

Teleconference Auditing: Opportunities for Regulators and Industry

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Scope

- FDA inspection by teleconference
 - Background to FDA Inspections
 - Circumstances of Q-Pharm's Inspection
 - Nature of the teleconference inspection
 - Outcome of Q-Pharm's teleconference inspection
- Lessons learned
- Implications for the future of inspections
- Opportunities for teleconference auditing



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Background - FDA Inspections

CFR TITLES

- 1 General Provisions
- 3 The President
- 11 Federal Elections
- 21 Food and Drugs

21 CFR

- Pt 1 General Enforcement
- Pt 11 Electronic Records
- Pt 50 Subject Protection
- Pt 56 IRBs
- Pt 58 GLP - nonclinical
- Pt 312 IND
- Pt 320 Bioavailability & BE

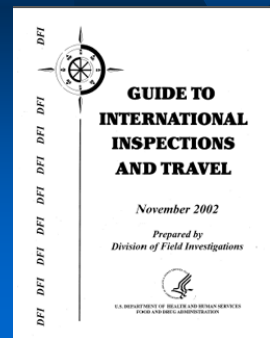
- *Guidance for Industry*
- *Compliance Program Guidance Manual*



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Background - FDA Inspections

- Routine v for-cause
- FDA SOPs
- Scope
 - Verify data
 - Regulations and guidelines
 - Subject protection
- Post-inspection
 - NAI - No action indicated
 - VAI - Voluntary action indicated
 - OAI - Official action indicated



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Regulations

Guidance



Source: Holobaugh, FDA



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Q-Pharm's Inspection Situation

- Pivotal trial
- FDA: Q-Pharm report & other information
- Change of plan instigated by FDA
- Rapid reorganisation
- Client surprise and unease
 - No one wants to be an FDA first!



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Nature of Q-Pharm's Inspection

- Opening: format explained
 - Two US sites, five FDA participants
- Virtual tour (provided electronically)
- Cycle: question – answer – follow-up
- Close of each teleconference:
 - Agenda and attendance for next day
 - Items for follow-up
 - Items to be provided prior to next teleconference



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Outcome of Q-Pharm's Inspection

- Achieved nearly all elements of a site visit
- Data accepted
- Letter but no Form 483
- Tough but fair assessment
- Respect for FDA abilities



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Lessons Learned - Technique

- Preparations
- Communications
 - Quiet room and teleconference phone
 - Meeting chair at each site
 - All non-visual - speak clearly/slowly
- Flexibility
- Expertise



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Lessons Learned - Science

- Project / Systems Design
 - FDA regulations, guidances, SOPs
 - Document all processes and evidence thereof
 - Use FDA data format
 - Think about the experiment
 - Consider the regulator's view
- Be prepared to prove ANYTHING claimed
- Be prepared to justify what was done



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Implications for Future Inspections

- Industry background
 - Risk management & limited resources
 - T/c audits to continue
- Refinement of methodology
- Technological innovation



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Opportunities for all Organisations

A tool for evaluation of subcontractors – potential and existing

- Particular use after an initial on-site visit
- Systems may include:
 - Policy – checklist
 - Evidentiary support – accreditation / certification
 - Vendor supplied documentation
- Plan with vendor and agree



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Considerations

Nature of the inspection
Supporting data
Resources
Expertise and systems available
Available technology
Cost
Confidentiality and privacy
Sustainability
Risk management



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Summary

- An interesting case study
 - Thankfully successful
- Lessons learned
 - Strength of 'good practices'
- Implications for the future of inspections
 - Only one of the changes on the regulatory horizon
- Opportunities for teleconference auditing
 - Benefits and savings



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