

UPS SampleSure™

UPS Professional Services



U.S. Federal Regulation That Impact You

Prescription Drug Marketing Act (PDMA)

- Enacted by Congress in 1988
- Designed to improve distribution control and minimize the diversion of drug sample
- Non-compliance can mean significant fines and penalties

UPS SampleSure™

UPS has been helping pharmaceutical companies manage key aspects of sample distribution challenges for years.

Now, a contract solution from UPS Professional Services, a business unit of UPS, combines all of our capabilities together.

- We support your operations and distribution
- You benefit from world class delivery service
- You meet all federal regulations

UPS Experience and Results.



UPS Helps You Satisfy The Federal Regulations

UPS' proven delivery confirmation capability and electronic recordkeeping systems help you

- Ensure that deliveries are received
- Capture and retain shipment and delivery information, meeting Prescription Drug Marketing Act (PDMA) requirements
- Streamline shipping and delivery reconciliation



UPS can help you meet PDMA requirements

Compliant and validated solution

Supports the Paper Reduction Act of 1995

- UPS offers automated visibility of shipments

Delivery signature capture and storage

Record retention for 3 years, plus the current

Detect diversion

- Custom data filters and reports
- Satisfy audit requirements whether it's 2 day or On Demand

UPS Validates to 21 CFR Part 11

Our solution and processes

- Are secure
- Ensure data authenticity
- Have change control procedures in place
- Ensure consistency of procedures and security
- Perform as intended/documentated to produce accurate, reliable and reproducible records

Don't Just Take Our Word For It

We worked with the *U.S. Federal Drug Administration* to ensure that UPS SampleSure met all regulations.

In, 2004 we hired *BuzzeoPDMA* to assist and monitor UPS SampleSure for compliance and validity.



**Next Steps and
Discussion.**



Thank You.