tzu* wrote about 2500 years ago: "When you know your enemy and you know yourself, then you must not be afraid of the outcome of 100 battles" [6]. What is new, is to systemize this common sense and to make it conscious to all staff members.

Several types of benchmarking are known:
- competitive benchmarking means comparing with direct competitors
- best practice benchmarking is comparing with best enterprises on the world market
- award model benchmarking means self-assessment by comparing with theoretical examples.

A further management concept (tab. 3) is policy deployment [6], a goal finding process. In former times, goal and action plans followed a cascade top-down to the action performing level. This hierarchical system should be replaced by vertical and horizontal processes (cross-functional deployment).

Table 3 Partial management concepts [6, 18]

1. Kaizen (continuous improvement concept)
2. Benchmarking
3. Policy deployment
4. Hoshin planning ("golden compass", management of objectives (MOO))
5. MBO, management by objectives
6. People empowerment
7. QMS, quality management system
8. Kanban
9. Just-in-time
10. Time-based management, time-to-market, speed management
11. Total productive maintenance
12. Quality function development
13. Simultaneous engineering
14. Lean production, lean management
15. Business reengineering
16. Listing criteria for measuring quality: reliability, availability of service ("the right result at the right time")
17. Analysis of trouble points and complaints(cause-effect diagram = fish bone diagram, Ishikawa diagram)
18. Strategic alliances, joint ventures
19. Profit center concept

People empowerment (tab. 3) is a very important management tool (to empower = befähigen, bevollmächtigen, berechtigen). According to an English-German dictionary "to empower" includes several meanings: to enable (to qualify), to entitle (to give the right to do), to authorize (to legitimate). Empowerment means to emancipate a frustrated conveyer belt workman to a responsible coworker. This is reflected by several definitions taken from the literature [6]:
- giving people the authority and autonomy to do their jobs,
- restructuring the contents of jobs to restore those elements of knowledge, planning, and decision-making stolen by tailored management; to return them into a greater degree of self-regulating power to control their own working day in the collective interest,
- staff motivation by involvement,
- human resource management.

The realization degree of empowerment increases from rights of the employees to propose to rights to be involved, and finally to rights to decide [6]. The management must stimulate the commitment to quality through all hierarchical staff levels.

Hoshin planning (tab. 3) means management of objectives instead of management by objectives and has also been called "compass management" because everybody is managing and moving in the same direction.

The most important management tool (tab. 3) for a laboratory is the implementation of a quality management system (QMS) as recommended by several international standards (see below).

Many other management concepts have been developed, some of which are also mentioned in tab. 3. These concepts are called partial concepts because they are somehow included in a comprehensive and integrative concept which is called total quality management (TQM). The essentials of TQM have already been outlined by *Deming* [14], one of the fathers of TQM, most of these are related to management of staff resources. The underlying hypothesis of employee satisfaction postulates that satisfied customers require satisfied employees. TQM leads to a new culture of communication between the employees with the customers.

These thoughts are included in the definition of ISO 8402 [3]: TQM is a "management approach of an organization, centered on quality, based on the participation of all its members and aiming at long-term success through customer satisfaction, and benefits to all members of the organization and to society". According to this definition TQM means "total customer satisfaction". However, it is not sufficient that the customers receive quality, he must also recognize this.

TQM is presently the most comprehensive quality management concept applicable to medical laboratories. It is not a new concept, but a structured summary of old ideas of business philosophy which are com-

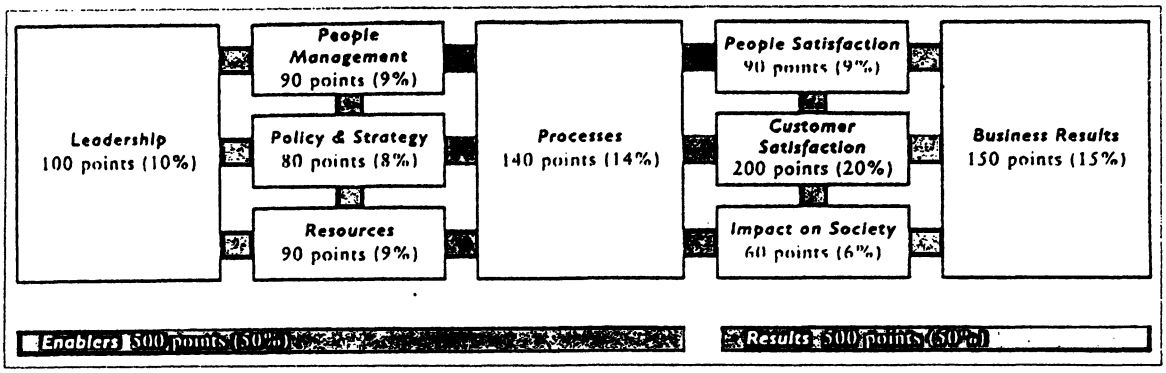

Figure 1 The TQM model of the European Foundation for Quality Management (EFQM) to obtain "business excellence " [15]. The 9 boxes are used to assess an organization's progress toward excellence. The enabler criteria are concerned how results are being achieved, the result criteria are concerned with what the organization has achieved and is achieving. The number of points given have been proposed by EFQM and show the maximum number that may be given to each of the criteria and the equivalent percentages. These figures were the outcome of a consultation exercise involving EFQM members and many other European institutions.

bined in one term. For laboratories, TQM is a management concept to realize GMLS, and QMS is only one, however, important element of TQM.

ECLM model for GMLS

The various quality aspects mentioned so far have been included in a model for GMLS by the ECLM project group. This is based on a model developed by the European Foundation for Quality Management (EFQM). The EFQM distributes a distinguished award which is comparable with the famous awards in Japan (Deming Award) and USA (MBNQA Award).

In 1987 president *Reagan* signed the Malcolm Baldrige National Quality Improvement Act by which a national quality award can be obtained. The European answer to this challenge was the creation of the European Foundation for Quality Management (EFQM) in 1988. The European award was given the first time to the European branch of Rank Xerox in 1992. The goal of these awards is to support the idea of TQM in the particular region.

The EFQM model (fig. 1) interrelates personnel, processes and results [15]. Better results by involvement of all employees in the continuous improvement of all processes. The 3 major columns represent top management (= leadership), process and business results.

In analogy to the EFQM concept, the GMLS model was developed for medical laboratories (fig.2). In this model are found [1]:

1. The 4 quality levels mentioned above: laboratory management, structure, analytical processes and results.

2. The 3 groups of management activities: normative, strategic (support) and operative activities.

3. The 3 traditional phases of laboratory medicine: preexaminational, examinational and postexaminational phase (preanalytical, analytical, postanalytical phase).

The preexaminational phase usually consists of processes outside the laboratory ("prelaboratory phase") and processes after the sample has arrived in the laboratory:

- The problem to be solved must be defined so that a clear question can be asked to the laboratory. The question can be e.g. "what is the concentration of potassium ion in a serum sample" or more complex "identify a microbe in a blood sample and give advice on proper treatment". The definition of the problem, or the formulation of the clinical question is the responsibility of the customer. If it is not clear, the laboratory has to provide sufficient advice to the customer (consulting) in order to achieve the "right" question.
- The laboratory has to provide information on the available test program and on effective test strategies.
- The laboratory should provide all information required for gaining the right sample (specimen) at the right time under the appropriate conditions.
- All information required for efficient transport of samples (quality, timing) shall be provided by the laboratory.

When the question raised by the customer is clear, the laboratory is responsible for the right answer, from the right sample, at the right time, to the right person, at the right cost [8]. Its effectiveness depends on the test quality concerning timing, diagnostic and analytical reliability (examinational phase).

In the postexaminational phase the analytical results are, if required, biologically validated (also called medical validation), interpreted and integrated in a final (usually cumulative) report with providing reference or therapeutic ranges. In some cases, additional consulting may be necessary.

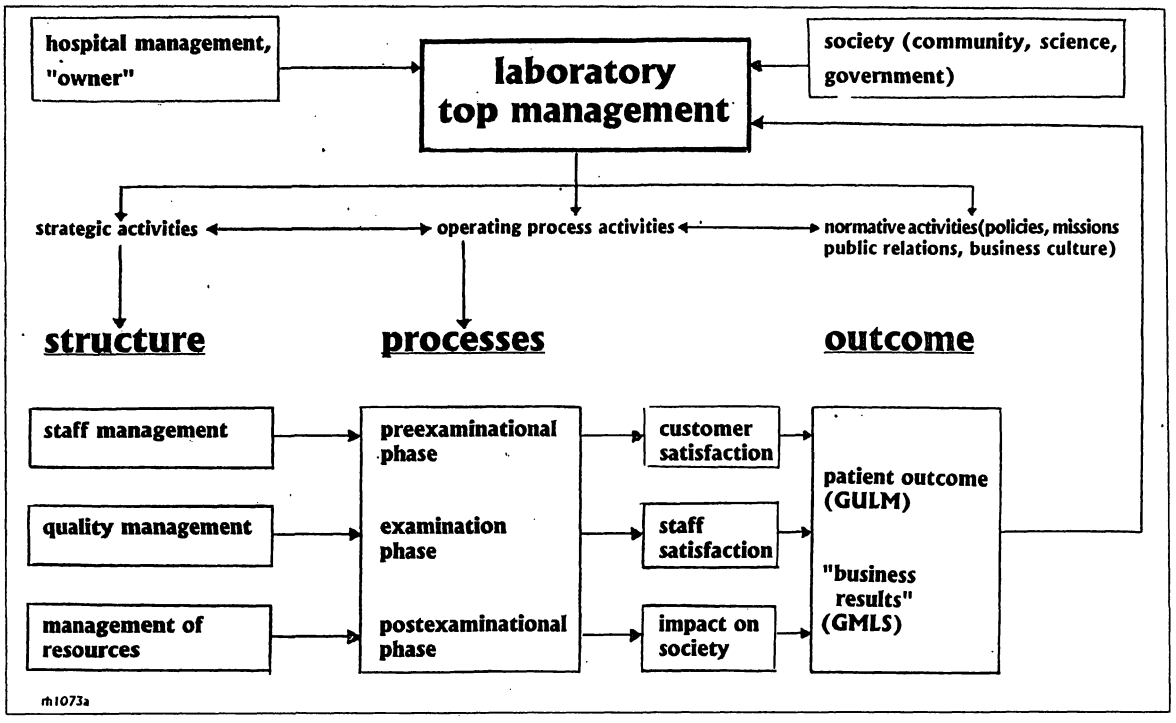

Figure 2 ECLM model for GMLS in analogy to the EFQM model in fig.1 [1]

The model of GMLS just outlined provides a definition or a vision of good laboratory services (GMLS). It introduces like the EFQM model a new type of thinking, a philosophy of "business life". It goes further than commitment to the customer, it includes obligations to the society. Furthermore, the responsibility for laboratory medicine as a discipline is somehow included. The walls of the laboratory must be overcome.

The top management must be involved in the development of laboratory medicine as a discipline on a (inter)national level, on a regional level which probably will be the key area for the survival of laboratory medicine and on a local level. "On a local level" means inside a hospital and includes cooperation with other laboratories which are not part of the business unit and involvement in POCT.

Implementation of TQM/GMLS

Whereas a generally accepted national or international guide for TQM is not available at the present time, several standards are known for an important partial aspect, the QMS. The ISO 9000 series are probably the most successful international standards for all kinds of production companies and service providing organizations. Then, the EN 45 000 series and the ISO/IEC Guide 25 have been published. The EN 45001 "general criteria for the operation of testing laboratories" are worked out only for laboratories.

It has been suggested that a workable, comprehensive quality system guideline is feasible by combining the best features of ISO 9000, EN 45001, ISO Guide 25, accreditation rules of the College of American Pathologists and of other accreditation agencies with the work already started by the committee of ISO/TC 212. It appears possible to have a universal quality system for medical laboratories [16], which might be developed in the direction of TQM.

Two different approaches have been described for the implementation of TQM [17]: the organizational and project based strategy in which top-down/bottom-up versus structure/culture elements are differentiated. In practice a mixture of the 2 strategies and the 4 elements will occur.

The organization strategy is characterized by fast development of TQM. Initially, such an approach has mainly a top-down characteristic. This strategy will have more chance to succeed if there is a greater need for change, because only then, when all members of the organization are prepared to change "radically" and "collectively" will it work. In the hospitals concerned, one tries to involve the employees from the branch organization into quality policy by giving training in methods and techniques of quality-care throughout the whole organization.

Project based strategy is characterized by slow development. In practice, the experiences of the employees are considered via the incremental solving of problems. Complex problems of a mostly interdisciplinary nature are dealt with at a later stage. To proceed from discrete projects to interdisciplinary organization related projects is not an easy step and needs more top-down control and attention. At a strategic level, it is necessary to draft a clear policy and offer facilities in order to embed quality care into the organization. In addition, project based implementation of TQM emphasis the role of the professionals. In the long run, this promotes the introduction of quality-policy.

It has been suggested that the chosen strategy is irrelevant and only the involvement of the specialists is of crucial importance. Many hospitals find it difficult to implement TQM in all departments. Gaps are reported between the TQM philosophy and the current hospital practice, characterized by its high level of professionalism [17].

TQM experts [5,17] are of the opinion that the introduction of TQM may take 5 to 10 years. It is therefore expedient to set milestones during that period in order not to lose focus. Reaching the milestones could be rewarded by awards with a progressive degree of difficulty. Such a model would indicate the degree of maturity of the TQM efforts in the enterprise [18].

A patented recipe for introducing TQM in a business unit does not exist. Implementation of TQM can only be achieved continuously. A simplified step by step procedure is shown in tab. 4. In the PDAC (fig. 3), also called Deming cycle, "check" is usually the weakest point.

Table 4 Simplified steps for implementing a quality management system

1. Study of national (European) guidance documents
2. Nomination of quality supervisor(s)
3. Information and stepwise involvement of all staff members
4. Actualization of standard operating procedures (logistic, test and equipment procedures)
5. Production of a quality management manual
6. Identification of deficits by check-lists (PDCA circle activities)
7. Implementation of internal audits
8. External audit by accreditation

Table 5 Four out of 14 errors listed by *von Eiff* [19]

1. The top management uses TQM only for public relations
2. The top management does not take the real leadership for implementing the TQM concept
3. The personnel is not prepared to take the responsibility for problem solving activities
4. The personnel are first asked to take initiative and then are frustrated

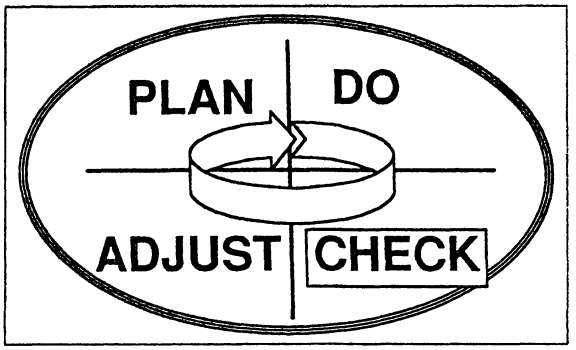

Figure 3 PDCA cycle (Deming cycle) as a tool for continuous improvement in all kinds of business organizations

The implementation of TQM has sometimes fallen into discredit, especially if serious errors occurred. *Van Eiff* [18] has listed 14 drawbacks of which 4 examples are reported in tab. 5.

Concepts for approving GMLS

After a QMS has been introduced in a medical laboratory, the efficiency of its functioning must be regularly surveyed:

1. by benchmarking (comparing with the best practice) and
2. by audits
2.1 internal audits (self assessment practices)
2.2 external auditing.

Two possibilities are usually offered for external auditing: certification and accreditation. Certification is usually based on the ISO EN DIN 9000 series and means approval that a QMS has been implemented. Accreditation is usually based on the EN 45 000 series, means approval of the conformity with a QMS, and includes the proof that the laboratory has the competence to achieve the quality. This proof can, for instance, be presented by results from internal and external quality schemes.

Certification and accreditation are usually organized by national bodies. Most bodies favor accreditation. The criteria to be checked are formulated in so called check lists. These check lists are more or less extensive. The British CPA has about 43 questions, whereas the College of American Pathologists (CAP) has several check lists with more than 1000 questions.

The implementation of TQM, or a QMS followed by accreditation has benefits and disadvantages. *Büttner* has pointed out the importance of implementing TQM in the sense of GMLS as a voluntary code of self-discipline [14]. Other benefits are listed in tab. 6.

Table 6 Benefits of implementing a QMS followed by accreditation

1. Voluntary code of self discipline
2. Higher quality with acceptable expenses (transparency, traceability, less cost of non-conformance, rapid integration of new staff members, less reruns, improved motivation of staff, clear structures, more efficient use of resources, etc.)
3. Improved compliance with laws, regulations, etc.
4. Participation in clinical trials which require accreditation
5. Defense support if accused of organizational deficits
6. Strategic advances for survival ("business excellence")
7. Performing examinations for customers which have implemented a QMS

Table 7 Evolution of the quality understanding in laboratory medicine

Stage	Objective
I.	Product quality ↓ Quality assurance programs
II.	+ Process quality ↓ Quality management system
III.	+ Management quality ↓ Total quality management (GMLS)
IV.	Total concept with including the customer: GMLS + GULM

In the case of an erroneous result which has led to damage of a patient the management may have to prove that the laboratory unit has no organizational deficits. Then, the successful implementation of a QMS may be helpful in the defense of accusation.

Often cited disadvantages are the burden of bureaucracy by implementation of the standards, especially the cumbersome management of documents which leads to a lot of paperwork and additional costs. However, the costs of avoidable errors and of disorganization have never been estimated.

European harmonization

The only harmonized accreditation activity has been started by the European Foundation for Immunogenetics (EFI).

The GMLS group of ECLM undertook an initiative for the European harmonization of various national approaches. For this purpose a workshop was recently hold in Düsseldorf. At this event, EAL (European Cooperation for Accreditation of Laboratories, founded 1.6.94 in Paris by combining WECC - Western European Calibration Cooperation - and WELAC - Western European Laboratory Accreditation Cooperation) was addressed to establish a "Scientific Advisory Board" to facilitate a bi-directional contact between the profession and the accreditation bodies at the highest level in Europe.

Conclusion

The concept of quality assessment has changed in the last decade and will further be modified in the future. In the evolution of quality assessment concepts for the medical laboratory, at least 4 steps can be recognized (tab. 7).

In the sixties quality assurance or assessment programs were established for the surveillance of the quality of the end product which, in the case of a laboratory, is the test result. It has been estimated in a literature survey of 800 publications related to laboratory errors that failures of proficiency testing are due to analytical errors in only about 1/3rd of cases. The rest belongs to the pre- and postanalytical phase [16].

Therefore, in the seventy's and eigthies the pre- and postanalytical phases became more and more important and it became necessary to include the entire process from taking the sample until providing information on test results to the customer. Quality management systems were developed (2nd stage). Many laboratories have meanwhile introduced a QMS or are on their way to do this.

For the future, 2 further stages are already proposed. In the 3rd stage, TQM will be implemented, and in the 4th stage, physicians should be included to achieve good use of laboratory medicine (GULM).

In the future, laboratory management must be more concerned with the customers satisfaction: the customer must recognize and appreciate the benefit received from the laboratory. Furthermore, laboratory management must be more concerned with satisfaction of the society: society must also recognize and appreciate the benefit it receives from the laboratory, from good use of laboratory medicine.

TQM and GMLS will always be a goal. Therefore, a laboratory can only be on its way toward this goal. All these efforts, however, may be in vain if the top management does not believe in their effectiveness. Then, it may be better not to start and to use the resources for other purposes.

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Transplantation von Stamm- und Progenitorzellen

2. Symposium und Workshop der „Interdisziplinären Gruppe für Labor und Durchfluß-zytometrie“

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