REGULATORY HARMONIZATION.....
What is the real question?

• Regulatory Harmonization?

• Product Harmonization?

• Cost Benefit Analysis?

• Needs based assessments?

• Or What?
Has this really changed?

• In the last 20 years the requirements has gone out of control
  – Negative samples – Increased X3
  – Sensitivity samples – increased X5
  – Timeline – From 1 year post development to at least 2 years, sometimes 3 or 4 years
  – Cost - Now its open ended!

• Global products are now very rare
  – If you do have one, there is no incentive to update it!
What does Regulatory Harmonization mean??

- Each Country / Region has a different set of requirements of Licensure
  - US FDA – CBER & CDRH
  - EU – CE Mark (Common technical standards)
  - Japan
  - Australia – TGA
  - Canada – Health Canada
  - China – SFDA
  - England – KEG
  - France – AFSSAPS
  - Germany – PEI list

- Some countries then require further testing for Blood screening use
Do we have common goals?

• Globally - Enhanced Safety of the Blood Supply

• High Quality “state of the art” products

• Low cost / High Value solutions

• But, the “Commercial” Industry has to make a return on investment
What can “we” do?

• A common set of needs from a Global perspective?
  – Cost benefit analysis
  – Return on investment

• Enhanced partnerships between the 3 key stakeholders?
  – Commercial
  – Blood & Plasma
  – Regulators

• Hold people accountable for choices that are made?

  • The choice is ours, this will only get worse…
DISCUSSION