



Breakout Session Summary

POST-MARKET SURVEILLANCE OF GENERIC DRUGS

Post-market Surveillance Breakout Session

- 100+ attendees
- Lessons Learned on Nitrosamines
 - Developing Analytical Methods
 - FDA/OPQ/OTR published analytical methods (not final, for guidance)
 - Orthogonal techniques for cross-checking primary analysis are provided
 - More detailed methods, maybe more information sharing early on
- Pharmacovigilance and Data
 - Inspections are positive
 - Generic industry has evolved, become more responsible,
 - Databases are available
 - Real word evidence or data from post-market surveillance
 - Lifecycle management
 - Data mining to utilize data available to make sure drug products are working as they are supposed to

Post-market Surveillance Breakout Session

- Post-market Issues/Lab Testing and Capabilities
 - The lansoprazole NG tube testing
 - Pillars of analytical chemistry tools are present at OTR, which is present in two locations (Silver Spring, MD and St. Louis, MO)
 - OTR's goal is to be research-ready for the next public health crisis
 - Develop high throughput, non-destructive, automated techniques
 - Inspections and sample testing
 - Nitrosamines guidance coming out soon
 - Pharmacovigilance inspection-had positive experience, generic industry has evolved, become more responsible, have databases
- Generic drug substitutability-Getting the Message out to Consumers!
 - Relay information to the doctors and pharmacists regarding how equivalency is established, the generic drug process



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