

# GLP Annual Review

## 2010 Summary

# OVERVIEW

- 2010 Deficiency data
- Review of mailbox activities (including breakdown of non-GLP subcontractor notifications)
- Website

## Inspection Activities – who we were and what we did

- During 2010 the GLPMA consisted of a Head (also senior inspector) five inspectors (1 expert, 2 senior, 2 accredited) and administrative support. In addition, a cross-trained member of the GCP team took part in a number of GLP inspections.
- 62 inspections had been conducted.
  - Implementations
  - Compliance monitoring
  - Triggered due to facility changes
  - Facility closures
- Inspectors travelled on behalf of EMEA to perform a number of study audits.

## 2010 Deficiency data - Critical

A single critical deficiency was raised last year. This related to system failure at a facility giving rise to a failure to adhere to test guidelines, study plans and SOPs. There was insufficient oversight of study activities, review of raw data and review of reports and it was not possible to reconstruct all study activities. None of the issues identified in by the inspector had been identified by the test operator, the study director or QA. Where these events constituted deviations from the study plan and/or test guideline, the impact upon the study had been neither evaluated nor reported.

In combination, this posed a significant risk to the studies conducted by the facility requiring immediate remedial action. The facility was re-inspected after 6 months and following an overhaul to the procedures and some staff changes, a significant improvement was noted and no further serious (critical or major) non-compliances were raised.

## 2010 Deficiency data – Majors

Total of 25 Majors raised

2 Study conduct

5 Organisation and personnel

4 Archiving

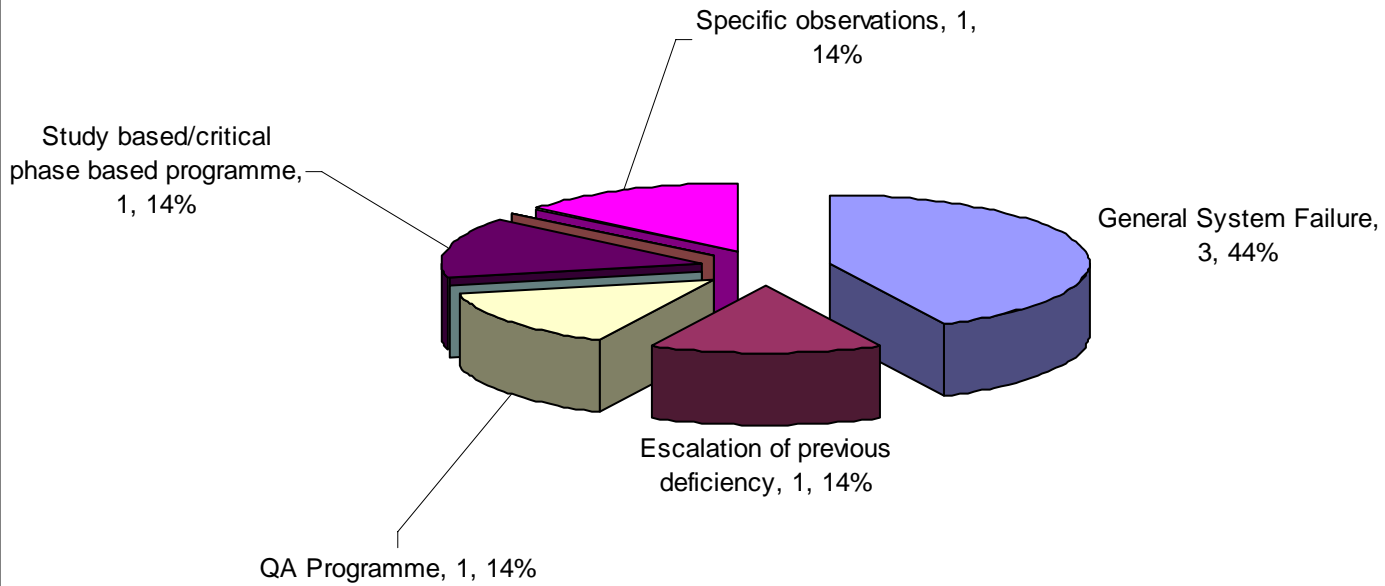
2 SOPs

7 QA

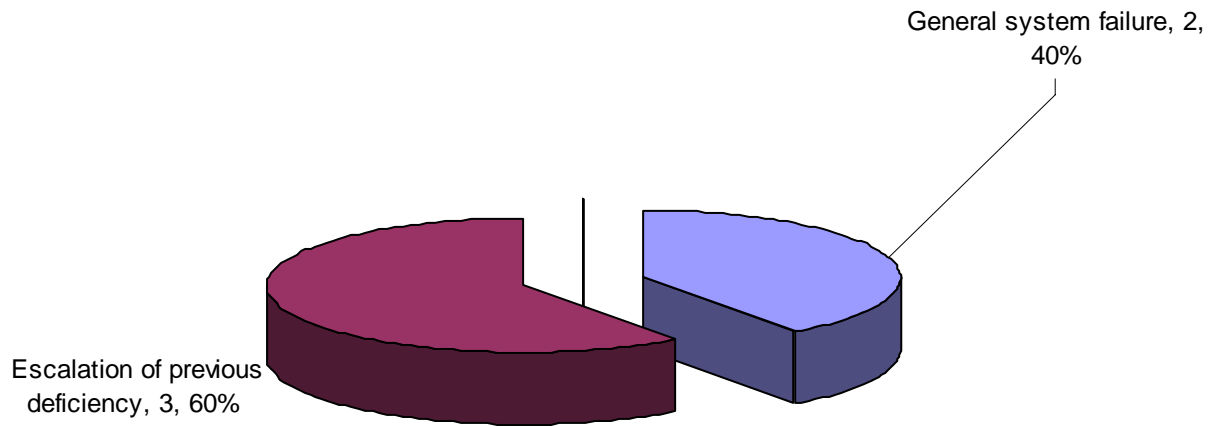
1 Facilities

4 Computerised systems

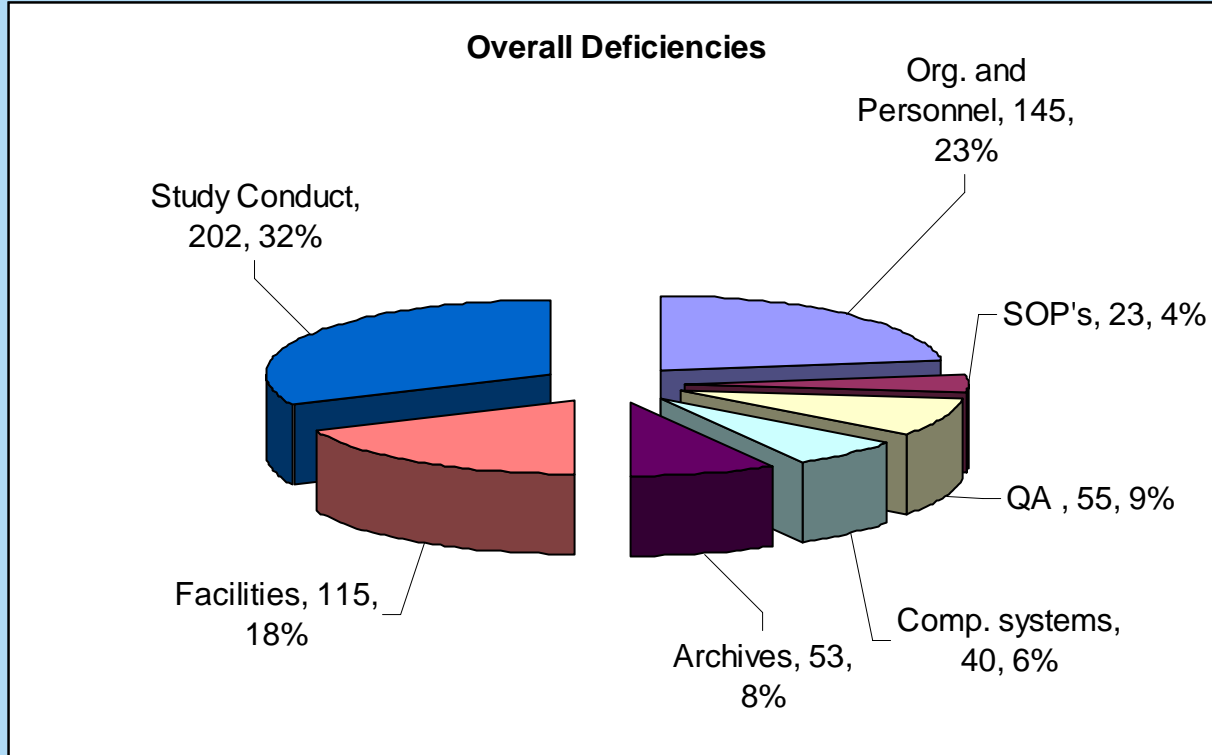
## QA Majors



## O+P Majors

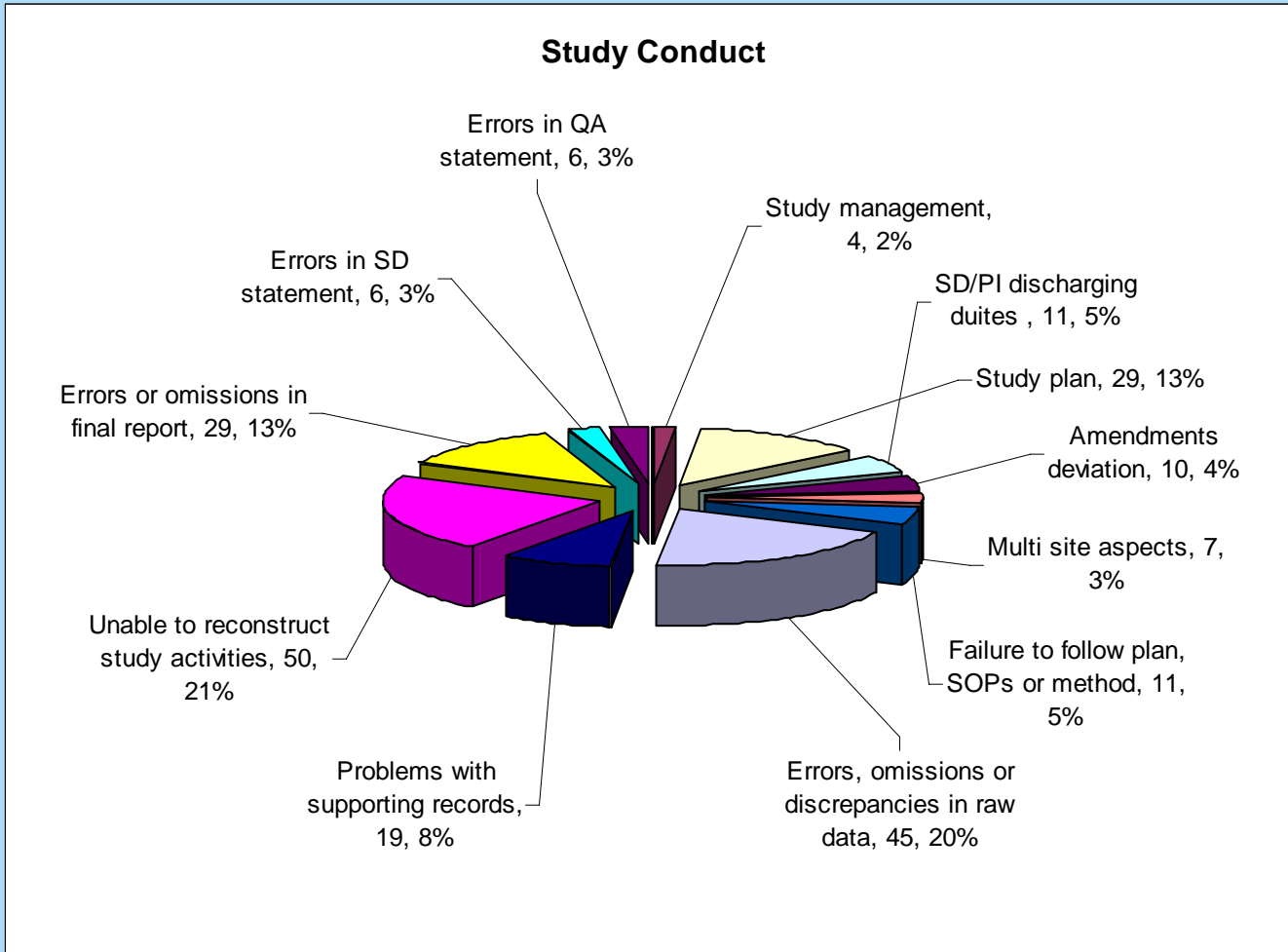


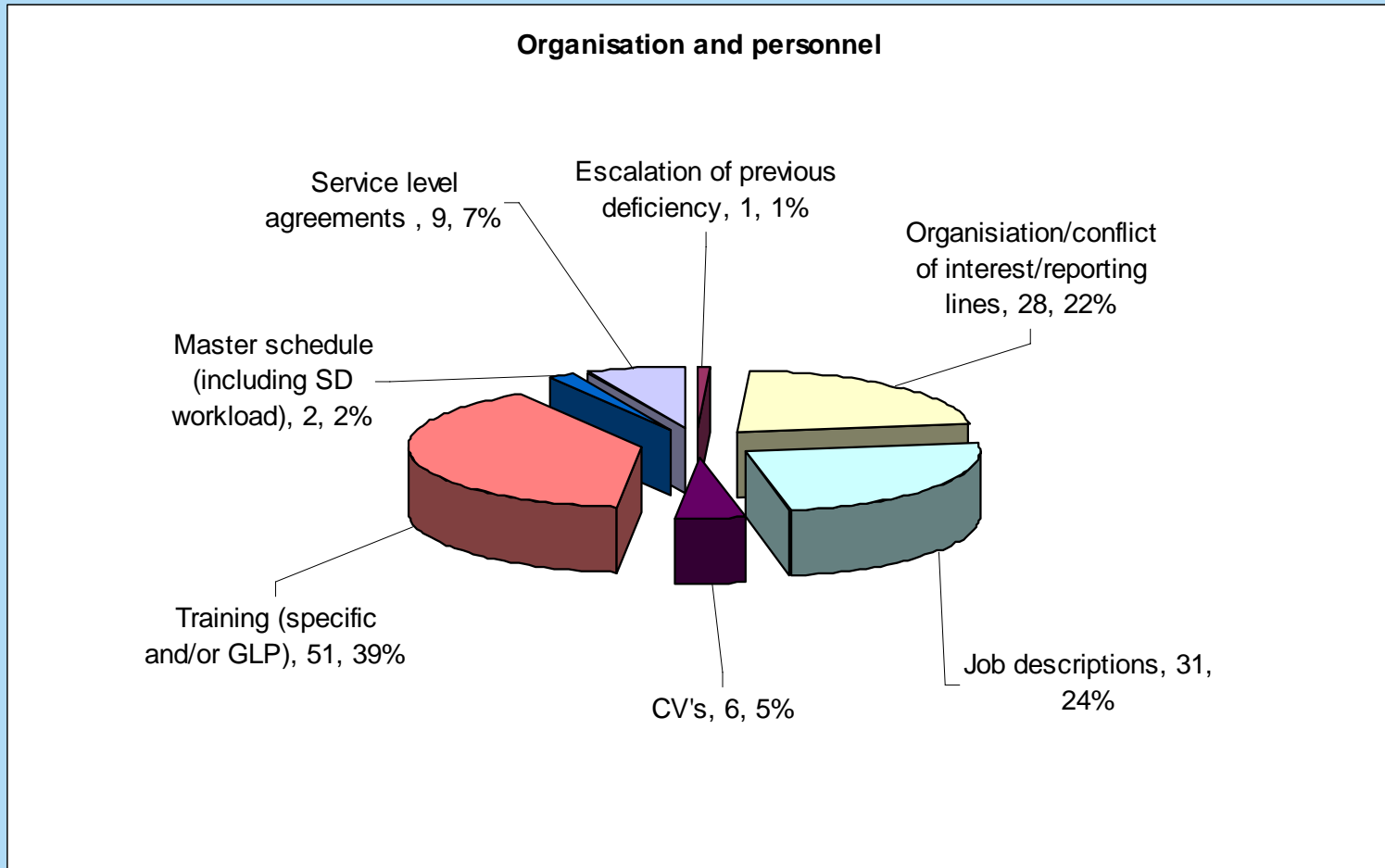
# 2010 Deficiency Data



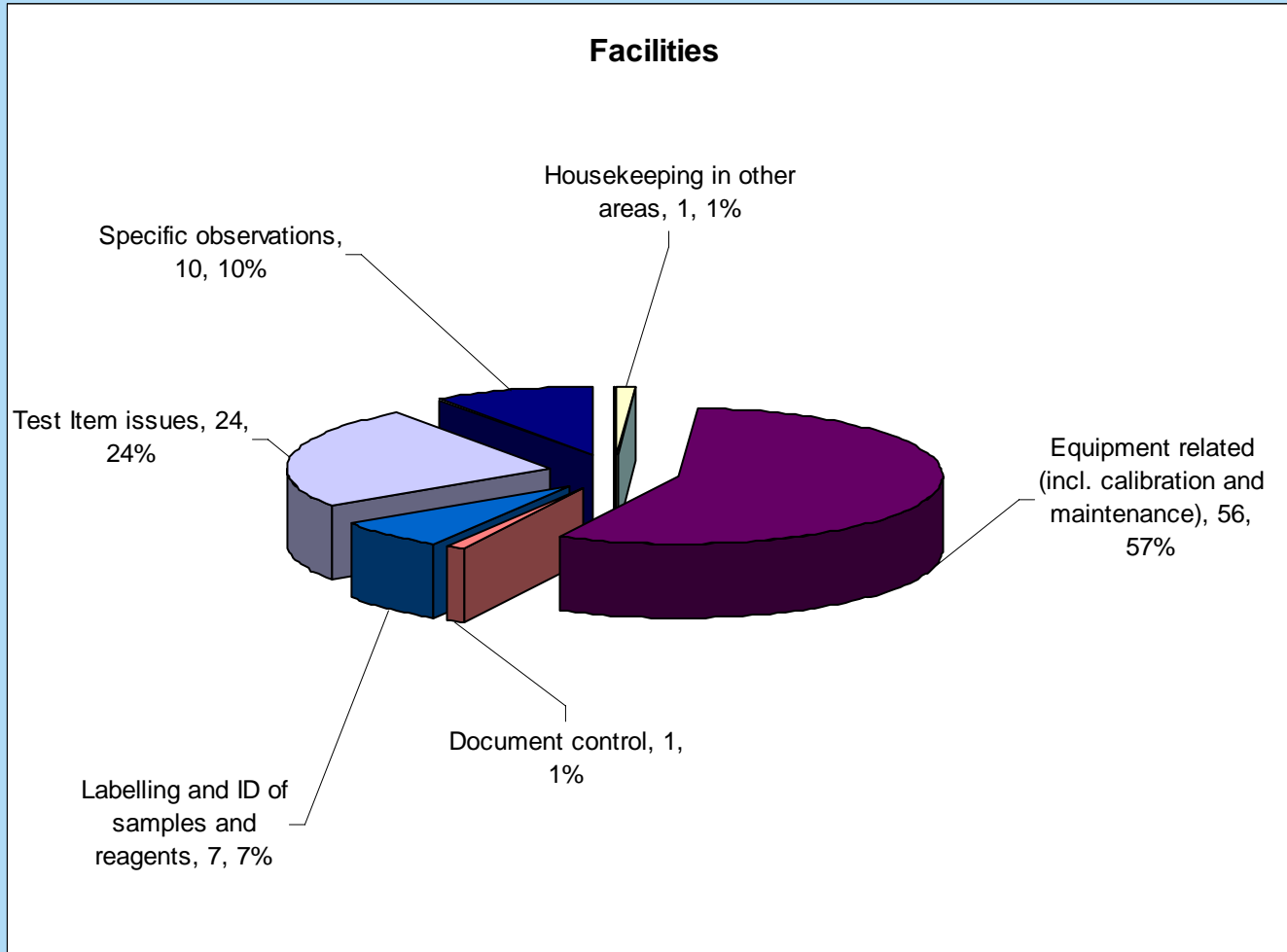
## 2010 Deficiency Data GLP “league table” positions

2010	2009	2008
Study Conduct, 34%	Study Conduct, 32%	Study Conduct, 31%
Organisation and Personnel, 20%	Organisation and Personnel, 23%	Organisation and Personnel, 19%
Facilities, 15%	Facilities, 18%	Facilities, 17%
Archives, 9%	QA, 9%	Archives, 11%
QA, 8%	Archives, 8%	QA, 10%
SOP's, 8%	Computerised Systems, 6%	Computerised Systems, 6%
Computerised Systems, 6%	SOPs, 4%	SOPs, 6%





# 2010 Deficiency Data



## 2010 Deficiency Data

### Deficiencies – Facilities Breakdown

Noted that a larger proportion of deficiencies are relating to equipment and test item issues.

Revised breakdown categories for 2011:

- Equipment related - maintenance
- Equipment related - calibration
- Equipment related - other
  
- Test item identification/verification
- Test item – other

This will allow us to assess the root cause of issues in this area using the 2011 data



## 2010 Deficiency Data Yearly evaluation

<b>Year</b>	<b>Total</b>	<b>Criticals (% of total)</b>	<b>Majors (% of total)</b>	<b>Deficiency (% of total)</b>
2008	985	10 (1.02)	38 (3.9)	937 (95.1)
2009	669	6 (0.90)	30 (4.5)	633 (94.6)
2010	680	1 (0.15)	25 (3.68)	654 (96.2)

## 2010 Deficiency Data Inspector consistency



Peer review process for all inspection reports prior to issue

Wider discussion where 2 inspectors cannot agree on either a finding or a categorisation

Review of all serious findings undertaken in January

# Thank You!

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