# TOP 10 CAPA's

The ten most common 'deviations' whereby a non-compliance situation occurs.


## Hyperion Pharma Consultancy

Vlasmeersestraat 90, Vught, NL
Bismarckstrasse 48, Tuebingen, D


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| TELEPHONE | E-MAIL | WEBSITE |
| --- | --- | --- |
| +31641221798 | info@hyperion-consultancy.nl | www.hyperion-consultancy.nl |

# TOP 10 CAPA's

## Background CAPA in a Quality System environment

When a company has to deal with non-conformities, e.g initiated out of

1. Audit observations
2. Complaints
3. Deviations (e.g. OOS, Batch record, error in HVAC installation)

ISO 9001 or the Eudralex Vol. 4 (EU GMP's) prescribed that you have to correct these as soon as possible and therefore quick intervention is necessary. Normally a due date will be set which should be achievable and realistic. The action to re-establish the conformity again is called 'corrective action' (CA), to prevent the recurrence of the deviation.

Next to that it is unlikely the non-conformity will occur again. So, it is important to look forward and to be proactive. Based on a risk assessment, it is necessary to determine which factors are potential, can be influenced or changed in order to prevent thoroughly re-occurrence of the same deviation. This action is called the 'preventive action' (PA).

## Top 10 CAPA

Based on more than 30 years experience, I have placed the following ten most important ones on a row but they are subsequently not ended:

1. Deviations, audit observations en complaints are followed by the right / correct CAPA.
2. The CAPA has not the correct action holder
3. The follow-up of the CAPA's were not on-time
4. The due date of a CAPA is not realistic
5. The setting of priority has not been followed (no risk assessment was in place)
6. Procedures are not followed
7. Root-cause analysis needs too much time, whereby the same deviations could occur again
8. No CAPA policy and / or underlying SOP's
9. Insufficient trained personnel
10. Unclear definitions (no 'Definition procedure'?)

Further information and explanation see above contact details.

T: +31641221798
E: info@hyperion-consultancy.nl