



Pharmatech Overview

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Company Overview

- Established in 1995. Based in Foster City, California
- Full service consultancy to the regulated life sciences industry comprised of seasoned industry and former agency experts.
- 120+ Clients worldwide, 95% Client Retention Rate, Average tenure 2 yrs, 10 clients 6-11 years
- Ranked #1 by Fortune 50 Pharma company for quality of work, timeline and budget management amongst 50 consultant firms
- Offices in U.S. and Asia

Centers of Excellence

Pharmatech End-to-End Support				
Technical Knowledge	Validation			
Program Understanding		Consulting		
Value-Budget/Timeline Management			Proj. Controls	
Quality/Compliance				Regulatory Compliance
Pharmatech Divisions	Validation	Consulting	Proj. Controls	Regulatory Compliance

Pharmatech's Unique Offering

- Combination of former FDA and Industry Experts to ensure and maintain sustained compliance
- In-house, hands-on expertise in the design, operation and validation of facilities, equipment, processes, automation and associated systems
- Technical and operational expertise to assist Contract Manufacturing Organizations and satellite organizations in technology transfer, validation and quality system compliance
- Thought leadership in Lean/Six Sigma, Risk Management, Quality by Design and Process Analytical Technology
- VC/MA Due Diligence

Alliance Partners

Pharmatech has established key alliances with the premier service providers in the industry:

- USA:
 - Remmele Engineering
 - Rockwell Automation
 - Novatek
 - TechSolve
 - Epcot Industries
 - AVATAR Labs
 - SPI-USA, Inc.
 - Global Quality Alliance
 - Cerulean.
 - ATS Automation, Inc.
 - EORM
- EU / SA:
 - Prado Advisors (UK)
 - SPI-Portugal / S.A.
 - French Bio/Pharma Transaction Brokerage
- India:
 - Epitome Technologies, Pvt. Ltd.

Sample PAI Client List



DEPOMED, INC.



NEKTAR™



Matching Proven Science With Proven Needs

CHIRON



Diagnostics





e-Pedigree

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The 2004 Counterfeit Drug Task Force Report & 2005 Update

- FDA framework called for a multi-layer approach to address the problem and included the following measures:
- Secure the ***product and packaging***
- Secure the ***movement of drugs*** through the supply chain
- Secure ***business transactions***
- Ensure appropriate ***regulatory oversight and enforcement***
- Increase ***penalties***
- Heighten ***vigilance and awareness***
- International ***cooperation***

Task Force Key Points

- Widespread use of electronic track and trace technology would help secure the integrity of the drug supply chain by providing an accurate drug "pedigree," which is a record of the chain of custody of the product as it moves through the supply chain from manufacturer to pharmacy;
- RFID is a promising technology as a means to achieve electronic pedigree (e-pedigree);
- Widespread adoption and use of electronic track and trace technology would be feasible by 2007

Industry Response

- Does not feel they need to comply unless there is direct enforcement
- 2-D bar coding is e-pedigree industry's eyes
- Price sensitivity is the key factor
- Little or no understanding of what *security* is or means.
- Consistent perception that the Wal-Mart exercise was a failure

Big Pharma 1

- RFID only on One Drug because it is the most counterfeited drug in the world
- Several key products have been targeted for 2-D bar coding
- No sensitivity to database risk exposure or tag authenticity
- Program assigned to a Director level individual

Big Pharma 2

- Not doing RFID
- 2-D bar coding in place for high value product only
- Volumes of 10-30K units
- Cost the primary reason for not pursuing RFID.
- Engaged a company to assist in RFID when the time comes. Anti-counterfeiting in a can.

What Will It Take?

- Pharma still focused upon the technology solution
- The solution must clearly show a strategic business advantage to be considered
- The solution must be easy to implement if it is going to be widely adopted
- Demonstrated value on the world stage- WHO/UN. Malaria medication in Africa

Conclusion

- E-Pedigree is in nascent phase with the pharma industry
- Pricing is the major impediment to implementation
- High value products justify using more secure solutions such as RFID
- No strategic sensibility is present yet in terms of security
- “Pharmerging” markets may change perception.
- Foreign contract manufacturers may drive increase valuation by US