



Lieferanten Management – Audit in der gelebten Praxis

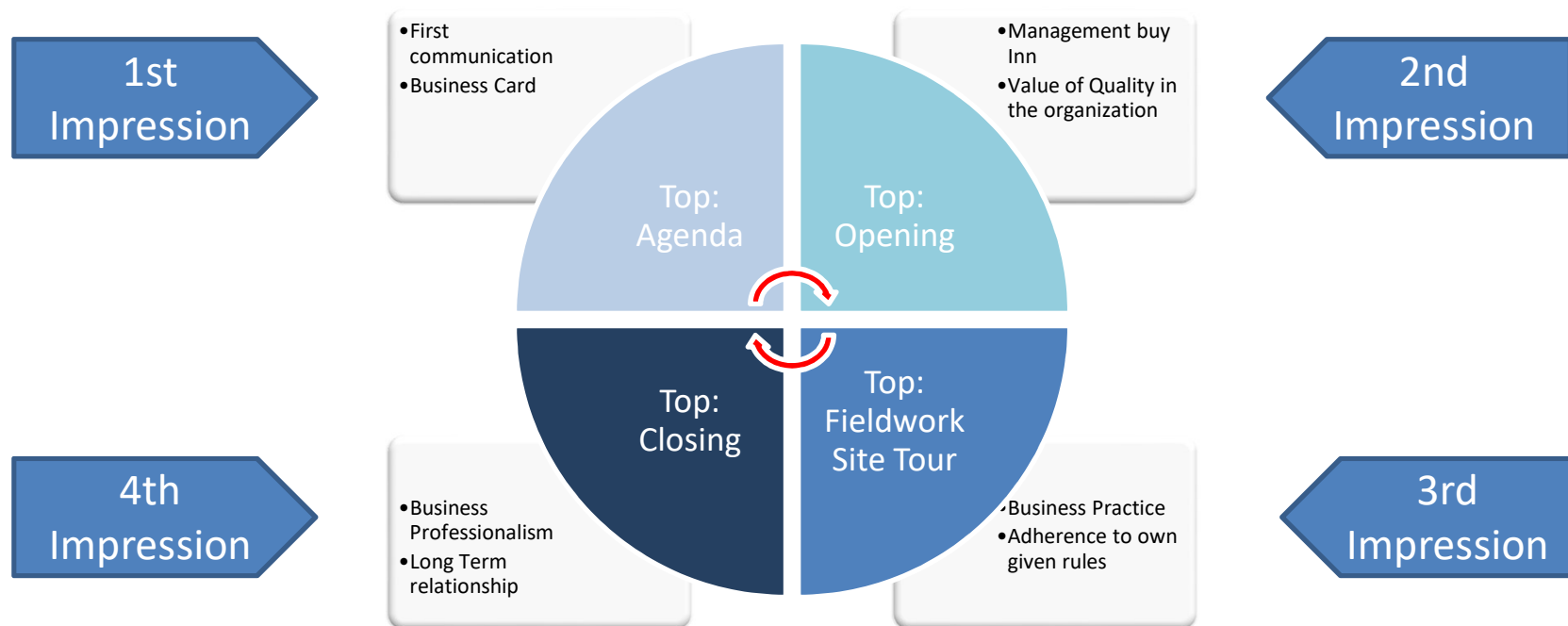
*Importance of first impression – where you can fail best
Gaining Indicators outside of the „Audit“ – not complex
Ideas for Reduction of Audit Cost – and stay compliant
Sharing „my“ favorite Agenda & its not about content*



Klaus Geissler, Short Intro

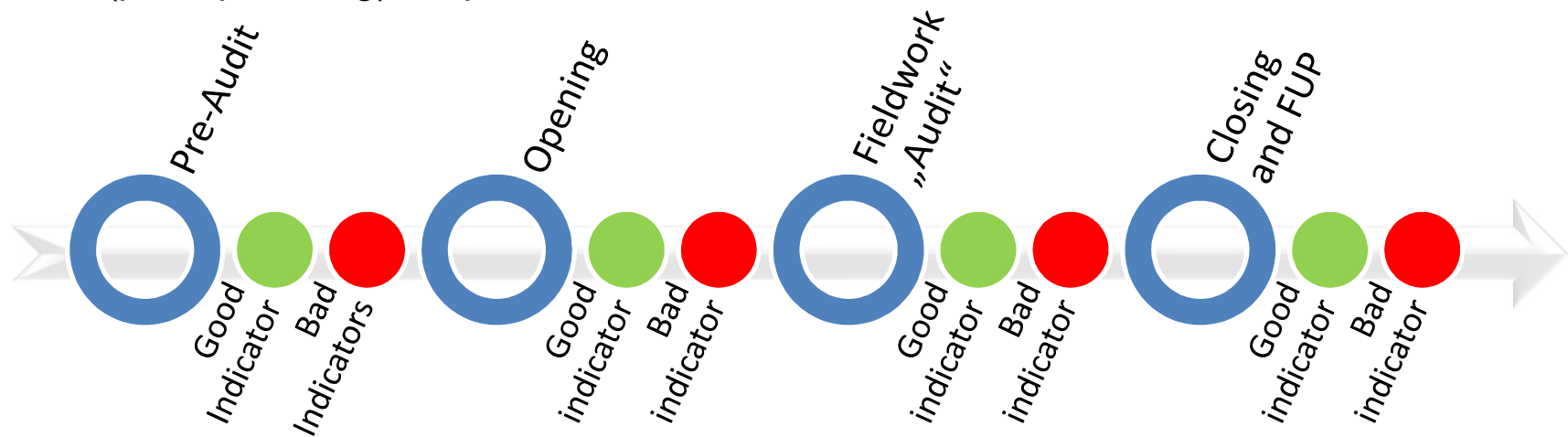
- | | |
|--------|---|
| 1998- | PhD Thesis in Molecular Virology and Microbiology, LMU Munich |
| 2002 - | Roche Diagnostics Development (Assay and Instrumentation), Penzberg |
| 2004 - | Quality Director Roche Applied Science (RUO), Penzberg |
| 2009 - | Corporate Auditor, Hoffmann La Roche, Basel |
| 2012 - | Divisional Quality Auditor Diagnostics, incl. all EMEA-supplier |
| 2019 - | Affiliate Quality Head Scandinavian Countries with the objective to transform into a harmonized QMS |

The first impression counts, ... but also the second, third, fourth!!!!



Supplier Audits: Collection of important Quality Indicators throughout the process

- Use the opportunity to get an impression of your supplier not just during the fieldwork („Audit“).
- Use the entire interaction & communication process as „audit“
- Compile information in all the process steps, otherwise you just get a limited (perhaps wrong) snapshot



Experienced Signals from in the Pre Audit Phase

Good Signals/ Indicators from Auditees

- Well worded short intro from Q-Representative, incl. R&R and future Email-communication
- Short phone call by the auditee, clarifying open topics, set up etc.
- Reply to Request for Information within a couple of days.
- Excellent, descriptive Quality Handbook
- Offer to further support for accommodation (NOT: PAYMENT, Site-program etc.!!!!)

??? Signals/ Indicators from Auditees

- Unclear who is responsible for you as customer
- You are getting all requested documents in 7 minutes or you have to remind them.
- “We have an electronic system and cannot pull out the information.”
- 10 Process descriptions (SOP) are requested, 8 delivered.
- The Quality-Handbook becomes confidential and cannot be shared
- ISO Handbook is not required by ISO 9001:2015
- “Can we postpone the audit the Q-Rep has just started?”

Experienced Signals from in the Opening Phase

Good Signals/ Indicators from Auditees

- Appearance of **all** (QMS)-functions (as described in the handbook) in time
- Adequately equipped, clean and order room or location
- People reacted appropriately, ask questions, have media to make notes

??? Signals/ Indicators from Auditees

- The Senior Manager or Senior Management is sick today (real men's flue) or has an important business meeting, ...
- Operations has no time, Representatives by the Quality Department only, or just nobody is joining on time.
- Meeting room dirty, or 2nd class if other meeting rooms are available
- Whispering, panic-communication once a point of concern is discussed
- Extensive buffet, gifts before the opening, „optical“ disruptions.

Experienced Signals during Fieldwork/Facility Tour

Good Signals/ Indicators from Auditees

- The Quality Manager is knowledgeable about the processes, supported by operations
- Tour along the value chain, no fog bombs
- Clean and orderly organized operational process
- Visible non-conformance areas/boxes/stations...
- Respect and adherence to rules: SHE, open computers (adherence to ISO 9001:2015 - 7.1.4 Environment for the operation of processes)

??? Signals/ Indicators from Auditees

- Any accompanying member of the auditees is volunteering for information, "... you want to ask this operator for it..."
- Intensive communication in your back when you just look at any subject
- the Q-Manager is constantly interrupting the "dome of silence".
- Intensive use of yellow invitations ... (also called "Post It").
- Personal comfort zone is getting smaller and smaller
- Tour during break time

Experienced Signals during Closing/FUP

Good Signals/ Indicators from Auditees

- Appearance of all (QMS)-functions (as described in the handbook) in time
- Clarifying questions
- Interest towards solutions and State of the Technique
- ...LIKE OPENING MEETING

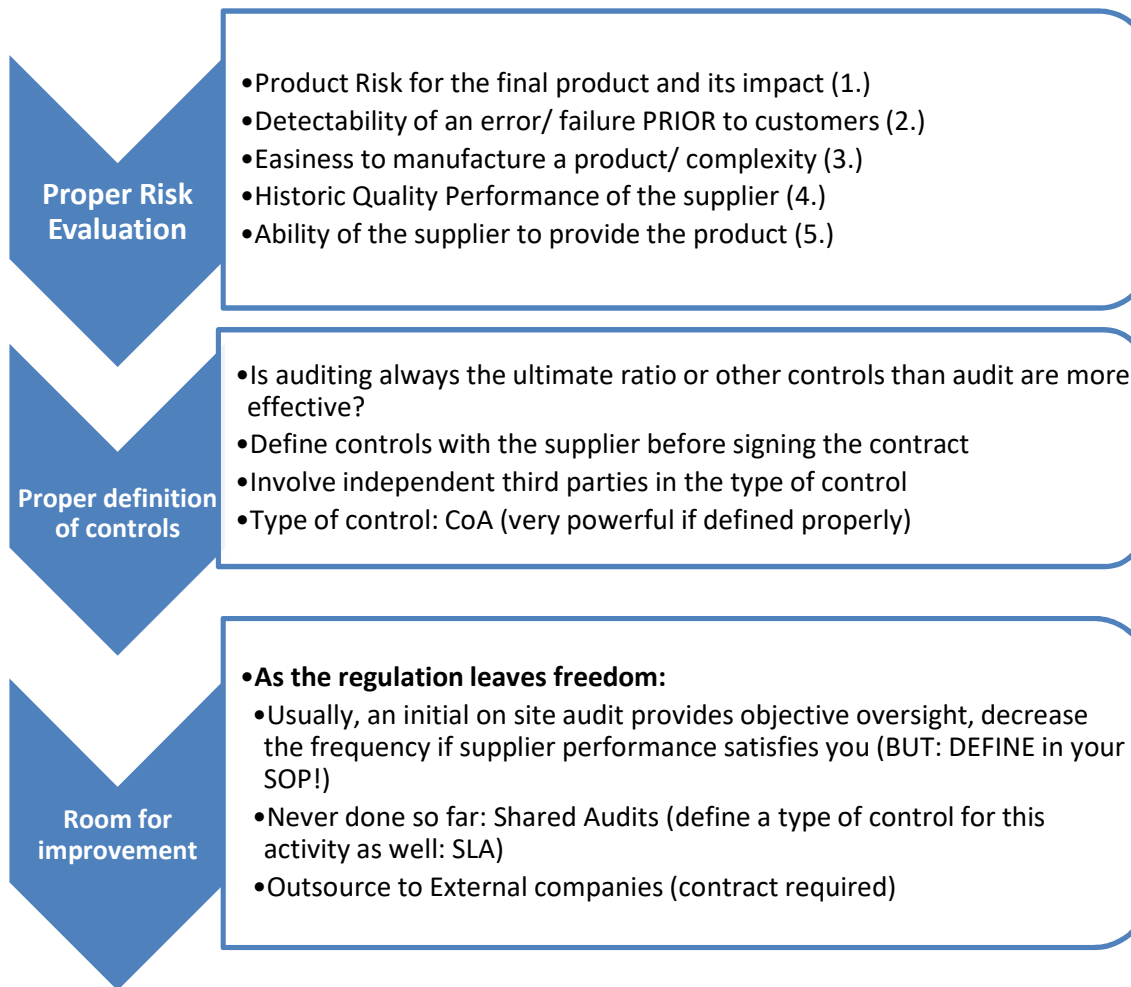
??? Signals/ Indicators from Auditees

- „ You didn't see the relevant documents“ ; „you didn't ask for ...“
- Citing ISO
- Providing new evidences
- Even not knowledgeable QMS-functions come up with „arguments“ and ISO requirements.
- Preparing a Contra-Closing Slide Deck
- ...We can't afford this ...,
...we are a small company....

Why auditing ??? Save Money. Re-Think product risk & costs



1. *Supplier-Audit is not required by ISO!*
2. *Barley described in 21 CFR 820.*
3. *Should always be the ultimate type of control, not the rule.*
4. *Much more important than the fact is the rationale and definition when to use this type of control.*
5. **Follow own established procedure!**



Agenda - Coverage & Sequence & Time Units

Time Units

			ISO 9001	ISO 13485
1.	Management Review Policy Objective	<ul style="list-style-type: none"> •First impression about Management Buy-in, sustainable or Bollywood? •Business Objectives or Quality Objectives, SMART, last year fulfillment rate -> Management Review 	4 5 6 9	4 5 6
2.	Facility Tour	<ul style="list-style-type: none"> •Real life picture: Pilcher or Pichler? Changing Perspective, use senses •Watch out for exemptions and non-conformities 	ALL!	ALL!
3.	Wrap Up session	<ul style="list-style-type: none"> •Catharsis of your mind: Strategize, perhaps align with Co and SME – without Auditee! •If they are good – let go (good for your company); stay away from the captain Ahab-approach 	---	---
4.	„Documentation Tools“ & Issue Management (Complaints, NCs and CAPA)	<ul style="list-style-type: none"> •Getting an idea of the robustness of electronic tools or manual processes •But: Ensure appropriateness of your expectation. 	7.5, 10, 7.4	4.2.4/5; 8.2.2; 8.3; 8.5
5.	Purchasing Controls	<ul style="list-style-type: none"> •Opportunity to look on level deeper into product quality • SCAR sustainable solved: impacts your organization mid term and long term 	8.4	7.4
6.	Product Design and Change Management	<ul style="list-style-type: none"> •Focus on Input from customers like you: Risk based/ assessed? All tested properly. •For changes: Proof of effectiveness is the ultimate ratio 	8.3	7.3
7.	Prep Closing Session	<ul style="list-style-type: none"> •Prepare your own exit: Now you leave here your own business card! •Focus on preparation of most controversial discussed topics (e.g. as backup) 	---	---

Besten Dank für die Aufmerksamkeit

Dr. Klaus Geissler
Roche Diagnostics
Klaus.geissler@roche.com