



COLUMNNA ANALYTICA

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Managing Laboratory Productivity and Quality (Hewlett-Packard's 9th Analytical Forum)

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'Managing Laboratory Productivity and Quality' was the title of *Hewlett-Packard's* 9th Analytical Forum, held on January 26 and 27, 1994, at its traditional venue in Egerkingen (Switzerland). The company and the scientific council in charge, Dr. Fritz Erni, Prof. Dr. Ernö Pretsch, Dr. Willi Vogel and Prof. Dr. H. Michael Widmer, scored a full success despite the limited travelling funds which are an unwanted fact today in many institutions. The maximum possible number of 120 participants met in Egerkingen and spent two stimulating days fully packed with provoking and informative lectures. Nevertheless, there were enough breaks permitting formal and informal discus-

sions which were continued also during lunch and dinner. Obviously the participants really wanted to learn and talk about productivity and quality. As a consequence, the lectures presenting new or applied analytical techniques were in a minority. And, as a good tradition, the organizing company was present with a large number of collaborators and with an exhibition of its most recent instruments but not with importunate advertising or seminars.

Although quality management problems had already been topics at the 1993 *Hewlett-Packard* Analytical Forum, it seems to become a most important issue for analytical laboratories in this and the coming years. This is the result of both

economic constraints and the need to establish formal quality control systems. Therefore, many lectures dealt with GLP (good laboratory practice) or EN 45000 (the European norm which is relevant for analytical laboratories). Also the more analytically oriented lectures presented highly sophisticated possibilities for cost-effective and even simple laboratory techniques.

The Analytical Laboratory – the Success Factor

In his opening address, Dr. Heinz Kirsten (*Hewlett-Packard*, Urdorf) stressed that the present economical situation is not only a 'regular recession' but is accompanied by many structural changes: industries are maturing, as a consequence their growth is slower; they are forced to save costs and to undergo more or less deep restructurations. A positive consequence of all this can be higher creativity which is urgently needed to master the challenges of the nineties: strategic cost reduction (also reduction of allocated costs), devel-

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opment of efficient organizations, innovative product development, and marketing with competitive costs. It is not possible to market in the future with the costs of the past! For the analytical laboratory the consequence is that it shall not be a simple data supplier but become a key entrepreneurial unit. It must be involved into the production cycle at the earliest stage. An instrument vendor such as *Hewlett-Packard* needs and wants to help the customers on all levels with seminars, brochures and technical support as well as with hard- and software which meets today's requirements.

Effizienz und Effektivität im Labor – das Richtige richtig tun

It is unusual that a business consultant such as Dr. *Christian Baer* (*BSG Unternehmensberatung*, St. Gallen) gives a talk for analytical chemists. This has the advantage that the public hears some irksome truths. The research and control laboratories are service centers which, from a superior point of view, are 'loss centers' and are not part of the core business. Therefore, they can be outsourced. To prevent this, the responsible persons need to recognize that their analytical services are a business like any other business. Its missions, objects, and processes should be clearly defined, and feedback should come in – if necessary by active demand. The offered service has to match a requirement and should be sold in adequate quality at a competitive price. The laboratory can become a profit center if its responsible persons start an active marketing and if all their activities are consumer-oriented. Perhaps the analysts need to acquire a more enterprising manner and self-consciousness. A prerequisite for any profit center is effectiveness and efficiency, doing the right thing and doing it right.

Analytical Management – a Key Business Factor

Dr. *Markus Gisin* (*Ciba-Geigy* Basel) stated that the most important changes in an analytical laboratory came from instrumentation and automatization in the last decades and even years. This will change now as further progress will come from new management methods and not from technologies. *Gisin* discussed the changing role of analytical chemistry during the lifecycle of a commercial product and stated that it is the only scientific discipline which is involved in all stages. This means that it is a key science, a fact the analytical expert can be proud of. The key success factors for good collaboration can be defined as follows: Our partners should appreciate analysts as business partners. Analysts should be involved in cross-functional teams and in decision making. Business process-related responsibilities should be assigned to them. Analysts should orient themselves proactively to business. They should make transparent their activities, expertises, resources, and costs. They need to integrate in and communicate with business processes and systems.

Any laboratory still having the reputation of being 'too late' and/or 'too expensive' or of giving 'wrong answers' needs to recognize this immediately and alter it at lightning speed.

Ansätze zur Kostenoptimierung in analytischen Laboratorien

Dr. *René Christen* (*Lonza*, Visp) gave an excellent illustration from his own experiences which confirmed the statements of the preceding speakers. Although the costs of analytics are only 2% of the sales in production or 10% of the expenses in research and development it is always worthwhile to optimize it, because wrong

analytics can be very costly if raw materials or end products pass or fail a quality criterion incorrectly. Moreover, it makes sense to perform the necessary analyses well and in time instead of making a wealth of cheap but poor analyses. It can be more difficult to not only optimize methods and techniques but to ask if they are really necessary; perhaps it is better to establish entirely new approaches. Usually there are timecritical, less critical and time-uncritical analyses to be performed by a quality control laboratory. In order to manage the inevitable peaks in workload it is necessary to recognize these three categories. Shift personnel is expensive, and perhaps it is not necessary in the laboratory. Instead of night work, autosamplers can be used; it is even possible to simplify the key analyses in such a manner that they can be performed by the shift personnel itself which works in the plant. This, however, needs a discussion with the persons responsible for production: what analyses are really necessary? How often need they be performed? Also the laboratory manager sometimes needs rethinking: Even an expensive instrument is 'cheap' if it works reliably and to capacity. And is it necessary to sign all the numerous analysis reports? If the data system is validated, there is no hindrance to let it print forms without signature, even those certificates which go to external customers.

Knowledge Based Systems as a Strategic Tool

Prof. Dr. *D.L. Massart* (*Vrije Universiteit*, Brussel) expects expert systems to become valuable tools for method validation. They are under-used today, perhaps due to over-expectations when they were introduced. However, they take over routine intellectual tasks, allow rapid deci-

sions and can be used as early warning systems. They can link two (or more) types of knowledge, e.g., method development and validation. The pre-requisite for expert systems is a formalized expertise: The problem must have been completely understood and described in a logical manner. Then they can be used as strategic tools because today statistics and chemometrics become more important and more complicated. Once a problem has been unfolded logically, it is not difficult to write an expert system because the necessary software packages such as Tool-book are commercially available. It is notable that the expertise is with the users themselves, so it is up to them to create expert systems; in most cases instrument or software vendors are not able to offer a tailor-made system. This can also be a reason for the rare use of expert systems: they are not an interesting enough good for commercial sale.

***In Vitro* Diagnostics – Analytical Chemistry Made Simple**

Dr. Louis J. Riceberg (*Ciba Corning Diagnostics*, Medfield) gave an insight into clinical *in vitro* diagnostics (IVD), a field where it was successfully possible to establish 'simple' (from the user's viewpoint) analytics. Its goal is to measure the presence of a substance in body fluids and tissues which helps in diagnosis, prognosis, treatment and monitoring of a patient. A well-known example is glucose analysis for the detection and treatment of diabetes. The advantage of IVD systems is that the customer can use a complete solution to a given problem consisting of instrument(s) and reagents. There is a guarantee that the system will work reliably and will yield accurate and reliable results. Little user training is needed. All methods used in IVD emerged from research in analytical chemistry such as

dioimmunoassay, NMR, HPLC, particle counting (blood cell analysis), pattern recognition (cell classification in pathology), enzymology, electrochemistry (blood pH and blood gases), or surface chemistry. A challenge for the future will be 'gene analysis' which today is demanding and time-consuming. In contrast to this the customer wants a quick and simple test method. In *Riceberg's* opinion a laboratory information management system is essential for routine clinical analysis; it is a money-saving tool because it can help to avoid unnecessary analyses.

Increasing Laboratory and Plant Efficiency with Flow Injection Techniques

Another simple-to-use analytical technique is flow injection analysis (FIA) and its descendant, sequential injection analysis (SIA). These methods were described by *Pamela Baxter-Palmer* (University of Washington, Seattle). They are well suited for rapid screening tests and can easily be automated and miniaturized. Little reagent solution is needed as was shown with the example of Fe^{2+} determination: the manual approach needs 100 ml of reagents and 25 min of time whereas FIA can do the analysis with less than 10 ml and within less than 1 min. Moreover, it allows to get away from volume measuring apparatus such as pipets and burets. The new SIA technique is more versatile than FIA, since it allows to change operational parameters very easily. A pump which can work in two directions and a control unit (personal computer) are needed. The technique is slower than FIA but produces (even) less waste. The analytical principles used involve colorimetry and turbidimetry (e.g., to determine biomass concentration in a fermenter), even acid-base titration with electrochemical consumption of the analyte and colorimetric determination of the

end-point is possible. After an analysis, the pump is switched on and the sample transported out of the electrochemical cell, so the next determination can be performed immediately after and in a fully automated mode.

Upgrading from GLP to EN 45001

Dr. *Klaus W. Mandelatz* (*Interlabor, Belp*) presented a topic which is of utmost interest for many analytical laboratories: What are the differences between Good Laboratory Practice GLP and the new European Norm 45001? Is it better to acquire a GLP certification or a EN accreditation? The good news is: Although EN 45001 needs higher requirements than GLP it is more content-oriented (whereas GLP is more formal-oriented) and produces less paperwork. The additional demands of EN 45001 over GLP are: a quality securing handbook (the collection of standard operating procedures for general affairs, methods and instruments), validated methods and certified reference materials. In favourable cases, a simple control chart over a long enough time can satisfy the requirements for validation. Whereas GLP cannot give any guarantee about contentional quality, EN 45001 can. The EN accreditation is granted in Switzerland by the Swiss Federal Office of Metrology in Wabern.

Practical Aspects of GLP in Environmental Studies

Dr. *Hans-Martin Müller-Kallert* (*RCC Umweltchemie*, Itingen) presented the enormous impact which was brought by GLP requirements into agrochemical research. Since GLP is now required for the registration of all kinds of compounds, including biocides, it is necessary to document the fate of a certain compound and



D.L. Massart



L.J. Riceberg



P. Baxter-Palmer



K.W. Mandelatz



H.-M. Müller-Kallert



S. Weinberg



H. Schrenker



R.M. Gy



R.E. Majors

its metabolites in the environment. For agrochemicals, this is done by incubation of the chemical with soil and column 'chromatography' (*i.e.*, the determination of breakthrough profiles), followed by chromatographic analysis of the products obtained. Within the last few years these GLP-required studies lead to a detailed description of the impact of agrochemicals on our environment.

Validation of Software for GLP Compliance

As already mentioned incidentally in the lecture of *R. Christen*, also the data system used in an analytical laboratory needs to be validated, a fact of great importance but of course of minor interest for chemists. This validation is performed by specialists such as Dr. *Sandy Weinberg* (*Weinberg, Spelton & Sax*, Boothwyn). It has to ascertain the evidence of (continued) accuracy and reliability, of management awareness and control, of audit trails, data integrity, and reviewer independence. It covers all kinds of laboratory automation systems (computer-controlled analytical equipment, laboratory information management systems, data analysis systems). *Weinberg* stated that in the development of new systems, the costs of validation are offset by savings in the design and implementing process.

Quality Management in Practice

Helge Schrenker (*Hewlett-Packard*, Waldbronn) presented how an instrument manufacturer implemented a quality strategy. Such a company is challenged in a double sense, because quality improving techniques should be brought not only into the firm but also into the instruments themselves (*e.g.*, with software which enables

or simplifies the validation of the analyses run with them). A quality improvement program needs to be simple (otherwise it will not be effective) and needs to reach all employees in such a manner that they understand the goals and realize their possible contribution to them. The necessary changes should be encouraged by an adequate management climate which includes information, support and training. The best motivating factor is the link between quality improvements and business goals.

Sampling as a Potential Quality-Destroying Factor in the Analytical Laboratory

Dr. *Pierre M. Gy* (Cannes) stressed and demonstrated (with too simple case examples) the importance of proper sampling before an analysis is performed. It can be assumed that for the public present, probably all well-educated analytical chemists, this effort was like carrying coals to Newcastle. Dr. *Gy* is the author of seven textbooks on the topic and is convinced that until recently, sampling has been confined by the analytical community within an intellectual 'ghetto'. Therefore, the science of sampling should be taught by universities. There is no doubt that sampling should obtain all necessary attention and should be acknowledged as such.

Integration of Automated Sample Preparation with Gas Chromatography

The final lecture by Dr. *Ron E. Majors* (*Hewlett-Packard* Wilmington) was a presentation of the instruments offered by the company for automated sample preparation. But it was much more than simply a public relation event. *Majors* discussed the driving forces for automation: sample

preparation is a bottleneck in most laboratories, sample loads are still increasing while the number and level of skilled workers is decreasing (at least in the USA), GLP and other regulatory requirements demand well-defined operations, health and safe requirements for employees and environment are increasing, and overall operating costs should be lowered. *Hewlett-Packard* offers a supercritical fluid extractor (7680 T), a robot (ORCA, *i.e.*, an optimized robot for chemical analyses), and a sample preparation module (PrepStation). All these instruments can directly be linked to a liquid, gas or supercritical fluid chromatograph. Supercritical fluid extraction – gas chromatography can *e.g.* be used for the determination of petroleum hydrocarbons in soil. The use of a robotic system for sample preparation guarantees better reproducibility than with manual operation and tests for precision and accuracy can be easily performed. The PrepStation allows to dispense, dilute, add internal standard, derivatize, heat, and evaporate in a fully automated and tailor-made mode; in an expanded version also solid phase extraction and filtration are possible.

Outlook

As a brief summary, it can be stated that analytical chemistry was never as challenging and demanding as today, but on the other hand it was never as easy and satisfactory as today. GLP and other quality assuring schemes are not troublesome, once they are established, but allow the chemists and technicians to do their work proudly and with great personal gratification.

The next Analytical Forum of *Hewlett-Packard* will be held on February 1 and 2, 1995, again in Egerkingen.