swissmedic

SPAQA

Prominent Inspection Findings (2008-2009)

Beat Schmid

25 November 2009

Swissmedic

swissmedic

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)

swissmedic

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

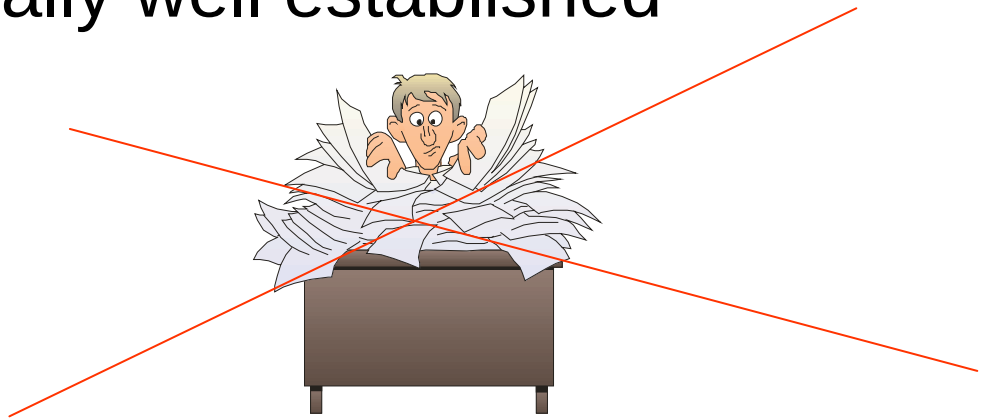
Angaben	Kurzzeitprüfungen	Langzeitprüfungen
Prüfnummer	x	x
Prüfleiter	x	x
Principal Investigator	x	x
Prüfgegenstand	x	x
Typ der Prüfung	x	x
Beginn der Prüfung	x	x
Ende der Prüfung	x	x
Datum der Archivierung	x	x
GLP / non-GLP Prüfung (ja/nein)		x

swissmedic

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



swissmedic

Facilities

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

swissmedic

Apparatuses, Materials, and Reagents

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

swissmedic

Test Systems

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

swissmedic

Test and Reference Items

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

swissmedic

Standard Operating Procedures

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

swissmedic

Performance of the Study

- Reason for changes to be indicated in the raw data
- Amendments declared as deviations

➡ Overall only few stipulations made

swissmedic

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

swissmedic

Archiving

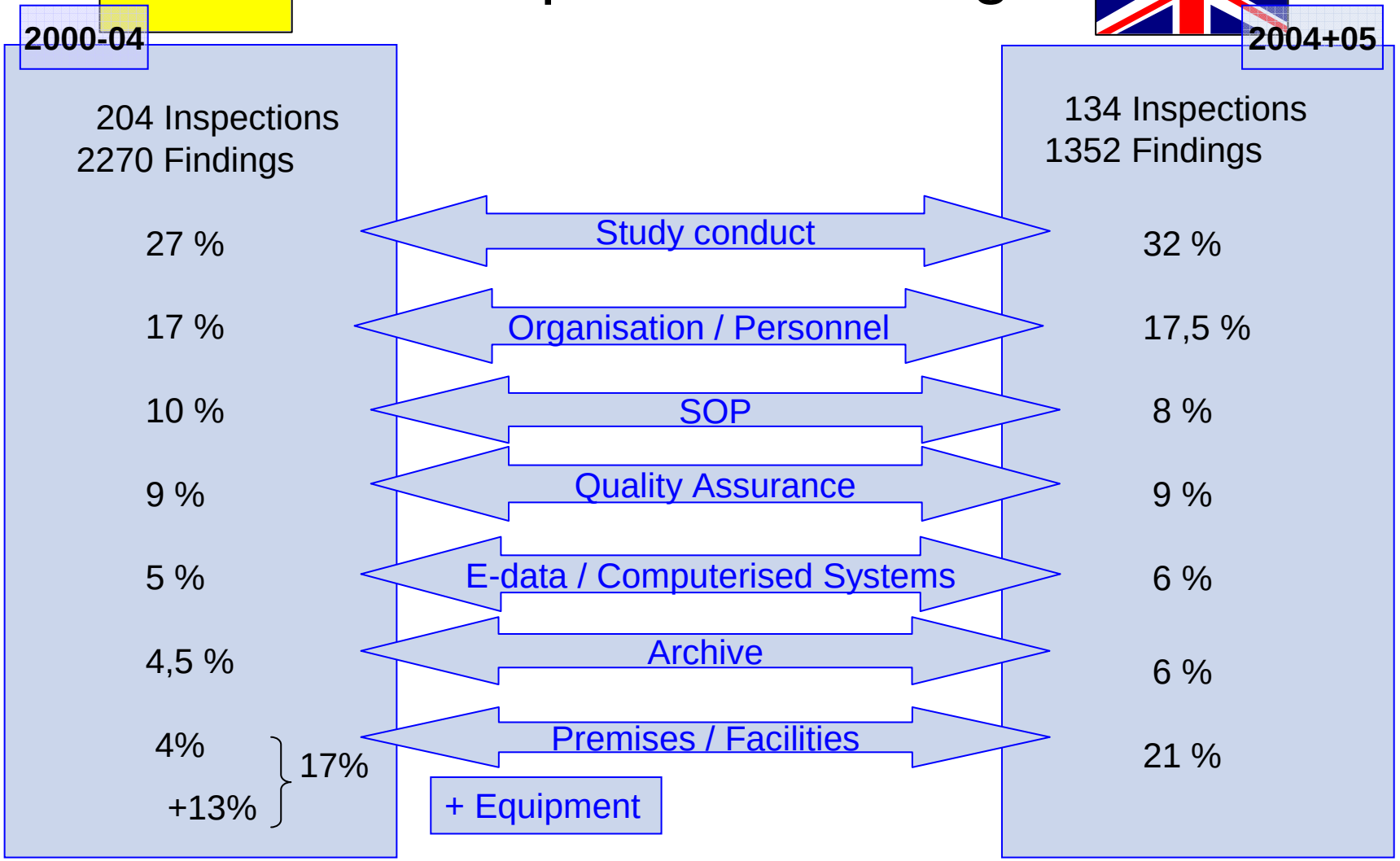
- “Working documents” have to be archived after study completion
- Limited space available

swissmedic

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

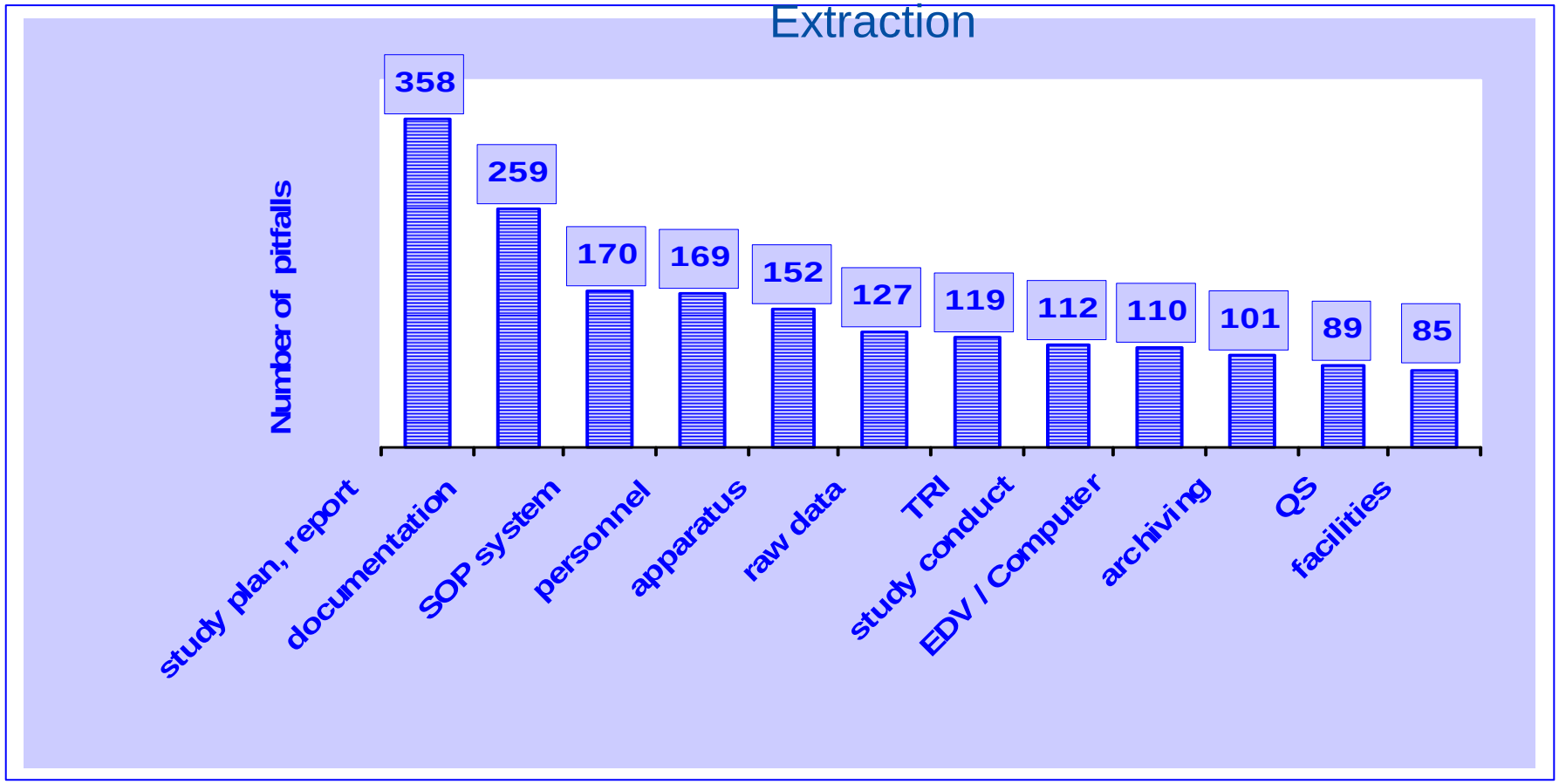
G and GB: Overview Inspection Findings



swissmedic

Germany: Inspection Findings

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



swissmedic

Thank you for your attention!