

SPAQA

Prominent Inspection Findings (2008-2009)

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General

- Parameter influencing inspection findings
 - Nature of test facility Inspection
 - First inspection
 - Full routine inspection, etc.
 - Size and organisation of test facility
 - Task of test facility
 - Areas of expertise
 - Multisite yes/no
 - Basis
 - Inspection reports of authorities
 - ~ 20 different sites
 - Stipulations only
- ➔ can be regarded as indicative for trends (not a scientifically/statistically sound tool)



Organisation and Personnel

- Description of organizational structure of the GLP test facility, and the reporting lines not clearly described
 - Responsibilities for double functions to be described in SOP
- Conduct and documentation of GLP training
 - GLP training of personnel (+IT)
- Master Schedule
 - Presentation

GLP - Newsletter 2004 /1

Angaben	Kurzzeitprüfungen	Langzeitprüfungen
Prüfnummer	x	x
Prüfleiter	x	x
Principal Investigator	x	x
Prüfgegenstand	x	x
Typ der Prüfung	x	x
Beginn der Prüfung	x	x
Ende der Prüfung	x	x
Datum der Archivierung	x	x
GLP / non-GLP Prüfung (ja/nein)		x



Quality Assurance Program

- Administrative issues mainly
 - Table of content of QA Program
 - Splitting up of QA-SOPs to improve transparency
- ➔ Continuous adaptations/revisions of QA SOPs are generally well established



Facilities

- Distinct labelling of GLP and Non-GLP zone (plan and “walk-through”)
- Description of access to specific areas (eg. server)

Apparatuses, Materials, and Reagents



- Calibration weight documentation
 - Periodical surveillance
- Temperature documentation of refrigerators to be archived

Test Systems

- Maintenance documents to be archived
- Concept of change control is absent (criteria for re-validation not defined)

Test and Reference Items

- Sponsor/supplier should indicate used quality system on the analytical certificate
- Expiry date to be indicated on test item

Standard Operating Procedures

- General minor deficiencies observed
- Review Process
 - is to be conducted according to local SOP
 - to be documented



Performance of the Study

- Reason for changes to be indicated in the raw data
 - Amendments declared as deviations
- ➔ Overall only few stipulations made

Reporting of the Study

- To be finalised in a timely manner after the inspection
- Raw data, samples, specimens: access and ease of traceability
- SD and PI have to sign final report and compliance statement individually



Archiving

- “Working documents” have to be archived after study completion
- Limited space available



IT

- Description/rules for IT system access (user and password) have to be available
- The concept for backups has to be defined and documented
- Individual findings in Validation Reports, and comments on archiving



2000-04

204 Inspections
2270 Findings

27 %

17 %

10 %

9 %

5 %

4,5 %

4%

+13%

} 17%

G and GB: Overview Inspection Findings



2004+05

134 Inspections
1352 Findings

32 %

17,5 %

8 %

9 %

6 %

6 %

21 %

Study conduct

Organisation / Personnel

SOP

Quality Assurance

E-data / Computerised Systems

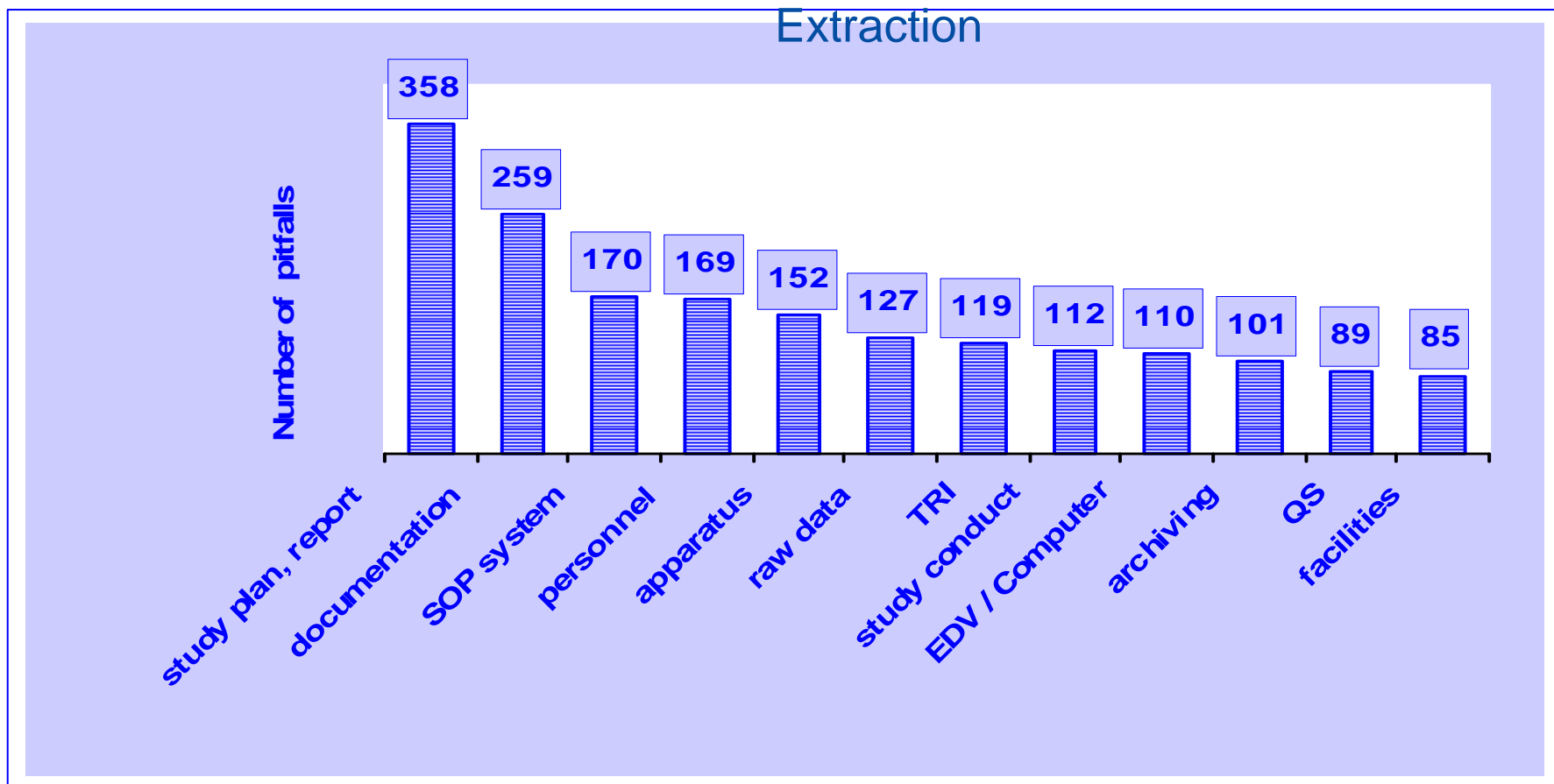
Archive

Premises / Facilities

+ Equipment

Germany: Inspection Findings

204 inspection reports (total number of pitfalls: 2270 (2000 – 2004))





Thank you for your attention!

