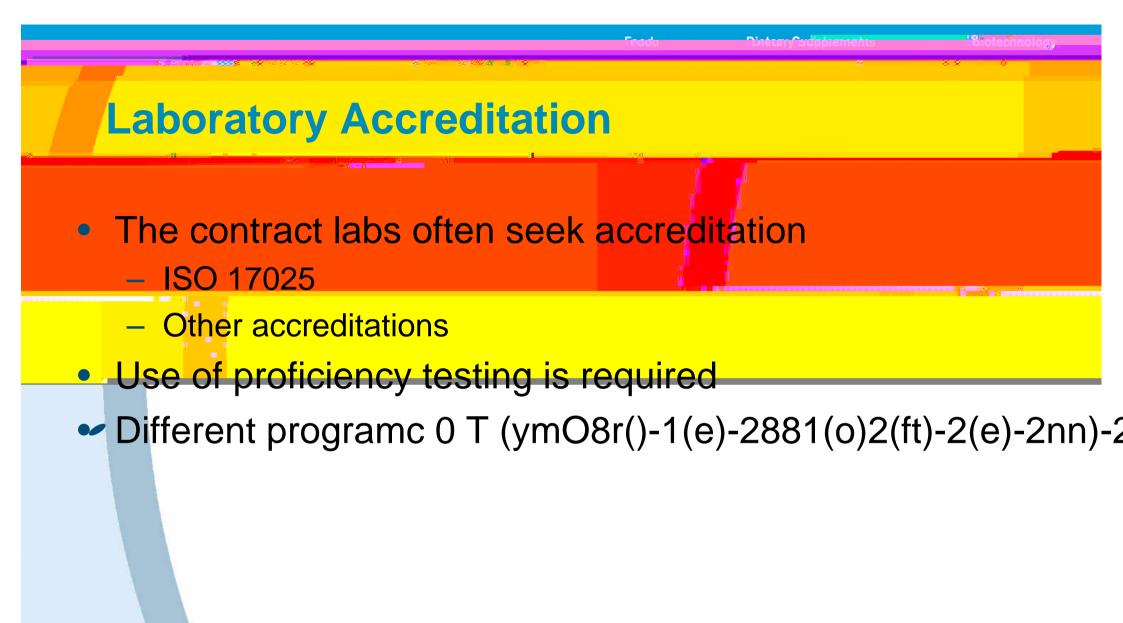
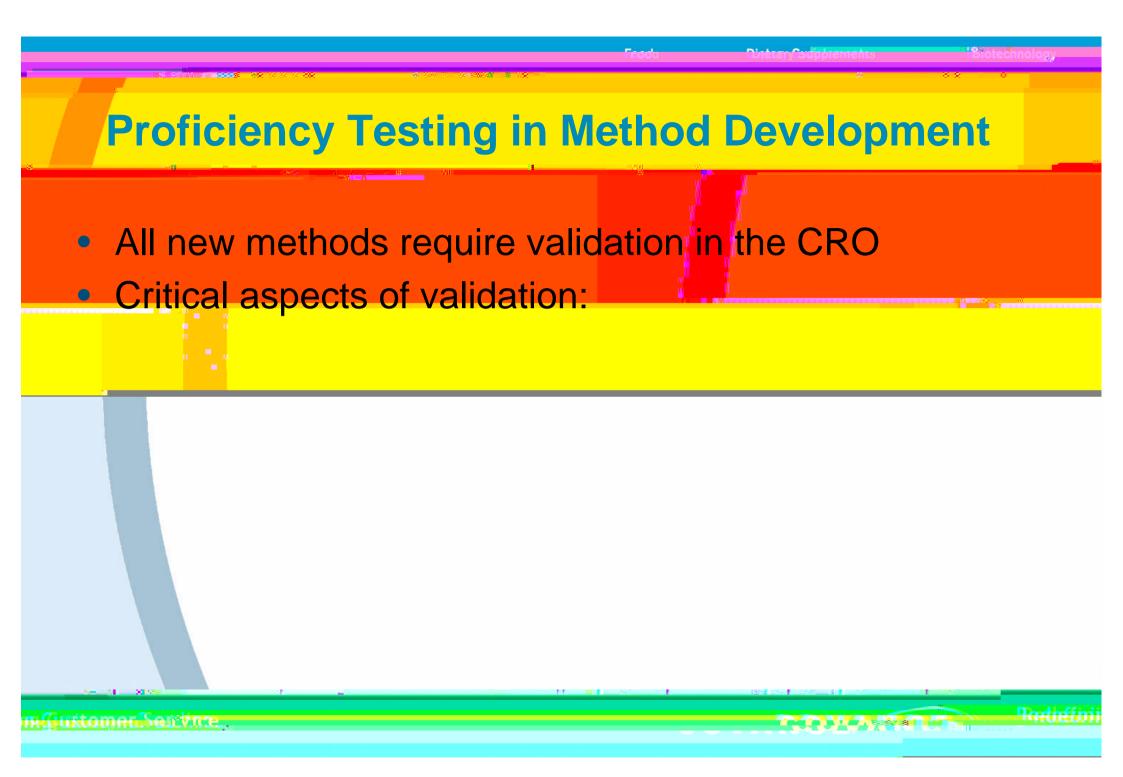
# The Role of Proficiency Testing in the Contract Laboratory Environment

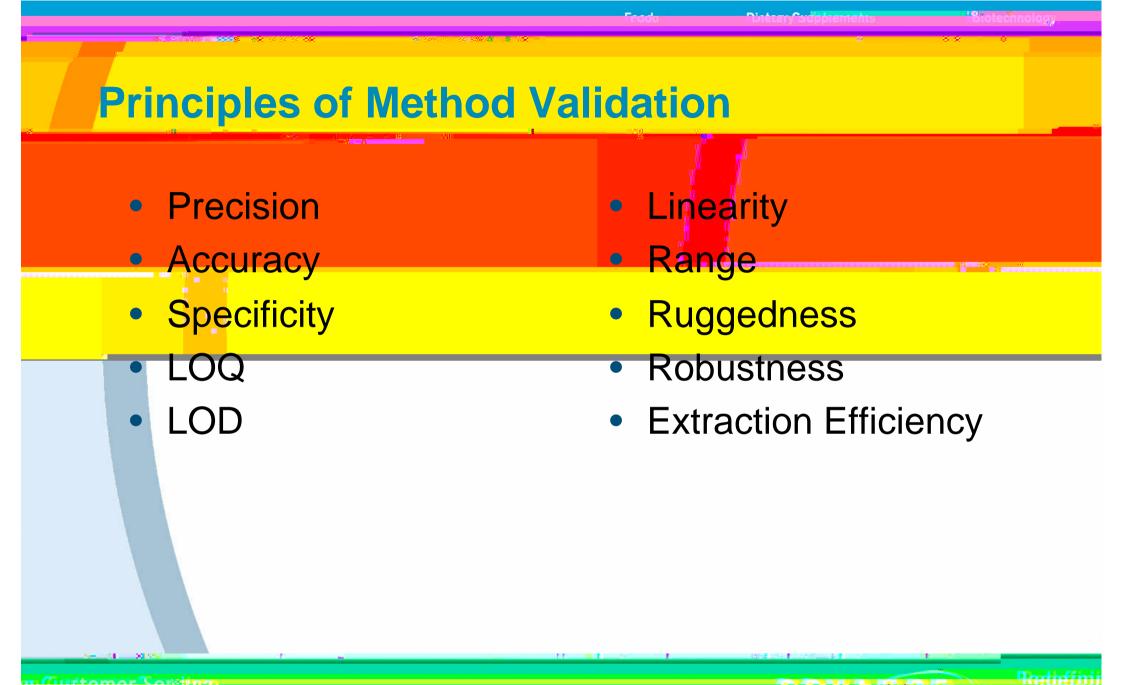
121<sup>st</sup> AOAC International Annual Meeting and Exposition 17 September 2007 Darryl Sullivan

# The Contract Laboratory World Independent third party testing facility Data are used for critical decisions The data must be frequently defended The contract lab2(n)-2(trt225)Tj 0 Wory is often criticized When data are "out of spec" or prob2(n)lemation

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# **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**

•	<b>Concentration</b>	<u>Repeatability (%)</u>	Recovery (%)	
•	100 <mark>%</mark>	1	98 <mark>-101</mark> -	un and a second s
•	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	

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## **Proficiency Testing in Analyst Training**

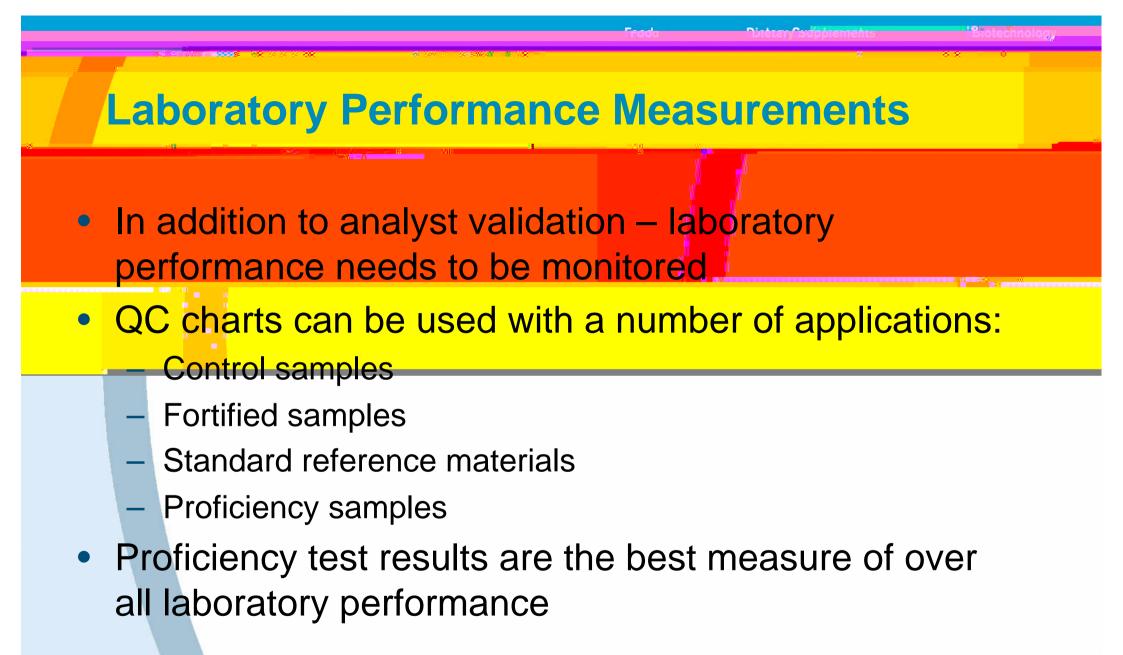
- Analyst training in important in the contract lab
- Training files are often inspected
- Training can include:
  - "In house" control samples
  - Proficiency samples
- Proficiency samples are a great tool for the "final performance evaluation"

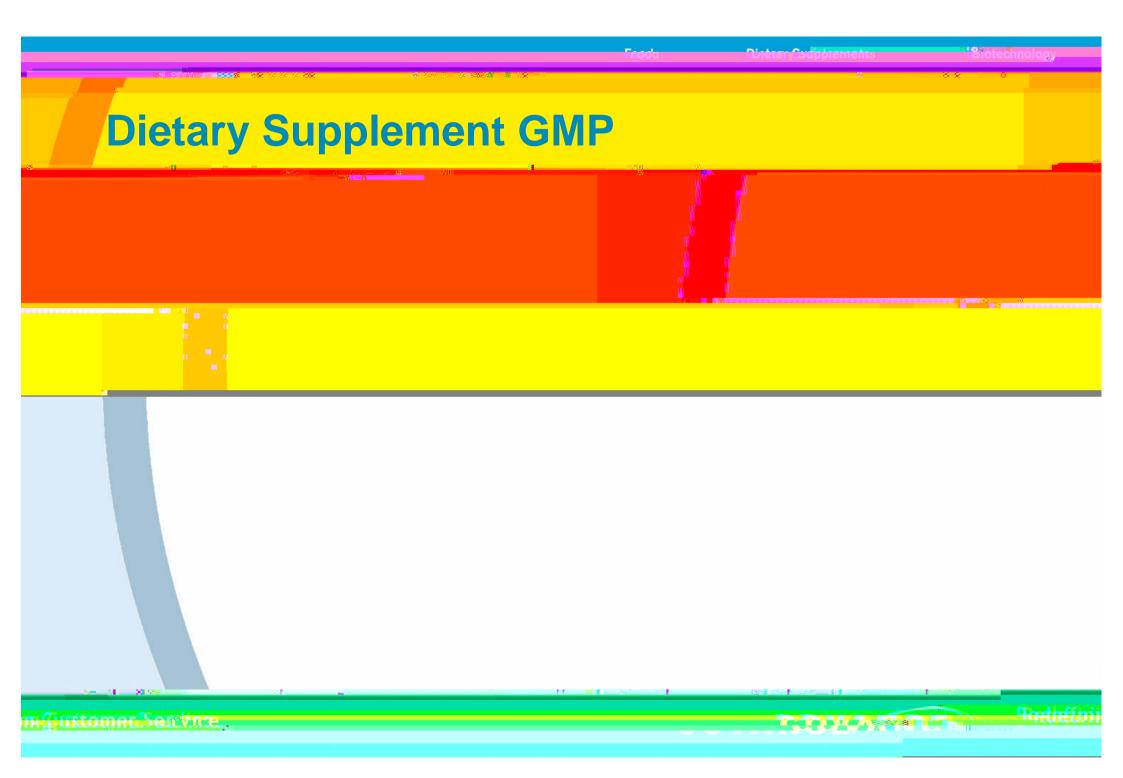
# **Proficiency Testing in Analyst Validation**

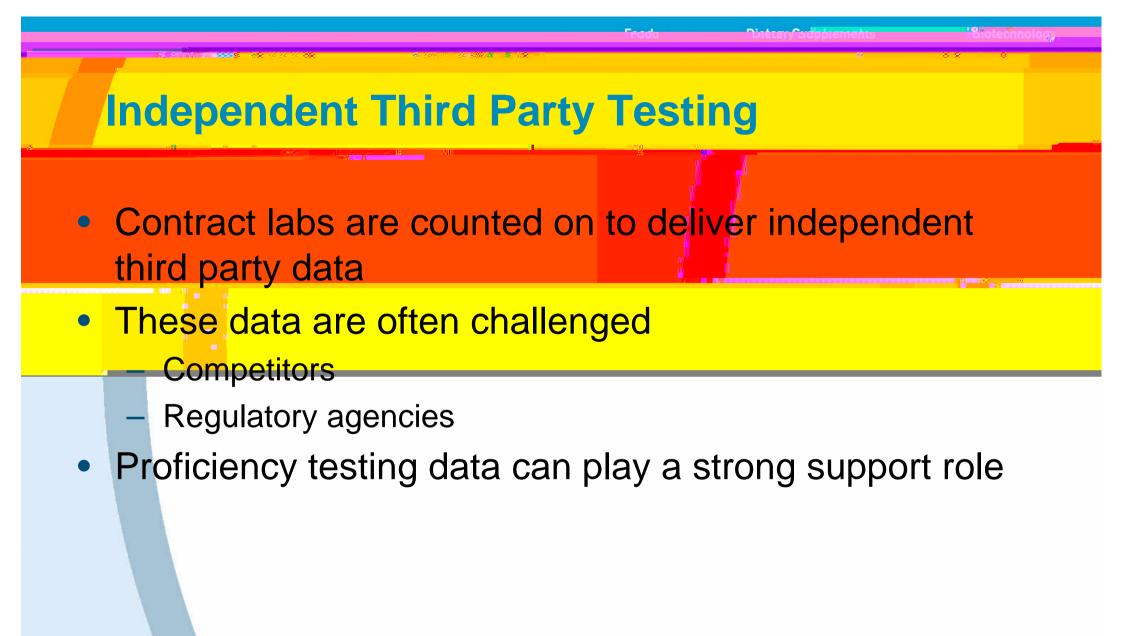
- Initial training is documented for all analysts in the laboratory
- Continuous evaluation of analyst performance
  - Duplicate samples
  - Control samples
  - Standard reference materials
  - Proficiency samples
- Proficiency testing provides the strongest continuing evaluation of analyst performance

# **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







n:Gustomer:Sou.v.ra

# 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

