

“New Edge” Technology in the Drug Testing Industry ? World-wide

Scientific Acceptance vs. Regulatory Acceptance

Bill Corl, IFDAT Houston, November 2011

- President Ronald Reagan –
 - 1986: Executive Order 12564 –
 - Drug-Free Federal Workplace
 - Creation of SAMHSA/DOT urine
- This was a landmark achievement at the time – but is it still the best standard?
- Countries/industries without gov't regulated testing have an opportunity to define their own standards with new edge technology



In the case of Alternative Matrices:

- Due to a 1996 Consultative Meeting in Beijing which reflected growing world-wide interest in the use of biological specimens other than urine and blood
- United Nations Office of Drugs and Crime (UNODC) published “Guidelines for testing drugs under international control in hair, sweat and saliva” in 2001



- Alternative specimens have been proven scientifically
 - For example, over 300 peer reviewed publications for the testing of hair samples
 - Over 5 million oral fluid samples analyzed showing comparable positive rates to urine analysis in the workplace market



Regulated vs. Non-Regulated Testing:

- Non-regulated markets pursue new edge technology due to demand
 - How do you know these labs are operating effectively?
 - ISO/IEC 17025 standard
 - College of American Pathologists
 - Participates in Proficiency Testing Programs
- Timing to regulated markets is more about the implementation of regulatory guidelines not necessarily the scientific acceptance

- A challenge to new methodologies is that the science may be perceived as untrustworthy, when in fact regulatory agencies simply may not have reviewed it and included it in the guidelines.

In the regulators defense:



- Regulatory agencies have limited resources
- Many decisions reach across multiple agencies
- Pressure by many special interest groups
- Sometimes it is better to let new technology stand the test of time in non-regulated industry

Scientific Advancements:

- Test better, faster and more accurate...
- More sensitive equipment
 - Lower levels of detection
 - THC Metabolite methods in hair
- More sensitive screening assays along with additional panels outside of the NIDA 5
- Science adapts to societal trends

Continuing Evolution of Methods

- Urine
 - Added additional panels
 - Amended cut off levels for opiates
 - Added metabolite criteria for opiates (6-acetylmorphine)
 - Added direct observation for inconclusive results

Continuing Evolution of Methods

- Hair
 - Much more precision is required for hair testing
 - To alleviate concerns with contamination
 - Wash procedures developed over the years
 - Metabolite criteria (Cocaine – Benzoylecgonine, Norcocaine, Cocaethylene)



Continuing Evolution of Methods

- Oral Fluid
 - Development and commercialization of homogeneous oral fluid reagents
 - Development of additional collection devices (volume indicators)
 - Expanded drug test panels offered by labs for oral fluid testing (extended opiates, cotinine)

Aside from the science - what is new edge technology?

- It is what clients demand:
 - More about data flow and turnaround time
- Laboratories, TPAs and MROs have to balance between speed to clients and regulatory issues

- Mobile Technologies



- Data Integration

- XML Integration -HR-XML format to add drug testing specific standards
- Challenges in Data Integration:
 - Older mainframe systems
 - Inflexible
 - Result information hardcoded
 - » If lab changes cutoffs not propagated through to partner

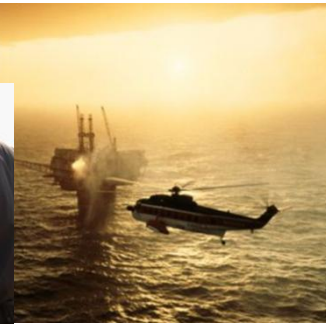
- **LIMS** (Laboratory Information Management System)
 - Real-time results to clients
 - Easier to Archive because disk space is cheap
 - Document management systems
 - Online CCF integration
 - Notes in extranet

- **Internal lab technology**
 - Barcode
 - Automation of methods

Current Examples:

- Brazilian Security Forces

- Online CCF system
- Data sent directly to laboratory
- Diminishes the possibilities of data entry error in translation of names



- Remote Oil rigs

- Need an easy-to-transport sample that will remain stable

- Court systems

- Using mobile devices to retrieve result reports in the courtroom

- In conclusion Scientific Acceptance vs. Regulatory Acceptance truly dictates how we view new edge technology
- This opens up tremendous opportunities for countries to develop their own regulations incorporating new edge technology



Questions?