



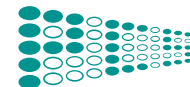
PHARMACEUTICAL
CONSULTANCY
SERVICES

INSPECTION METHODS

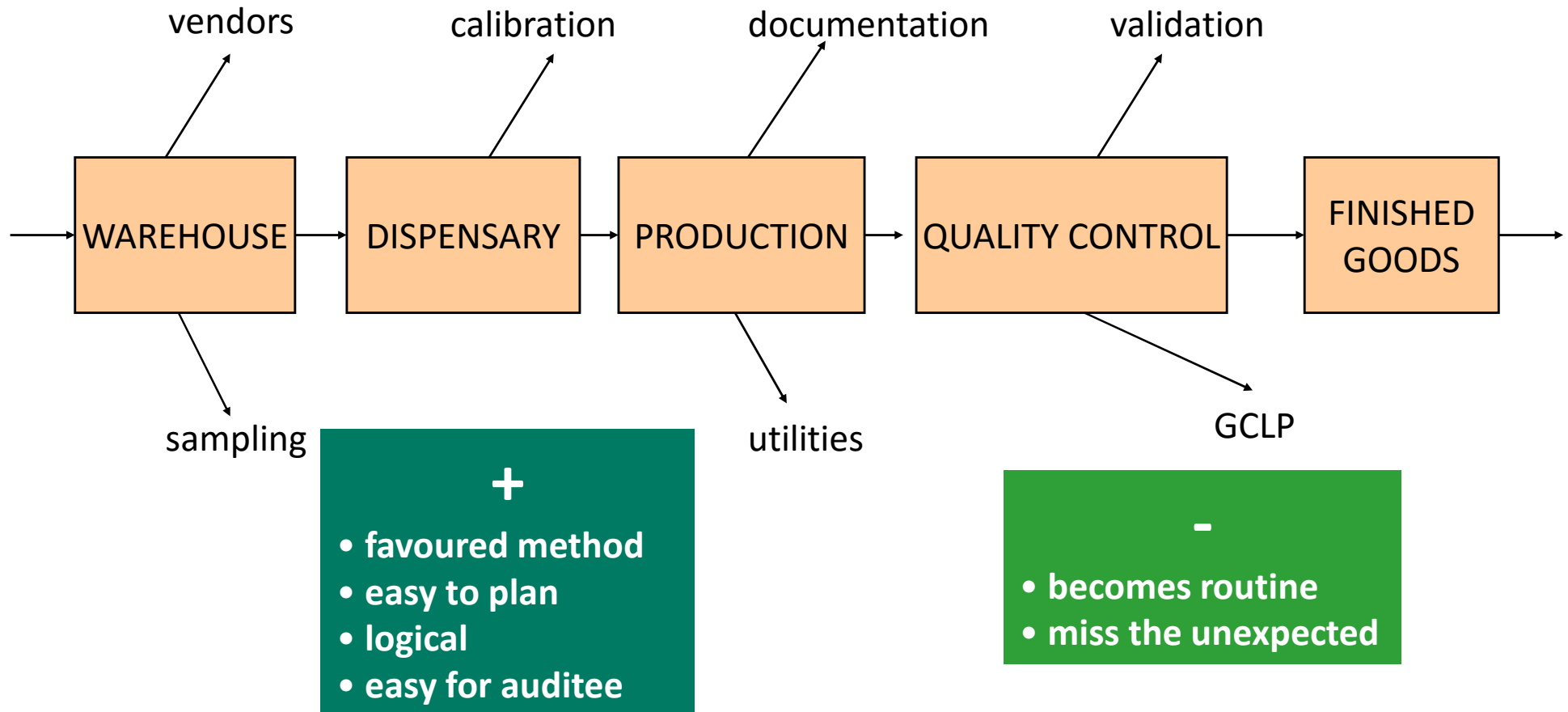


INSPECTION: METHODS

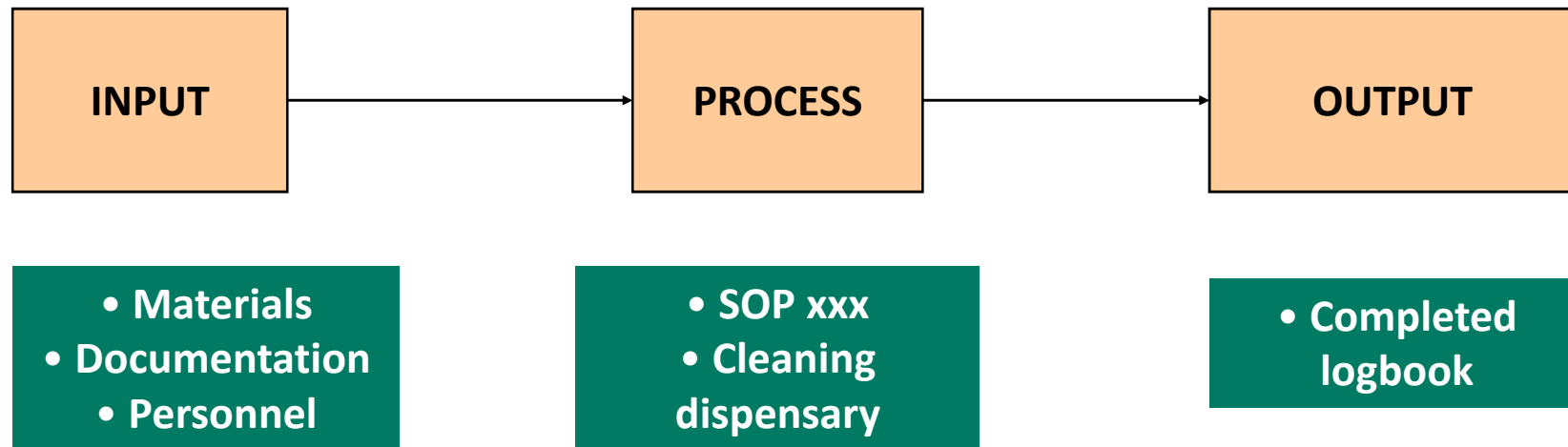
- TRACE FORWARD
- TRACE BACK
- PRODUCT SPECIFIC
- DEVIATION / COMPLAINT-BASED
- PRODUCT LICENCE (Market Authorisation)
- DOCUMENT TRAIL
- THE CHECKLIST AUDIT
- RANDOM



TRACE FORWARD AUDIT



TRACE FORWARD



The Trace Forward logic applied to a single unit operation



TRACE BACK AUDIT

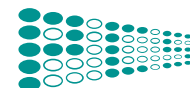
- Essentially the reverse of trace forward

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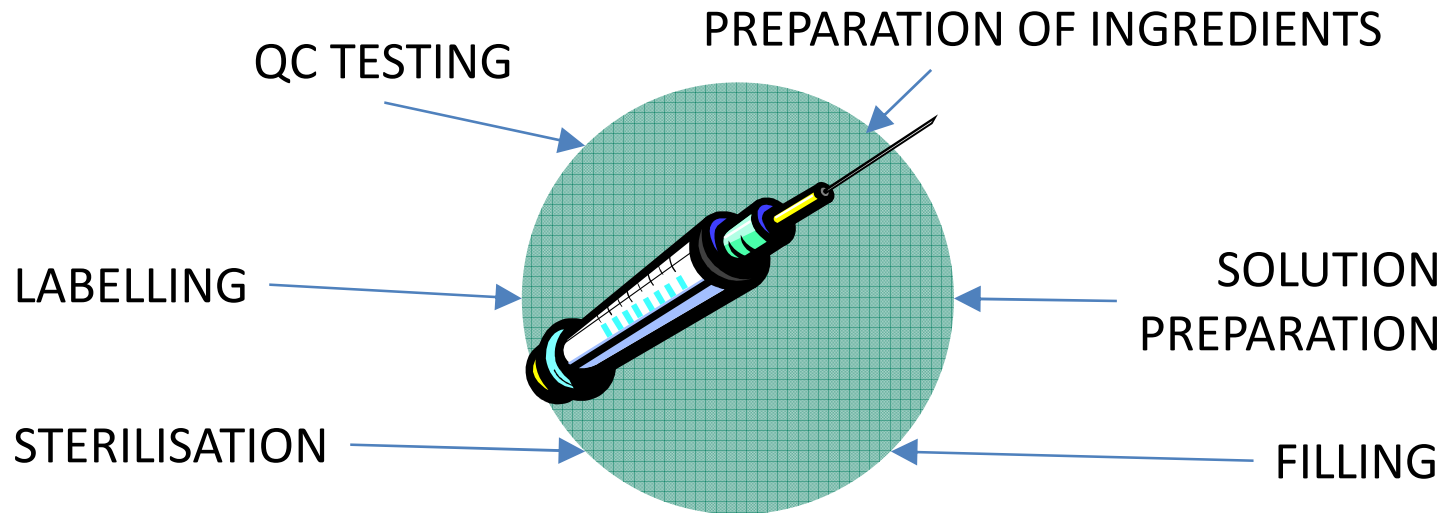
- Easy to plan
- Logical
- Can be used to vary approach

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- No major disadvantages



PRODUCT-SPECIFIC AUDIT



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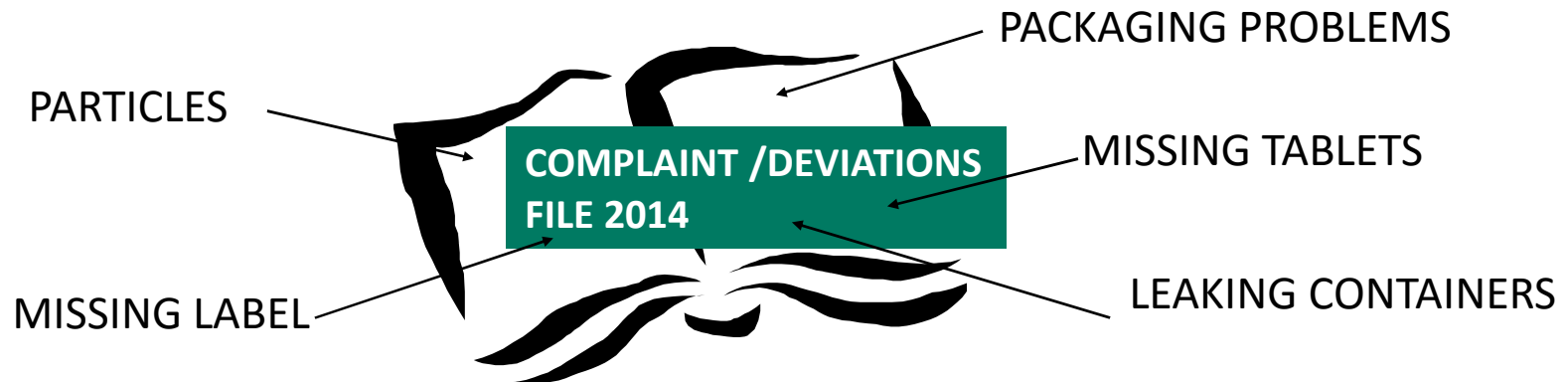
- highly specific
- logical
- detailed

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- time consuming
- not everything noted
- confined to specific
 - product



COMPLAINT / DEVIATION-BASED AUDIT

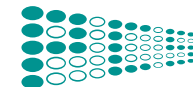


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- Learn from mistakes
- Allows improvement

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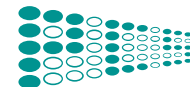
- Specific
- Considers small part of operation
- No value as compliance audit



COMPLAINT AUDIT

- Can be extended to internal as well as external complaints, e.g.
 - Deviations/failure investigations
 - OOS investigations
 - CAPA programme

HIGH CALORIE DIET FOR AUDITORS!



LICENCE AUDIT

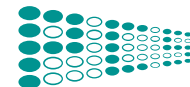


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- Compliance
- Clear requirements
- Easy to perform

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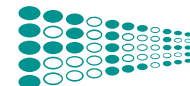
- No real disadvantages



CONTRACT BASED AUDIT

- Can be used for external audits, e.g.
 - Supply level agreements with suppliers
 - Service level agreements with contractors
 - Quality agreements
 - contracts

**Any officially / legally binding document
provides starting point for audit**



THE CHECKLIST AUDIT

- CRITERIA CHECKLIST (e.g. EU GMPs, CFRs etc.)
- DEPARTMENTAL CHECKLIST
- COMPANY-SPECIFIC

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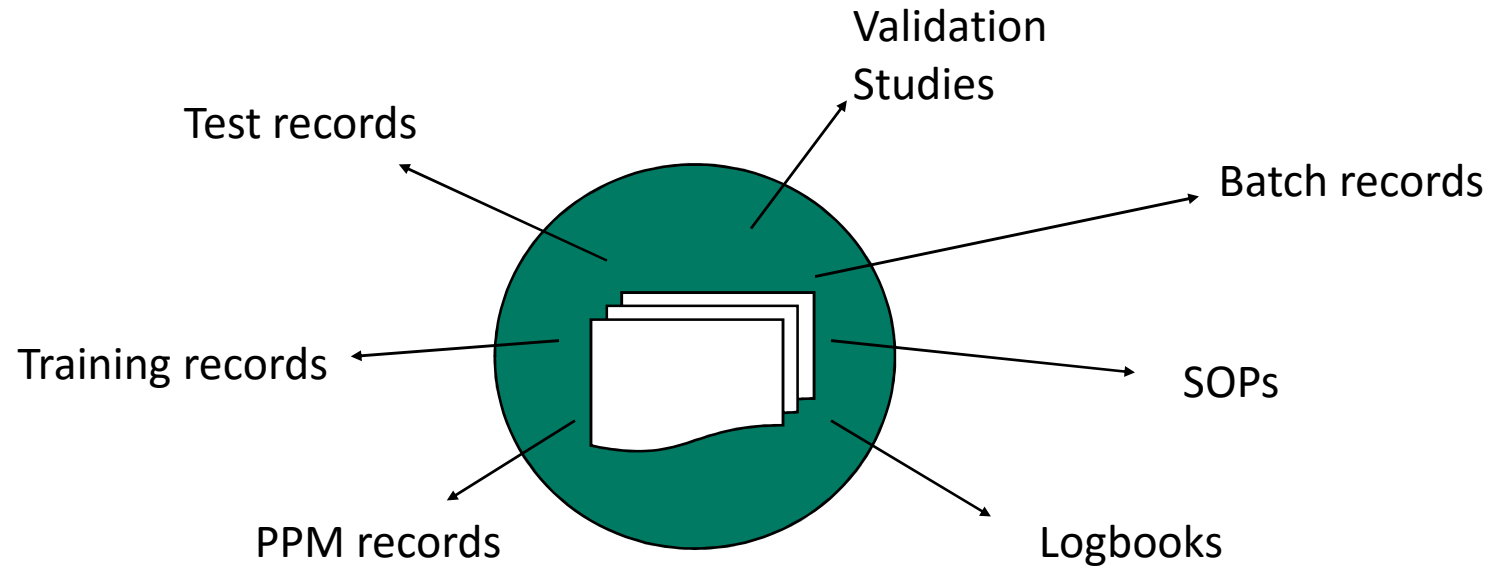
- Easy to use
- Avoids missing issues
- Good for inexperienced auditors
- Easier for auditee
- Allows quantification; GMP rating system

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- Restrictive for experienced auditors
- Reduces complex issues to YES or NO
- Reflects preconceived ideas
- Focus of audit is more on checklist, rather than operators
- Allows quantification; GMP rating system



DOCUMENTATION AUDIT



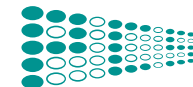
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- Good insight into QS
- Easy to perform
- Specific

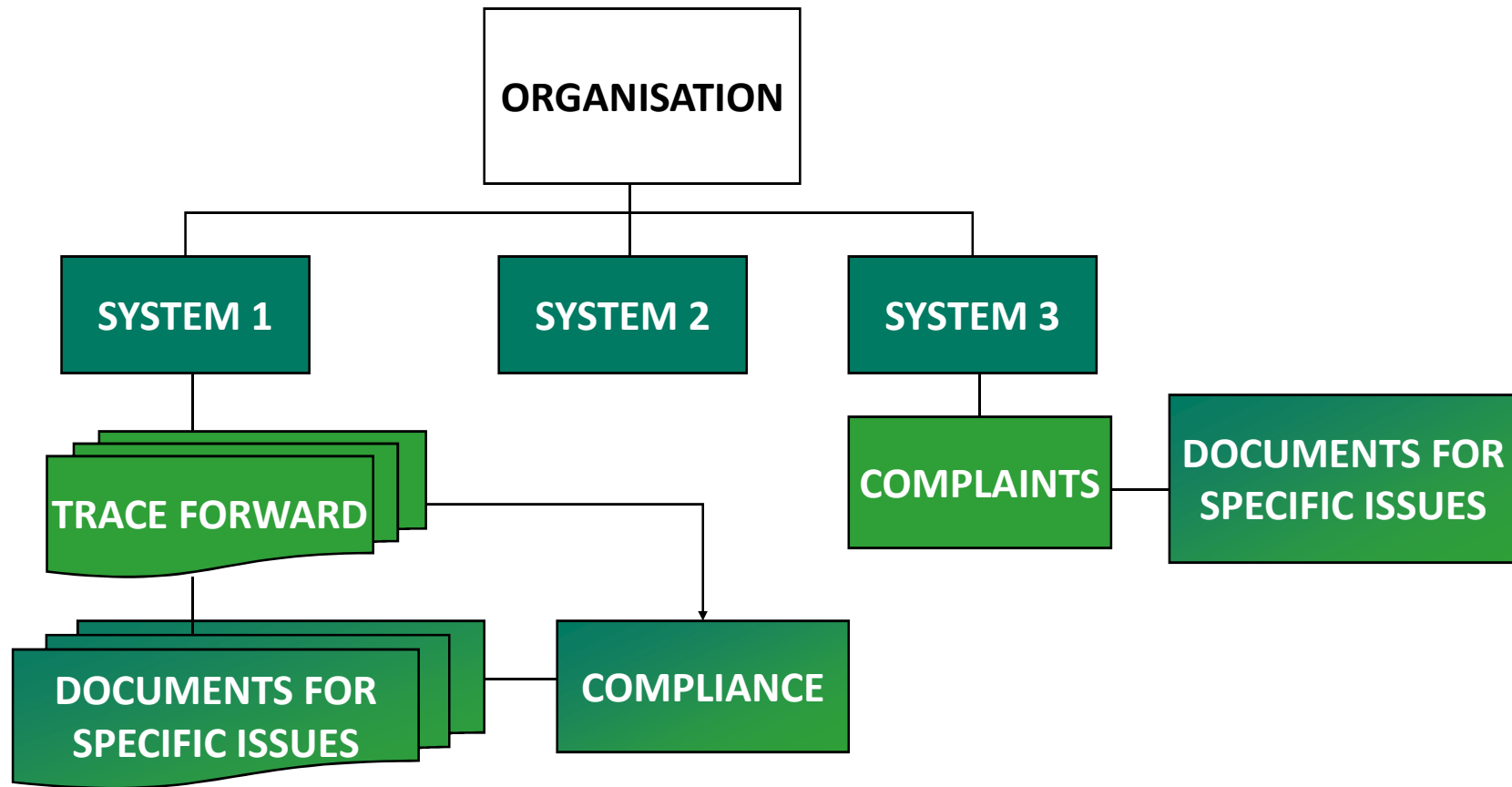
ALL BATCH - SPECIFIC

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- Difficult for auditee
- No plant tour
- Focuses on human error

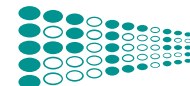


TYPICAL AUDIT STRUCTURE

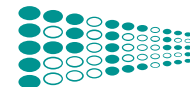
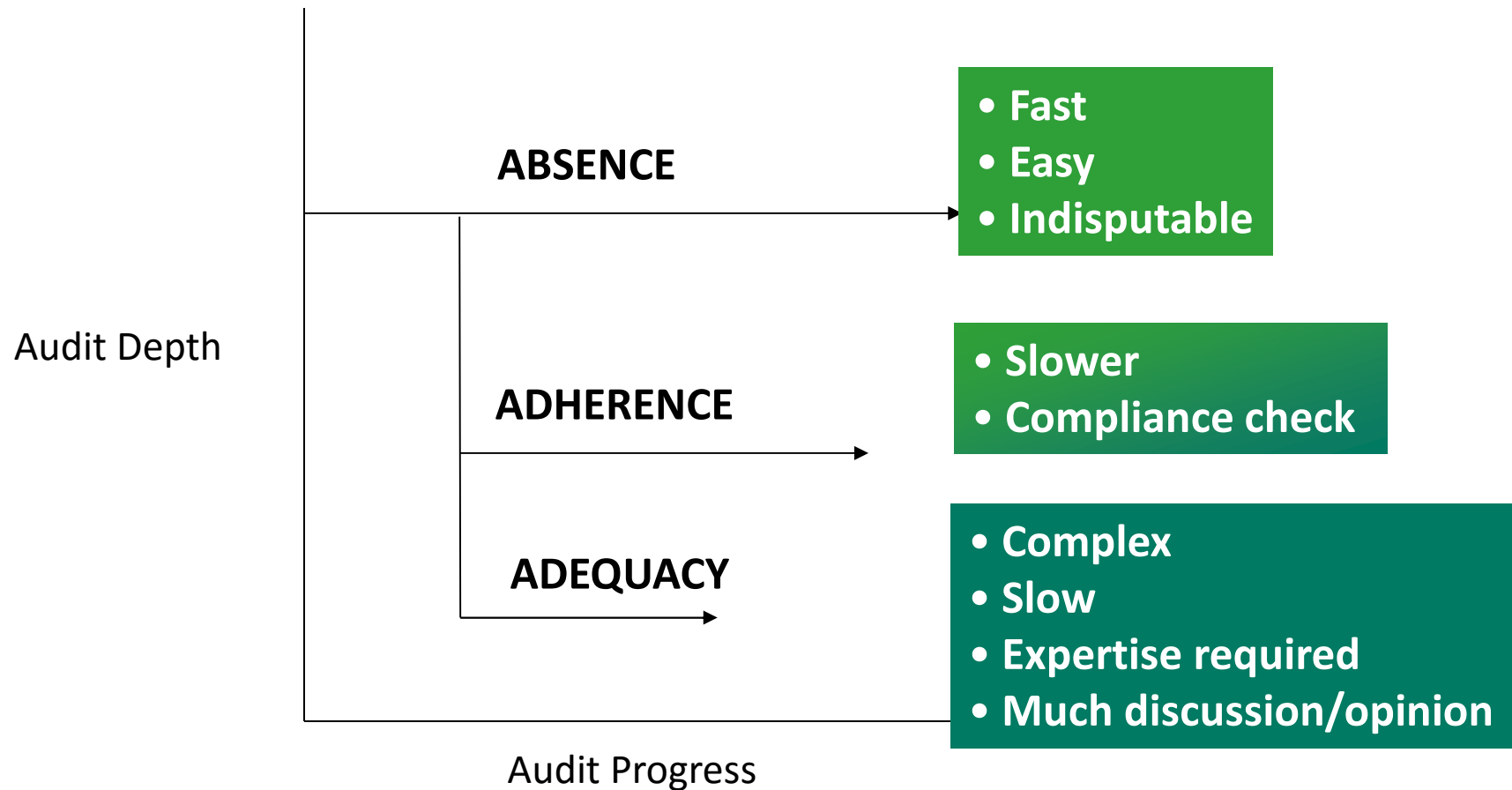


ANNOUNCED VS UNANNOUNCED AUDITS

Announced	Unannounced
<ul style="list-style-type: none">• Right people present• Allows auditee to plan• Allows “clean up”• Shows trust• Length can be set in advance• Cooperative	<ul style="list-style-type: none">• Possible key people absent• No time for planning• “As is” situation• Demonstrates suspicion• Unpredictable• Adversarial

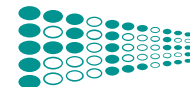


INSPECTION DEPTH

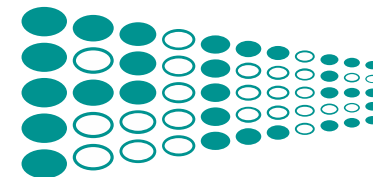


REMARKS

- Any inspector does have it's own interest (background) and strong/weak points
- Any inspector/inspection might use one of the approaches discussed and “skip” as a result other approaches.
- You may not consider a situation being “approved by an inspector”, if she/he has made no comments.
- Neither: while one inspector may have no comments, another might give you a critical/major/minor observation/483



**THANK YOU FOR
YOUR ATTENTION**



**PHARMACEUTICAL
CONSULTANCY
SERVICES**

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Veluwemeer 112

3446 JD Woerden

T +31 (0)182 – 503 280

M +31 (0)6 – 23 047 982

F +31 (0) 182 – 502 589

info@pcs-nl.com

www.pcs-nl.com