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
  - >>>>>>
  - >>>>>>
- Some countries then require further testing for Blood screening use
  - England – KEG
  - France – AFSSAPS
  - Germany – PEI list
  - >>>>>>>>
  - >>>>>>>

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?**
  - **<u>The choice is ours</u>**, this will only get worse…

DISCUSSION