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A Focus for Analytical Chemistry in Europe

**Data analysis
Breakout session feedback**

Conveners
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Participants

- 23 participants
- 7 different countries
- 3 from universities
- 3 from pharma
- The rest from Government/State labs

Worked in four groups to discuss questions

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Questions for discussion

- Who carries out data analysis in your organisation?
  - Individual scientists, statistics team…
- Is data analysis a regular part of the training programme in your organisation
- What data analysis tools do you use?
  - spreadsheets., type of software…
- Have there been any significant changes in regulatory/accreditation requirements in relation to data analysis?
- What are the challenges?
- What guidance/standards do you use – is further guidance needed?

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Who carries out data analysis in your organisation?

G1 by themselves, no stats team – for State Labs

G2 by stats team in universities

G3 by stats team reviewed by chemists; individual analysis

G4 by themselves, and a stats team in a university

CONCLUSIONS
- In Govt/State labs there are no statistics teams – the data analysis is performed by chemists (themselves); individual analysis
- In universities – there are teams for statistics

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Is data analysis a regular part of the training programme in your organisation?

G1 Learn by themselves, Method specifics, keep up with current developments, more training needed to keep up with the latest development on use equipment

G2 Optional/occasional/annual training with Supervisor approval; non-regular training; optional training; Forensics – Evaluation of evidence (Compulsory); Internal training – on-line

G3 External training Courses (EPA/Hospital); assumed prior acknowledge

G4 No structured training – self directed

CONCLUSIONS

- In Government/State labs the training is either optional, occasional or annual and needs the Supervisor's approval
- There is often no-regular training/internal training
- Training by themselves
- More training is needed to keep up with the latest developments – instrumentation, regulatory requirements

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What data analysis tools do you use?

G1 Quality Analyst, EXCEL, Equipment software

G2 MatLab(UNI), EXCEL, STATISTIC Lab, SPSS, Chemometrics, STATGRAPHICS, Quality Analyst, LIMS, R

G3 ORACLE, EXCEL, R

G4 Quality Analyst, NCSS, MINITAB, GUM (for control charts), SIMPCA-P, TRACE Finder

CONCLUSIONS

- Used a wide range of tools: EXCEL(4), LIMS(4), Quality Analyst(4), ORACLE (2), R(2)   and
- SPSS, Chemometrics, STATGRAPHICS, NCSS, MINITAB, GUM (for control charts), SIMPCA-P, TRACE Finder

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Have there been any significant changes in regulatory/accreditation requirements in relation to data analysis?

G1 ISO 17025, risk based thinking; IT issues; ISO15189 (data protection)

G2 ISO 17025 – will it impact

G3 – Regulatory requirements; Robust stats; PT provider (impact of ISO 13528); WFD – meeting more regulatory requirements; ISO 17025

G4 - PT provider; data integrity; Pharma

CONCLUSIONS

• Specific changes for PT providers

• Uncertainty on the possible impact of ISO 17025

• Pharma labs – data integrity requirements – ALCOA

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What are the challenges?

G1 Timeframes (unrealistic requests from clients); staffing; data compatibility; loss of back-up; different versions of software; data back-up; software security

G2 Lack of understanding, lack of training; writing code

G3 archiving, retrieving data; pooling of data, backing-up of data

G4 lack of training; keep up with changes in guidelines; inconsistent applications; time; not appreciating value of statistics inside organization

CONCLUSIONS

• Lack of time

• Lack of understanding; limited training

• Data management issues: back-up data, archiving, retrieving data

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What guidance/standards do you use – is further guidance needed?

G1 to get free tips – good info and expertise to be shared; guidance on basic statistics, which method to apply, how to proceed

G2 ISO 17025; regulation arising from EU regulations, best practice manuals

G3 support some training for different standards; support on how to do the validation – a manual on how to proceed for validation

G4 acknowledge gap in chemometrics; 1703, QbD; quick guides in different techniques such as LCMS;

CONCLUSION
- Basic statistics guidance
- Guidance on specific techniques
- ISO 17025 – its impact