Where is it Safer to Have My Testing Performed?

Assessment Landscape in Europe

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Laboratory medicine in Europe

.... highly heterogeneous landscape

France: ≈4000 small labs; key role of pharmacists
Germany: high degree of centralization

EFCC – European Federation of Clinical Chemistry

*EC4 syllabus*, a first document for harmonization of training
Laboratory Medicine in Germany

Dominant role of physicians

5 year postgraduate curriculum
including microbiology and transfusion medicine
→ Specialist in Laboratory Medicine ("Arzt für Labormedizin")
approx. 1000 (of 300,000 physicians)

also: Specialist in microbiology; Specialist in transfusion medicine;
Pathologists; Specialist in human genetics
Laboratory medicine in Germany

High degree of centralisation

5 trusts cover ≈ 70% of the laboratory market

Outsourcing of hospital laboratories, increasing importance of POCT

Relatively low cost level of testing

≈ 3% of health care expenses for laboratory medicine
Laboratory medicine in Germany

Laboratory technicians:
3 year non-academic training
equal to Bachelor in most other European countries

Final responsibilities for test results always at a physician
Essential document on laboratory medicine on the EU level


Defines responsibilities of IVD industry

Aims to facilitate the commerce of products

Requires traceability of assays to methods of higher metrological order

*Directive 98/79/EC* is compiled into national regulation and laws by each country
Structure of quality assurance in Germany

Law on medical products (derived from the EU directive)
Law on the use of medical products

→ “A state-of-the-art quality management system has to be implemented.”

Essential document developed by a committee of the German Medical Association:
*Guidelines of the German Medical Association for Quality Assurance in Medical Laboratories (“RiLiBÄK”)*

Regarded as state-of-the-art by justice
Structure of quality assurance in Germany

RiLiBÄK is based on ISO 15189

Part A: structural requirements of labs
   (template for SOPs; matrices of competence, internal audits, quality management handbook ...)

Part B: details of quality control in quantitative analyses
   (internal and external QC; list of maximum tolerable bias and imprecision)
Structure of quality assurance in Germany

Monitoring the adherence to RiLiBÄK
→ *Boards of Weights and Measures*

RiLiBÄK is obligatory for *all* medical laboratories

“*A laboratory is a room where an analytical system is operated.”*
Structure of quality assurance in Germany

Shortcomings of commercial assays have to be reported to a federal bureau of the Ministry of Health.

Proficiency testing: two institutions certified by the German Medical Association.

Formal Accreditation of Laboratories: Majority of labs is accredited by the German Accreditation Council. Not mandatory.

No supervision of QM by EU authorities.
... I think regulation of QM is appropriate and useful in Germany