

The Role of Proficiency Testing in the Contract Laboratory Environment

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The Contract Laboratory World

- Independent third party testing facility
- Data are used for critical decisions
- The data must be frequently defended
- The contract lab is often criticized
- When data are “out of spec” or problematic

Laboratory Accreditation

- The contract labs often seek accreditation
 - ISO 17025
 - Other accreditations
- Use of proficiency testing is required
- Different programs

Proficiency Testing in Method Development

- All new methods require validation in the CRO
- Critical aspects of validation:

Principles of Method Validation

- Precision
- Accuracy
- Specificity
- LOQ
- LOD
- Linearity
- Range
- Ruggedness
- Robustness
- Extraction Efficiency

Proficiency Testing in Method Development

- All new methods require validation in the CRO
- Critical aspects of validation:
 - Accuracy is often measured with fortified samples
 - Proficiency testing is a great accuracy tool
 - Method performance can be measured
 - True accuracy can be determined in the sample matrix of interest

Method Validation - Acceptability Criteria

<u>Concentration</u>	<u>Repeatability (%)</u>	<u>Recovery (%)</u>
• 100%	1	98-101
• 10%	1.5	95-102
• 1%	2	92-105
• 0.1%	3	90-108
• 0.01%	4	85-110
• 10 g/g (10 ppm)	6	80-115
• 1 g/g (1 ppm)	8	75-120
• 10 ng/g(10 ppb)	15	70-125

Proficiency Testing in Analyst Training

- Analyst training is important in the contract lab
- Training files are often inspected
- Training can include:
 - “In house” control samples
 - Proficiency samples
- Proficiency samples are a great tool for the “final performance evaluation”

Proficiency Testing in Analyst Validation

- Initial training is documented for all analysts in the laboratory
- Continuous evaluation of analyst performance
 - Duplicate samples
 - Control samples
 - Standard reference materials
 - Proficiency samples
- Proficiency testing provides the strongest continuing evaluation of analyst performance

Proficiency Testing in other Qualifications

- In addition to analyst training the proficiency testing program can be used in many other applications in the contract laboratory
- These may include:
 - Qualification of new instruments
 - Qualification of method modifications
 - Method extensions
 - Use of new reagents

Laboratory Performance Measurements

- In addition to analyst validation – laboratory performance needs to be monitored
- QC charts can be used with a number of applications:
 - Control samples
 - Fortified samples
 - Standard reference materials
 - Proficiency samples
- Proficiency test results are the best measure of overall laboratory performance

Dietary Supplement GMP

Independent Third Party Testing

- Contract labs are counted on to deliver independent third party data
- These data are often challenged
 - Competitors
 - Regulatory agencies
- Proficiency testing data can play a strong support role

Independent Third Party Testing

- The greatest challenge the CRO faces – litigation
- The data are scrutinized by the legal system
- The results are “attacked” by hostile lawyers
- All QC tools become important
- Proficiency testing can make the difference

Use of Proficiency Testing in Litigation

- Proposition 65 Class Action suits for acrylamide
- Data between two labs is being compared
- No AOAC Official Method is in place
- The two labs use different method
- The two labs get different results
- Use of a proficiency testing program gained a significant advantage

Summary

- The contract lab has many uses of proficiency testing
- These programs can aid significantly in the laboratory QC programs
- The contract lab must constantly defend its data

Conclusion

- Thank you for your attention
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