American Medical Device Summit

Reducing Product Review Times and Steps to Ensure Smoother Global Approvals

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September 12, 2014

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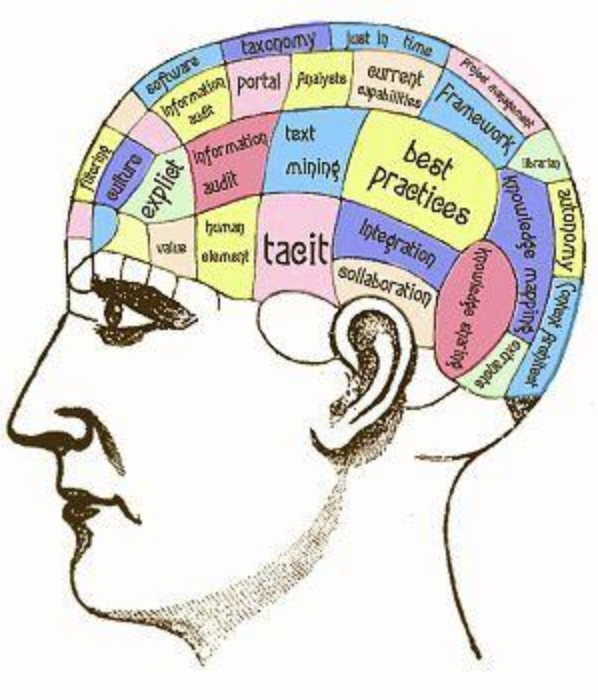
Objective :

- Identify Key Challenges in the Global Market
- Things to consider when developing your regulatory strategy including some successful practices
- Discuss Pros and Cons
- Answer questions *(if time permits)*





Challenges Industry faces in today's global world

- Constant changing regulations
- Different classifications
- Is it a medical device at all?
- Health IT requirements – Different regulators
- Varying requirements for Labeling Content
- Utilization and Recognition of Standards
- Practice of Medicine Differences
- User and their skills differences
- Approval in Country of Origin
- Traceability and UDI Requirements
- Need for Clinical Evidence and associated requirements
- Submissions package variation
- Localization of submission, device and labeling



How do we tackle these challenges?

- Begin planning at concept phase
- Regulatory Planning – Document it!
- Countries planning on distributing solution
  (Assume Marketing is lying to you when they say, "It's US Only")
- Early and Often Interaction with Regulator(s)
- Engage global personnel
- Leverage standards but understand how they are used in the different jurisdictions
- Make use of Industry Groups
- Use IMDRF Methodologies
- Benchmark and Network
- Ask lots of questions and keep listening!



The Good

The Bad

The Ugly

- A lot of work spread out over a long period of time
- Lots of record keeping
- Alignment across many regions (IMDRF)
- Learn from others in industry
- Standards - supports consistency
- Engagement with stakeholders (Internal & External)
- Increased alignment (Internal & External)
- Benefit/Risk balance

Remember, Regulations is a Profession not a Job so enjoy it and realize, there is never just ONE answer!



Thank you very much!

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