Dear expert team,

the introduced GENERAL requirement for testing reagents under 6.19 is very critical and needs at least to be concretized.

This general requirement demands quality control departments for testing: In detail this means to write instructions, define specification, validate. Additionally, the reagents needed for the testing of the reagents needs to be tested or not?
This all can not be the requirement for each reagent (like a freshly prepared eluent consisting out of Water and MeOH 1:1).

With strict interpretation the quality control unit will start to test for testing - the true performance of the control departments, and with that, the safety of the drugs will decrease dramatically.

Please define the reagents to be tested to the extreme unstable/critical ones. Since written instructions are to be followed during preparation of the reagents anyhow, the safety of not critical reagents will be sufficient (in most cases tested during SST-criteria).

Furthermore the verification of the test methods needs to be defined in detail. Since there is any guidance missing authorities will lean on method validations. With this the Ph. Eur. is not needed any more, because any method needs to be validated anyhow.

Thanks for confirmation of receipt and that my comments are send to the right address.

Dirk Barth

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