



Information about SKUP and SKUP-evaluations

Scandinavian evaluation of laboratory equipment for point of care testing

SKUP is a Scandinavian co-operation for evaluation of near patient laboratory equipment. The co-operative commitment is made between DEKS in Denmark, Noklus in Norway and Equalis in Sweden.

The aim of SKUP

The purpose of SKUP is to improve the quality of near patient testing in Scandinavia.

The SKUP-evaluation

The SKUP evaluation gives objective and supplier-independent information on analytical quality and user-friendliness of laboratory equipment. The evaluations follow common guidelines. To fully demonstrate the quality of a product, the end-users should be involved in the evaluations.

The evaluation protocol

For each specific evaluation a detailed protocol is worked out in co-operation with the manufacturer or their representatives. The aim of the evaluation, the process of the analytical work and the selected comparison method are presented. The protocol is approved by the parties before the evaluation starts.

Quality goals

To qualify for an overall good assessment in a SKUP evaluation, the measuring system must show satisfactory analytical quality as well as satisfactory user-friendliness. Analytical quality goals are set up by SKUP and presented in the protocol, together with principles for the assessments.

Contract

A contract is signed between SKUP and the company requesting the evaluation. Details about the evaluation, time perspectives and evaluation costs are clarified and agreed upon.

The evaluation model

SKUP offers various kinds of evaluations. In principle, the end-users always participate in the evaluation. The end-users also give their opinion on the user-friendliness according to a questionnaire compiled by SKUP. Details about the evaluations are evident from the evaluation reports presented at SKUP's website. If possible, SKUP evaluations are carried out using three lot numbers of test cartridges from separate and time-spread productions.

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Pre-marketing evaluations

A confidential pre-marketing evaluation can be arranged for equipment not launched onto the Scandinavian market. The report from a pre-marketing evaluation will be kept confidential as long as the system is not launched in Scandinavia.

Supplementary evaluations

Based on a previous SKUP evaluation, SKUP offers supplementary evaluations of product modifications and new models. Prior to a supplementary evaluation, possible options must be discussed to clarify whether testing the modified properties alone is sufficient or if a full evaluation is recommended.

Special evaluations

SKUP evaluations can also be organised with focus on a special question or issue.

Costs

The client must place instruments, reagents, check solutions and necessary supplementary equipment at SKUP's disposal for the evaluation. All expenses connected with the evaluation are to be covered by the client, of which 1/3 of the amount is due to be paid when accepting a proposal of a SKUP evaluation, 1/3 when the contract is signed, and the remaining 1/3 when receiving the report. Approximate costs for SKUP evaluations are presented at SKUP's website. More detailed information about the price associated with the various types of evaluations will be given upon request.

The evaluation report

SKUP is responsible for the processing of data and for writing the evaluation report. The report is written in English. Attachments with raw data are included in the final report received by the requesting company. Raw data is not a part of the public report unless it is required for interpretation of the results.

Commenting on the report

The report will be submitted to the requesting company for comments. SKUP will consider any proposed alterations and make accepted changes to the report. If the requesting company disagrees with SKUP's interpretation of the results, the requesting company has the opportunity to add an attachment to the report. Depending on the content of this enclosure, there may be a response from SKUP as well.

Rights and responsibility

SKUP will contact the requesting company if any technical problems occur with the equipment during the evaluation. The evaluation can be stopped if SKUP and the requesting company agree. SKUP takes no responsibility for any indirect effect as for example loss of business profit caused by the results or assessment in the SKUP report. SKUP and the requesting company have the right of ownership to the raw data and the right to publish them. If the evaluated measurement system is already marketed in Scandinavia, the report will always be published at www.skup.org by SKUP.