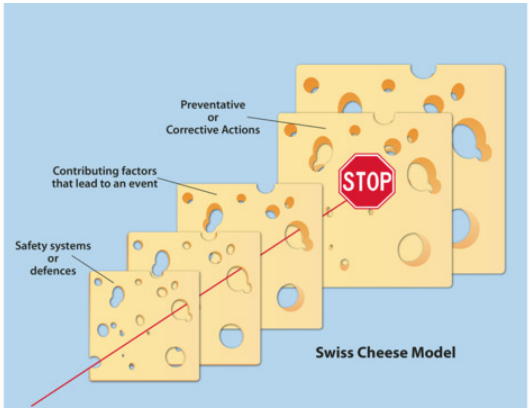
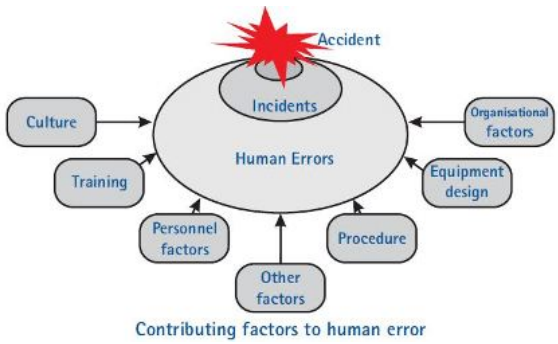
Investigation & Reduction of "Human Errors" in API manufacturing

Dr. Carsten Wangnick

(Carbogen-Amcis AG, Hauptstr. 171, 4416 Bubendorf, Switzerland)
carsten.wangnick@carbogen-amcis.com

The topic Human error in manufacturing becomes more and more prominent as so called "Human error" are responsible are one of the main reasons for deviations in production of APIs as well as drug products and the reduction of human errors is a common topic of discussion in the GMP environment especially during audits.
Therefore the reduction of "Human Errors" is one of the major aims of the Quality Management and one aspect to improve the overall level of Operational Excellence.
Some companys even strictly banned "Human error" from the list of "Root Causes" for an incident as there are always other "contributing factors" which provoke the human error.





The lecture will outline how to deal with deviations / incidents which seem to be caused by a human error.
The approach how to properly investigate the incident and really getting the detailed picture of the situation the failure happened will be presented.
It will depict the tools used to perform these investigations and which ensure an adequate quality level of such a human error analysis and show the overall results of one year "Human error reduction program".