Cogent QA Ltd
Pharmaceutical Quality Support

Audit Report Writing Training
Danish Society for GCP

Thursday 24th September 2015

Presented by:

Julian Reeves, Cogent QA Ltd.

Cogent QA Ltd
Pharmaceutical Quality Support

Session agenda

08:30	Welcome, introductions and course objectives
09:15	Presentation 1 - Back to Basics *What is an audit? Whose audit is it anyway? Why do it?*
09:40	Workshop 1 - Getting organised *Organising audit notes for an effective report*
10:00	Break

Session agenda

10:20 Workshop 1, continued

- *followed by exercise feedback and discussion*

11:00 Presentation 2 - Validating audit findings

Ensuring objectivity to determine conformity or non-conformity

11:25 Workshop 2 – Validating audit findings

- *followed by exercise feedback and discussion*

12:00 Lunch

Cogent QA Ltd
Pharmaceutical Quality Support

Session agenda

13:00 Producing the report

- *The aims of audit reports*
- *Getting the contents and structure right*
- *The importance of clear and concise narratives and findings*
- *Grouping findings*
- *Grading findings*
- *Using recommendations*
- *The Executive Summary*

15:00 Break

Session agenda

15:20 Workshop 3 – writing clear and concise reports

Taking report text and improving its clarity

- followed by exercise feedback and discussion

16:30 Final questions, closing remarks

17:00 Course close

Cogent QA Ltd
Pharmaceutical Quality Support

Introductions

- Your name
- Your current role
- Auditing experience?

Course objectives

To improve skills in:

- Categorisation
- Evaluation
- Prioritisation
- Summarising
- Reporting

Cogent QA Ltd
Pharmaceutical Quality Support

Course objectives

- To improve skills in taking evidence from an audit and turning it into an objective, clear and effective report
- To provide simple tools and develop practical solutions to your questions
- To help you develop systematic and standardised techniques

Cogent QA Ltd
Pharmaceutical Quality Support

Not covered in detail…

- Audit programme
- Planning an audit
- Observation and note taking
- Audit metrics
- Trend analysis
- Interpersonal skills

Cogent QA Ltd
Pharmaceutical Quality Support

Training Methodology

- Presentations
- Workshops
- Discussion

Cogent QA Ltd
Pharmaceutical Quality Support

1. Back to basics

Cogent QA Ltd
Pharmaceutical Quality Support

What is an audit?

- A systematic, independent and documented process for obtaining **audit evidence** and evaluating it objectively to determine the extent to which **audit criteria** are fulfilled.

Definition: ISO 19011 international standard

Cogent QA Ltd
Pharmaceutical Quality Support

Definitions – ICH GCP

- **Audit** - A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

- **Audit report** - A written evaluation by the sponsor's auditor of the results of the audit.

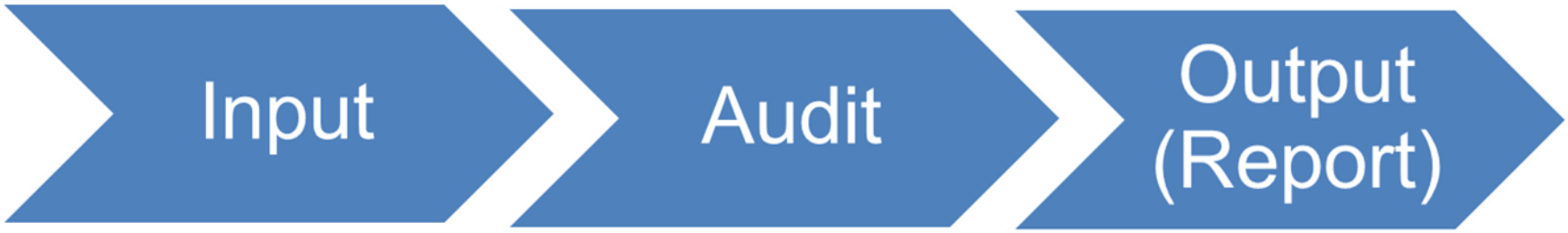
Cogent QA Ltd
Pharmaceutical Quality Support

Why Audit?

- **Compliance** with legal requirements
- **Compliance** with contractual requirements
- **Compliance** with documented quality system
- **Continual improvement**

Cogent QA Ltd
Pharmaceutical Quality Support

The Audit Process



Cogent QA Ltd
Pharmaceutical Quality Support

Getting Started…

Verify

- **Client**
- Objectives/scope
- Audit criteria
- Audit procedures

Capture all of these in the **Audit Plan**

Cogent QA Ltd
Pharmaceutical Quality Support

The Audit Process

- Planning
- Preparation
- Performance
- *Evaluation of evidence*
- **Reporting**
- Follow up, closure & improvement

Cogent QA Ltd
Pharmaceutical Quality Support

Audit Performance

Collating evidence

- Sufficient sample size?
- Verified objective evidence?
- ‘Conformity’ or ‘non conformity’?
- Audit trails closed out?
- Positive evidence, i.e. to mitigate severity?
- Objective evidence based upon FACTS?

Cogent QA Ltd
Pharmaceutical Quality Support

Audit Analysis Inputs

- Audit evidence
  - Documents and Records reviewed
  - Facilities inspected
  - Interviews with personnel
- Audit notes

Cogent QA Ltd
Pharmaceutical Quality Support

Audit Report Inputs

- Observations from evidence
  - Evaluated against audit criteria (conformity/non-conformity
  - Categorised (per area/topic)
  - Graded (Critical, Major, Minor, etc.)
  - Prioritised (importance, urgency)

- Report format
  - Standard template?
  - Recommendations required?

Cogent QA Ltd
Pharmaceutical Quality Support

Audit Report Outputs

- Action! (Sponsor/auditee)
- Audit response and follow-up
  - Effective CAPAs
  - Improvement plans (compliance/business)
- Audit records
- Impact on audit programme
- Impact on operations and development programme
- Trend analysis and metrics

Cogent QA Ltd
Pharmaceutical Quality Support

2. Validating Audit Findings

Cogent QA Ltd
Pharmaceutical Quality Support

Audit Findings – writing valid findings

By 'valid' we mean that findings must…

- Contravene a requirement (regulatory, procedural, contractual, etc.)
- Describe a confirmed issue
- Be objective (written, verbal, and/or visual evidence)
- Keep personal or Company opinions out ("I feel you should do it like this…")
- Define the scale of the problem (how much/many did you audit?)

It is OK to not have findings…really, it is!!

Cogent QA Ltd
Pharmaceutical Quality Support

Validating findings - REALISE

R

Equirement - what is the requirement?

Activity - what activity is being audited?

Location – where were these activities taking place?

Issue – what is the concern?

Scale – how big is the problem/sample? Isolated or systemic?

Evidence - what objective evidence has been collected?

Cogent QA Ltd
Pharmaceutical Quality Support

REALISE - example

Requirement – where is the requirement defined?

Trial protocol PRR-002 section 8.4

"Frozen plasma samples may be stored on site at -20°C for a maximum of 4 weeks before being shipped to the central laboratory"

Cogent QA Ltd
Pharmaceutical Quality Support

REALISE - example

Activity – what is the activity being audited?

On site storage of frozen plasma samples

Cogent QA Ltd
Pharmaceutical Quality Support

REALISE - example

Location – where is the activity taking place?

Freezer AH04 within the biochemistry department

Cogent QA Ltd
Pharmaceutical Quality Support

REALISE - example

Issue – what is the nature of the concern?

Serum samples have been stored on site for periods up to 6 months prior to transfer to the central laboratory

Cogent QA Ltd
Pharmaceutical Quality Support

REALISE - example

Scale – How big is the problem?

Samples for 8 out of the 10 enrolled subjects were stored on site for more than one month prior to transfer. Samples for subject #01 were stored for 6 months (175 days)

Cogent QA Ltd
Pharmaceutical Quality Support

REALISE - example

Evidence – what is the objective evidence?

Sample Log forms and Sample Shipment Forms contain dates of sample storage and shipment.

Cogent QA Ltd
Pharmaceutical Quality Support

The finding – issue first:

On reviewing Sample Logs and Sample Shipment Forms, it was observed that frozen plasma samples for 8 out of the 10 recruited subjects (#01-#08) had been stored on site in the biochemistry department -20°C freezer for longer than the 4 weeks maximum allowed by the protocol.

Specifically, for subject #01 the samples had been stored for almost 6 months (175 days).

Ref. Trial protocol PRR-002 section 8.4

Cogent QA Ltd
Pharmaceutical Quality Support

The finding- requirement first:

Trial protocol PRR-002 section 8.4 requires that "Frozen plasma samples may be stored on site at -20°C for a maximum of 4 weeks before being shipped to the central laboratory"

On reviewing Sample Logs and Sample Shipment Forms it was observed that frozen plasma samples for 8 out of the 10 recruited subjects (#01-#08) had been stored on site in the biochemistry department -20°C freezer for longer than one month.

For subject #01 the samples had been stored for almost 6 months (175 days).

Cogent QA Ltd
Pharmaceutical Quality Support

Workshop 2:

Using REALISE to validate findings

Cogent QA Ltd
Pharmaceutical Quality Support

Workshop 2 – validating findings

Objective

- To understand the key attributes of audit findings using REALISE

Task

- *Using REALISE,* determine whether the audit results provided constitute valid findings.
- *Discuss* any issues encountered by the group during the feedback session. Was the group able to validate as true findings? If not, what would you do next?

Cogent QA Ltd
Pharmaceutical Quality Support

3. Producing the Audit Report

Cogent QA Ltd
Pharmaceutical Quality Support

Report Aims

Overall, to document the audit results and findings **clearly** and **accurately:**

- Conclusions (identify compliance status, key issues)
- Convey audit results to audit client/management
- Demonstrate need for: correction, corrective and/or preventive action

Cogent QA Ltd
Pharmaceutical Quality Support

Report Content

The audit report should provide a **complete**, **accurate**, **concise** and **clear** record of the audit and should include the following:

- The audit objectives
- The audit scope (organisational/function units, processes and systems)
- Identification of Audit Client
- Auditor(s) - team leader and team members
- Date(s) and place(s) where on-site audit activities were conducted
- A summary of the audit process, including the uncertainty and/or any obstacles encountered (e.g. limited sample size)
- Confirmation that the audit objectives have been met in accordance with the audit plan, and any areas not covered
- Listing of findings

Note synergy with Audit Plan (good preparation = efficient reporting!)

Cogent QA Ltd
Pharmaceutical Quality Support

Report Content

- Background information on organisation
- General observations – summaries of processes, systems, facilities, procedures/data reviewed, etc.
- List of staff interviewed
- List of documents reviewed
- Summaries of findings

Cogent QA Ltd
Pharmaceutical Quality Support

Report Content

Or, as a minimum, provide:

- Purpose of the audit
- Scope of the audit
- Findings identified

Cogent QA Ltd
Pharmaceutical Quality Support

Report Content

- Formal communication of audit findings and conclusions to audit client

- Audit reports should therefore be:
  - Objective
  - Factual
  - Clear
  - Concise
  - Unbiased
  - Timely

Cogent QA Ltd
Pharmaceutical Quality Support

Report Content

Audit Findings, which must:

- Be factual
- Supported by objective evidence and agreed
- Flag importance, not minute details
- Aim to find root cause
- Be specific and concise
- Be understandable! (Issue first then supporting evidence)
- Be tied to a requirement/audit criterion

Cogent QA Ltd
Pharmaceutical Quality Support

Report Content

Words to use with care!

- Inadequate
- Unsatisfactory
- Lacking
- Weak
- Unacceptable
- All
- None
- Significant

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

Use of a standard template … consider:

- Executive summary
- Grouping and presentation of findings
- Location of most significant issues to achieve maximum impact
- Logical flow of information
- Use of tables
- Where recommendations should be listed, if permitted (in accordance with audit scope)

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

Exercise good writing practice:

Be…

- **Clear**
- **Concise**
- Complete
- Consistent
- Correct

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

“Clear” means immediately understandable

Ambiguity suggests the writer is uncertain or subjective and can lead to misinterpretation …

“I washed my dog in the sink then used it to wash the dishes.”

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

“Concise” means written clearly and fully using as few words as possible but not in note form.

A clear and concise report will always have a greater impact than a report that is clear but unnecessarily long.

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

Concise…an example:

Experiments are described which demonstrate that in normal individuals the lowest concentration in which sucrose can be detected by means of gustation differs from the lowest concentration in which sucrose (in the amount employed) has to be ingested in order to produce a demonstrable decrease in olfactory acuity and noteworthy conversion of sensations interpreted as a desire for food into sensations interpreted as a satiety associated with ingestion of food.

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

Concise…an example:

Translation

Experiments are described which demonstrate that a normal person can taste sugar in water in quantities not strong enough to interfere with his sense of smell or take away his appetite.

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

We want to try and avoid writing long and overly verbose passages of text, which, although punctuated, have absolutely no impact on the reader because by the time they (i.e. the reader) arrives at the end of the passage, they have absolutely no idea what the author was trying to say, and therefore the reader loses interest and as a result he or she may have missed out on receiving some vital information relevant to the compliance of the system, facility or process being audited.

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

- Use short, simple sentences…
- …but avoid paragraphs with too many sentences
- Be aware of spacing
- Use white space
- Lists (indented) or tables are easier to read than paragraphs of text (e.g. lists of interviewees or documents)

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

- Use a consistent ‘style’ for text i.e. same indents, font type and size, heading level etc.
- Use clear headings for sections, tables etc.
- Use past tense..??
- Use titles or functions rather than names

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

- Numbers: 0-9 use word. > 2 digits: use numerals unless the first word of a sentence
- Consistent and unequivocal date convention: e.g. ddMMMyyyy
- Clarify abbreviations, acronyms and initials at least once

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

- Don’t wait too long to write up your audit notes!
- Read through your report at least once as if you are a recipient. Does it make sense? Is it complete? Can you pre-empt questions?
- Use your colleagues – get the report checked (peer review and QC?)
- A well-structured report creates a stronger impact -
  - Its messages are more easily understood
  - It facilitates better CAPA style responses

Cogent QA Ltd
Pharmaceutical Quality Support

Report Structure

Remember…

…a strong message can be lost by poor visual presentation. A basic awareness of design can help you communicate more effectively by improving the appearance of your work…

Cogent QA Ltd
Pharmaceutical Quality Support

Grading Audit Findings

Cogent QA Ltd
Pharmaceutical Quality Support

How Important is a Finding?

Seriousness, or severity, should be based on:

- Conformance with the defined standard
- Impact

Cogent QA Ltd
Pharmaceutical Quality Support

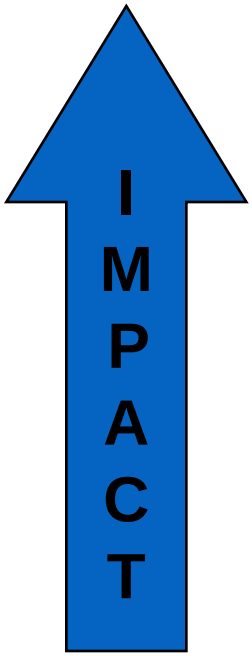
Get things in proportion

Consider:

- Frequency?
- Sample size?
- Reason?

Cogent QA Ltd
Pharmaceutical Quality Support

Get things in proportion



- Risk to the public or the environment
- Risk to study or trial data integrity
- Breach of regulatory requirement detail
- Protocol deviation
- SOP deviation

Cogent QA Ltd
Pharmaceutical Quality Support

Advantages of Grading

- Conveys what is important and/or urgent
- Helps auditee to prioritise actions
- Provides metrics regarding the overall standard
- Informs management
- Leads to a shared understanding

Cogent QA Ltd
Pharmaceutical Quality Support

Disadvantages of Grading

- Requires consistency between auditors
- Increases potential for conflict

Cogent QA Ltd
Pharmaceutical Quality Support

To grade or not to grade…

- Some audit organisations simply report nonconformities, believing the auditee is the best judge of the significance of the nonconformity.
- The auditee organisation knows its process better than an auditor.
- But, auditors (should) know the significance of nonconformities relative to the audit criteria.
- A decision not to grade *might* cause auditors to be lazy and collect only evidence of imperfection rather than enough evidence to identify systemic issues.

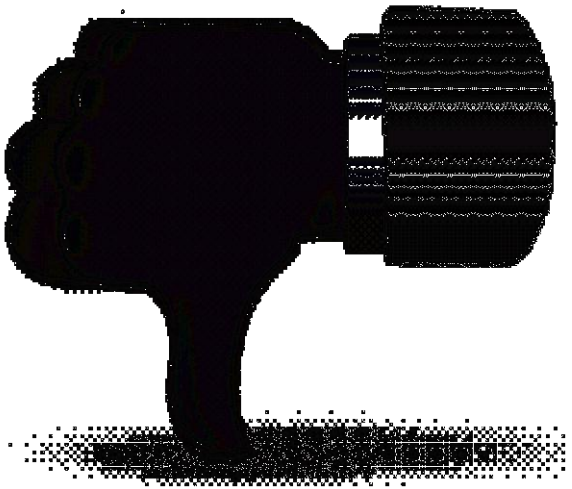
Cogent QA Ltd
Pharmaceutical Quality Support

Grading

An aid to communication

A barrier to communication

A source of friction



Cogent QA Ltd
Pharmaceutical Quality Support

Should auditors make ‘Recommendations’?

Cogent QA Ltd
Pharmaceutical Quality Support

What does a Recommendation mean?

- Is it a definite ‘instruction’ to the auditee?
- Is it just a ‘useful suggestion’ (take it or leave it)?
- Does it require a response, or further investigation/action?

… is the meaning defined within your organisation?

Cogent QA Ltd
Pharmaceutical Quality Support

Risks and Benefits

- As an auditor you may have years of experience and seen a lot of ways of doing it
- Surely that's worth passing on!
- If the auditor has a solution, shouldn't they share it so that the problem can be fixed as soon as possible?
- A good training opportunity
- Teambuilding with QA

Cogent QA Ltd
Pharmaceutical Quality Support

Risks and Benefits

- Providing a solution risks the auditor taking responsibility/ownership – this reduces independence from operations
- Operations team may become dependent on the auditor
- The operators know their job better than an auditor!
- May create resentment

Cogent QA Ltd
Pharmaceutical Quality Support

Risks and Benefits

- The auditee might do what the auditor recommends without considering more optimal solutions.

- On a subsequent audit, the same auditor could be verifying its own corrective action recommendations, resulting in a conflict of interest.

Cogent QA Ltd
Pharmaceutical Quality Support

Suggested rules

- Define what a recommendation means
- Define when and where it can be used
- Define how (if) it should be responded to
- Consider locating recommendations in a separate section of the audit report, not associated with findings
- Consider a location outside the audit report
- Consider a separate audit type to generate recommendations

Cogent QA Ltd
Pharmaceutical Quality Support

The Executive Summary

Cogent QA Ltd
Pharmaceutical Quality Support

Executive Summary

A very important section of the report…

- This may be the only section that management reads!
- Locate the summary at the front of the report
- Convey the key messages…Bad news? Good news?
- Ask for a peer review to ensure the intended meaning is properly conveyed!

Cogent QA Ltd
Pharmaceutical Quality Support

Executive Summary

Suggested contents:

- Details of auditee and type – e.g. GCP, GMP, GLP, etc; routine, for cause, pre-contract qualification audit, etc
- Audit purpose
- Auditor/audit team details
- Compliance statement..? (based on sample audited!)
- State if audit objectives were met (if not explain which were not met and why)
- Statement of number and categorisation of findings, and include a summary of any critical and/or major findings

Cogent QA Ltd
Pharmaceutical Quality Support

Report recipients

Communicate!

- Give warning of any serious issues as they arise. How will ‘critical’ issues be communicated?
- Verbal/email summary may precede a written report
- Listen to feedback but don’t compromise; facts should override emotions…

e.g. auditees don’t like findings!

Cogent QA Ltd
Pharmaceutical Quality Support

Peer Review

- Objectivity
- No hanging statements – has compliance been assessed and determined?
- Validated findings
- Leave out personal opinions - be constructive
- Compare to standard criteria
- Remember – clear and concise
- Read as if you are an intended recipient or auditee

Cogent QA Ltd
Pharmaceutical Quality Support

Workshop 3:

Writing Clear and Concise Reports

Reducing the Fog Factor

Cogent QA Ltd
Pharmaceutical Quality Support

Workshop 3
Writing Clear and Concise Reports

Objective

- To understand the importance of writing clear and concise report and findings text to ensure the audit report is easily understood by the reader, and that the report makes the strongest possible impact.

Task

- Read through the executive summary provided and improve the conciseness and clarity as much as you can while maintaining (or improving!) the impact and key message(s) of the summary.

Cogent QA Ltd
Pharmaceutical Quality Support

Audit Report Writing

Some final reminders:

- Close out audit trails – any further questions?
- Are findings valid?
- Is the issue isolated or systemic?
- Be clear who you are writing the report for
- What are the key messages? Executive summary
- Use writing techniques to optimise presentation
- Be clear and concise throughout