Quality Control in C.A.T. GmbH & CO Chromatographie und Analysentechnik KG

Quality control has been of prime concern in our company. From the following list of practices observed in our laboratory I believe you can gain an impression of the standard of our quality management.

1. C.A.T. is located in a building of an industrial zone near by Tübingen, which is build 1982: Facilities: laboratory, five offices and one mechanical workshop and one cellar for storage.

2. Each sample received is immediately allocated an analysis number, comprising customer specific code number together with a consecutive number unique for each order (eg. XXXX012 for the twelfth order of company XXXX) and consecutive numbers unique for this sample and performed analysis (e.g. XXXX012-5 for the fifth sample of the twelfth order of company XXXX, XXXX012-5-1 amino acid analysis, XXXX012-5-2 TFA determination). All data associated with this sample e.g. date of receipt, consignee, data of analysis, raw data, name of analyst etc are stored under this number in a central computer. The samples are marked with this number but instead of the number an abbreviation unique for the customer is used (XX for company).

3. The analyses are performed according to SOP's prepared and where necessary revised by the chemist responsible for quality control.

4. All methods are validated. Accuracy, standard deviation, linearity, limit of detection, limit of quantitation and selectivity have been determined and are checked regularly.

5. All standard substances and reagents are identified by their batch number and date of expire.

6. For each analytical instrument a log-book is kept, in which both the analyses and servicing are documented.

7 Instruments required for the analysis are calibrated:

balances daily using two traceable weights

heating blocks monthly

pipettes daily

refrigerators weekly.

Suitability test are run when the method has been changed latest weekly.

The results are documented in log books which is kept for each instrument.

8. Raw data will be stored for up to 15 years in paper form such as chromatograms, integrator reports, standard chromatograms, analyses reports, calibration reports validation reports and log books. The period of storage will be adapted according to the relevant regulations. Thus, the complete raw data of all analyses performed since the inauguration of our company in 1985 are in our archives.

9. Sample specimens remaining after analysis are achieved and stored for minimum one year at room temperature, although most customers relieve us of this requirement.

10. A “QM-Handbuch” is kept and describes all necessary items regarding quality control.

Customers of ours which established quality control systems have audited our company in order to secure their quality standards. These audits either satisfied the customer fully or led to improvements in our quality control system. We are inspected by the FDA (2004, 2008) as well as by the German authorities (2006) to perform analyses under GMP conditions.