



## **INTRODUCTORY REMARKS**

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Why should we talk about Quality Assurance (QA) during this European Conference? There are two answers:

1. Service and test laboratories which must earn money on the market are forced by the market, by the customers, to introduce and operate a QA system. Otherwise they are not fit for competition.

The same is true of service and test laboratories of big companies, which render their services only within their respective company. These internal service units, too, are subject to the market requirements and – for the sake of the whole company – they have to have a QA system.

By the way: The pharmaceutical industry has very strict QA systems which are – in general – too far-reaching to be used in average industrial production. Anyway, it takes time and money to establish and maintain such a system. The scope of the formal components of the system will be relatively extensive and, possibly, these components will not even bring about an immediate improvement of product quality. They will, however, contribute to avoiding mistakes which are costly and time-consuming, and they may involve the introduction of a control loop which will ensure that product quality is improved step by step.

The first two contributions by Mr. Willcocks and Mr. Groboth deal with QA systems in a service unit of industry and in a test laboratory that is operated to earn money.

2. We have many research institutes and laboratories in national institutions, academies, scientific societies, universities. The scientists working in these laboratories are convinced that they perform excellent measurements with the required know-how and that they produce high-quality results that are reliable and comparable with results achieved in other laboratories of the same kind. In many cases, this opinion is correct, in particular if scientists use well checked and calibrated equip-

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ment with which they are acquainted, and if they are experienced enough to be very critical throughout the whole process from sample preparation to the measurement, to the evaluation of the measured data and to the presentation of the results.

These scientists are able to state an uncertainty which is reliable, because they are familiar with the restrictions and limitations of the measuring techniques applied by them. Nowadays, more and more people who are not sufficiently specialized, experienced and familiar with a particular measuring technique use commercially available black boxes: sample in, press button, result out; they do not have the knowledge and experience required to perform a really critical assessment of the uncertainty of results. However, a result without a reliable statement of the uncertainty is useless.

QA also serves as a counterweight to the world of black boxes. QA compels people to check the equipment, QA compels to think and to say something about uncertainties. By the way, many publications do not state uncertainties of results at all and many of the given uncertainties are – in my opinion – estimated in an only superficial manner and are not more than the outcome of wishful thinking.

Scientific laboratories should use those elements of QA, laid down in the relevant international standards, which may serve to ensure the reliability and equivalency of measurement results, including uncertainties. And the key term here is: traceability, that means the property of a result of measurement to be related to appropriate measurement standards, through an unbroken chain of comparisons.

In laboratories where experienced scientists perform research work, the formal components of a QA system will, and should, be relatively small – compared with those of an industrial service laboratory – but they must ensure validity.

Aspects of traceability and standardization in general and for research laboratories as well will be covered by the contributions given by Dr. Richardson and Dr. Sarge. Finally, the president of ICTAC, Prof. Ted Charsley, will talk about 'what could or should be done' perhaps by joint effort of the national TA societies.

The definition which is most important for this workshop, namely the definition of 'quality', is as follows:

'Quality is the totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.'