Outsourcing Partnerships. A Contract Test Laboratory's (CTL) Perspective

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Global Top Decision-Makers Study: United States

- Overall according to the study, "The majority of top U.S. companies are more satisfied with the results of their Business Process Outsourcing initiatives than are executives worldwide, with cost savings either meeting or exceeding expectations."
Regulatory Scope

- JP
- EP
Partnership

Strategic Partnerships involve Outsourcers acting on company needs to achieve optimal resource utilization; is a great possibility that can benefit all, be formalized and customized.
Commitment
CORE COMPETENCY IS TESTING

- Courage
- Possibility
- Being a Yes
- Freedom for another to choose
- Vision/FOCUS
- Stand
- Creativity
Quality (you know when it is absent)

- Being reliable.
- Being accurate
- Being clear
- Being “The Best”
- Timely reporting
  - metrics
Integrity

- The results are what they are.
- Brainstorming, analysis, effort and systemized always lead to ...
Insight

• Difficult problems are not obvious even if they involve the routine.

• Failure Investigations lead to Breakthroughs!
Communication

- So important
- Verbal--in person, on phone, by proxy
- Written Report
- Executive Summary
- Meetings - make time available
- e-mail
Flexibility

- Customization for sponsor needs.
- In terms of report presentation, test methodology.
Outsourcer’s Needs

- Control
- Speed
- Cost Effectiveness
- Education
- Brainstorming
- Resource Optimization
- Capacity
Needs (cont’d)

- Experience
- Education
- Reputation
- Data Management 21 CFR Part 11
- Personnel
- Facility
- Contracts
Contracts

- Procurement
- PROJECT (ad hoc)

- Versus

- (STRATEGIC)

Executive level contact between parties
Audits

- 60% In person
- 100% Provide Audit Agreement
  - 33% Provide Written comments
- 40% Mail
  - 0% Provide Written comments
- Timeline 100% NMT 2 Days
CTL Warning Letters (WL) - FDA Web Information

- WARNING LETTER
- CERTIFIED MAIL
- RETURN RECEIPT REQUESTED

Small Number viz a viz Manufacturers

2000-3
1999-2 -1 Unacceptable for new drug applications
1998-4- 1 Unacceptable for new drug applications
1997-2- 1 Unacceptable for new drug applications
Warning Letters-continued

- # Registered Pharmaceutical Cos. 2000

2000 #Warning Letters CBER+CDER ~52

- # Contract Test Laboratories (All types) 6000

- 2000 #Warning Letters ~3

- (okay to feel safe with CTL Industry)
Main Topics CTL WLs

- Documentation Control
- Re-testing (BARR type)
- Failure Investigation
- Inaccurate reference to USP
- Non-validated methods
- Unwritten Methods
- Lack of GLP
NJPQCA

THE END
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