

Information Technology

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(1997-2003: R&D IT at Parke-Davis and Eli Lilly)

The Gold Standard:
Consumers know that the FDA has tested their medications, food, ...

Your
generic drug
is safe and effective.
And we've got the results to prove it.



When FDA approves your generic drugs, it ensures they are safe and effective. All generic drugs are put through a rigorous, multi-step approval process. From quality and performance to manufacturing and labeling, everything must meet FDA's high standards. We make it tough to become a generic drug in America so it's easy for you to feel confident. Visit www.fda.gov/cder/ or call 1-888-INFO-FDA to learn more. **Generic Drugs: Safe. Effective. FDA Approved.**



Item # 241034
U.S. Department of Health and Human Services
Food and Drug Administration

Lately, we've
learned that
it's hard to
keep that
promise



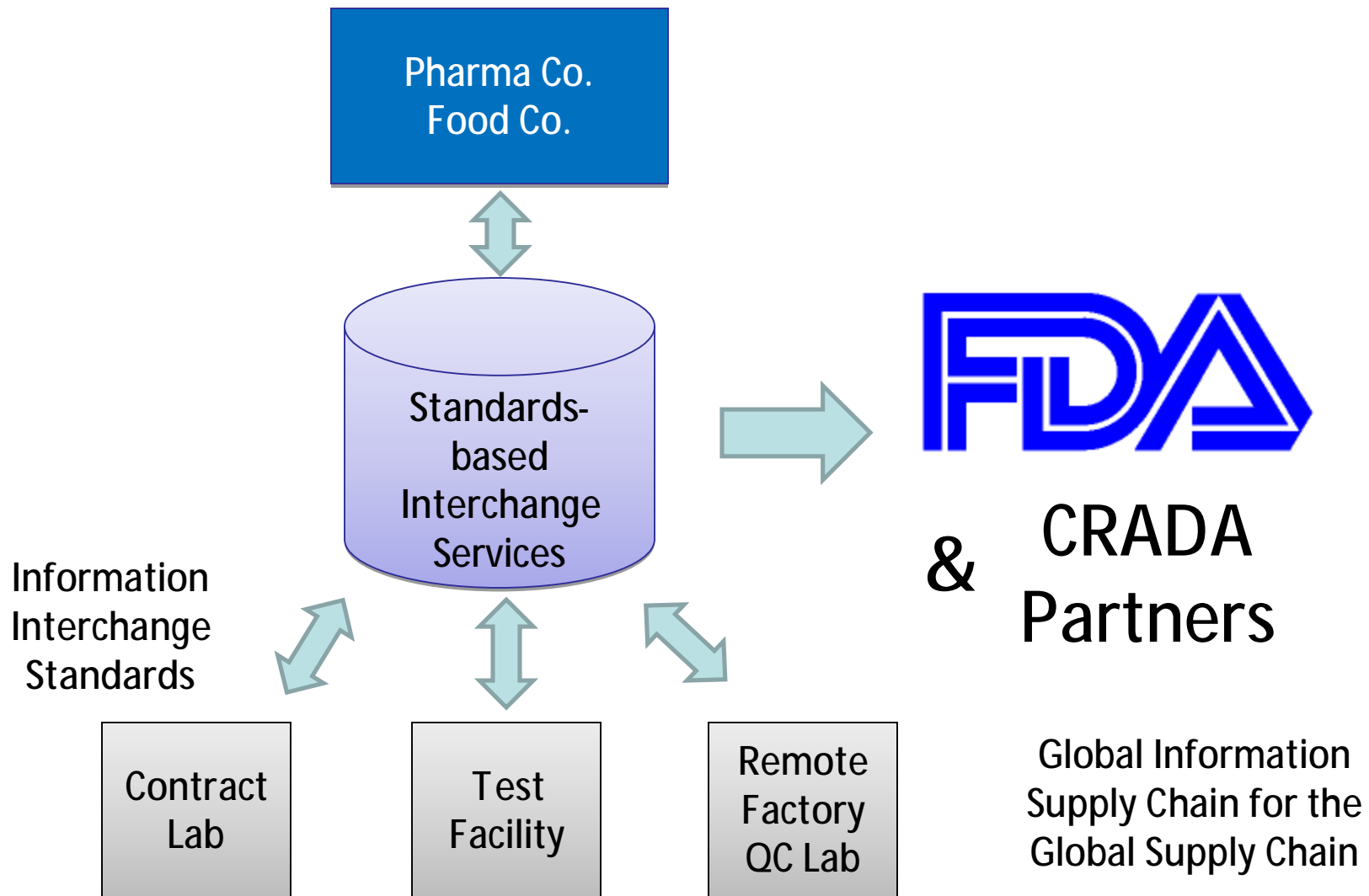
The entire
testing
infrastructure
is based on
computers



There are
innovative
technologies
to help ... but
FDA uptake?



View of the Future: A Global "Information Supply Chain"*



Existing Capabilities (Current Situation)

- IT infrastructure is *outdated* and *unstable*.
- No *Continuity of Operations* (a.k.a. *Disaster Recovery Plan*).
- Suboptimal FTE(IT/Scientist) and Contractor mix, induces downward spiral of
 - Poor alignment with *Regulatory Science* mission,
 - Project driven IT products that become silos,
 - Talent recruitment and retention issues,
- Huge gap from IT Infrastructure to information supply chain to “knowledge management” for support of decision making processes.

“What the FDA Needs to Do” (first)

- Start at cycle of talent recruitment.
 - Address FTE (IT/Scientist) and Contractor mix
 - Address recruitment challenges, competitive landscape
 - Enterprise architecture includes regulatory scientists.
- Leverage IT budget increases with CRADAs
 - Insures technology input from many stakeholders.
 - Shares development costs with many parties.
 - Aligns FDA investment with technology directions.
 - Input CRADA best practices from NCTR experiences, and similar plans in genomics area.