



Workshop G

Biomarkers: Critical Path Through Science, Regulation And Common Sense

**Sousan Altaie, Ph.D.,
Scientific Policy Advisor, Office of In
Vitro Diagnostics, CDRH, FDA**



History of the Biomarkers

- Three distinct periods in the history of biomarkers:
 - middle ages to the 18th century, bedside medicine used biomarkers
 - between 1794 and 1848, hospital medicine used biomarkers
 - from that time forward, laboratory medicine used biomarkers



Ancient Biomarkers

- Oldest test on body fluids was performed on urine before 400 BC.
 - Urine poured on the ground, if attracted insects then boils was the diagnosis



Ancient Biomarkers

- Hippocrates related the appearance of bubbles on the surface of urine specimens to kidney disease and chronic illness.
- Rufus of Ephesus described hematuria, at around AD 50 and attributed it to the failure of kidneys.



15th and 16th Century Biomarkers

- Thomas Willis (1621-1675), was the first to notice the characteristic sweet taste of diabetic urine
- Dobson in 1776 proved that the sweetness of the urine and blood serum in diabetes is caused by sugar
- Home developed the yeast test for sugar in diabetic urine in 1780



20th Century Biomarker

- Wassermann test for syphilis (1906)
 - The biomarker is anti cardiolipin antibody in syphilitic patients
- Abelev shows elevated alpha-fetoprotein in patients with testicular teratocarcinoma (1967)
 - The biomarker is an antigen



Our Objectives

- To discuss how biomarkers are utilized in the regulatory arena
 - as diagnostic tools for patient management and therapeutic dosing
 - as biological markers for biological product characterization
 - as biological markers for medical product safety
- To discuss the FDA's pilot process for biomarker qualification.



Our Speakers

- Francis Kalush, Ph.D., Scientific Reviewer, Office of In Vitro Diagnostics, CDRH, FDA
 - Biomarkers as in vitro diagnostics
- Federico Goodsaid, Ph.D., Office of Translational Sciences, CDER, FDA
 - Biomarker qualification process
- Kathryn M. Carbone, M.D., Associate Director for Science, CBER, FDA
 - Biomarkers for product quality
- Martin Shaw, Senior Scientific Officer, Biomarkers, Biotrin International
 - Biomarkers for product safety (early kidney damage)
- Klaus Olejniczak, Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany
 - European regulatory bodies and Safety Biomarkers