

GMP, GCP & (

& Quality Control

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Art of GMP auditing - for auditor and auditee

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Summary: Often we see 3^{rd} party audits only as a duty of the customer, which can be sometimes for the auditee painful like a dentist. The presentation will clarify some general points about the interaction between auditor and auditee.

Additionally it will give some ideas how audits can be a win/win situation at least for theauditee. I will combine this with examples of several years experience from real life. Good and not so good practice will be discussed. Overall we will discuss soft skills and strategies. This makes the presentation applicable for different type of audits.

Structure:

- a) General Introduction GMP Audits of suppliers
 - Situation
 - · Role of Auditor
 - Role of Auditee
- b) Fail to plan = Plan to fail A valid rule for both sides
 - How the auditee can prepare his audit
 - The destructive strategy
 - The constructive strategy
 - How the auditee can prepare his audit
 - How the auditor should prepare his audit
- c) The Audit
 - How it can be a win-win situation?

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