

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



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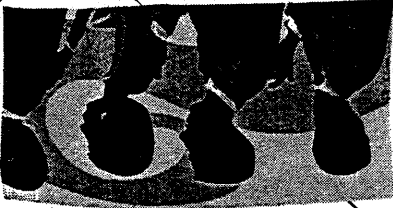
PDA 2001 Annual Meeting, 3 Dec. 2001 Washington, DC

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."

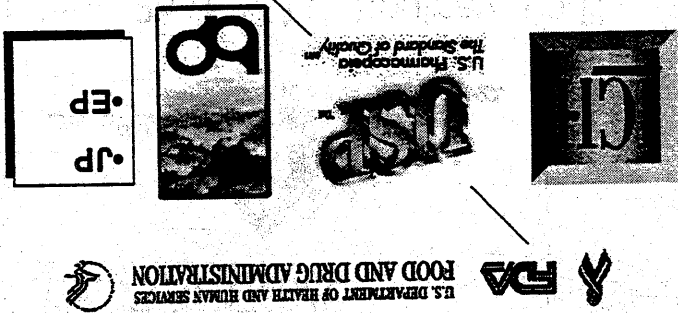
Partnership

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.



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Regulatory Scope



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Commitment

- Courage
- Possibility
- Being a Yes
- Freedom for another to choose
- Vision
- Stand
- Creativity



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Quality

- Being reliable.
- Being accurate
- Being clear
- Being "The Best"
- Timely reporting



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Integrity



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

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Insight

- Difficult problems are not obvious even if they involve the routine.
- Failure Investigations lead to Breakthroughs!



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Communication

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



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Flexibility



- Customization for sponsor needs.
- In terms of report presentation, test methodology.

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Outsourcer's Needs

- Speed
- Cost Effectiveness
- Education
- Brainstorming
- Resource Optimization
- Capacity



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Needs (cont'd)

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

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Audits

- 60% In person
- 100% Provide Audit Agreement
 - 33% Provide Written comments
- 40% Mail
 - 0% Provide Written comments

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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

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Main Topics CTL WLs

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

