Building a Serialization Compliance Management System

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Amgen Inc. (Oct. 2012)

About Amgen

- Amgen discovers, develops, manufactures, and delivers innovative human therapeutics.
- A leader in biotechnology since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe, effective medicines from lab, to manufacturing plant, to patient.
- Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, bone disease, and other serious illnesses.

Amgen serves patients in 76 countries

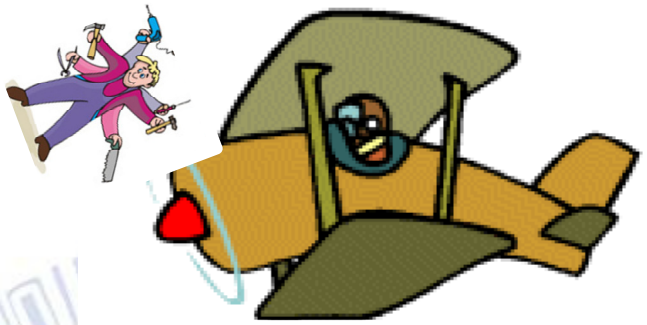
Building a Global Serialization Compliance Management System

The Challenge:

- Monitor and define serialization compliance requirements and solutions for the company's expanding global footprint;

and

- Establish processes and ensure support and resources to deliver and maintain the identified solutions.



It's like building the plane while flying it!

There is a History to This

- 2004, FDA/MIT: Anticipate RFID by 2007
- 2004, California: Pedigree by 2007
- 2006, California: Serialization required by 2009/11
- 2008, California: Serialization required by 2015-17
- 2008, EU DG Enterprise: Options to Combat Counterfeits
- 2009/10, Turkey Planning and Implementation
- 2010, China Electronic Monitoring of Essential Drugs
- 2011, EU Falsified Medicines Directive

The Prism of California/US
This is a Technology Issue, Right?

- Yes,
  - California has defined requirements: Serialization by 2009/11 2015/16 and e-pedigree
  - Europe is defining its requirements but looks like GS1 standards
  - So, work on the lines and IS support is essential to comply
  - Creation of a “corporate serialization project”
- But,
  - More than a few “outliers”
    - Bollino, Turkey, Argentina, China, etc
  - Regulations in formation
    - Can we influence? What do we build for?

We need a Technical Project, but something more, too

Legislative Echoes in Europe Something's Happening: Watch It

- Deliberate Falsified Medicines Directive process
  - Delegated acts shall set out … the characteristics and technical specifications of the unique identifier of the safety features
- Are the technical requirements going to be different from CA?
  - From a product manufacturing perspective—No
- We have systems in place for other issues, right?
  - Bollino for Italy, Belgium; 2D Matrix for France

Ok, a Technical Project, with monitoring

Developments Elsewhere Regulatory Can Fill the Gap, Right?

- Yes,
  - Turkey, Brazil, China, South Korea, India
  - Regulatory identifies and defines requirements
  - Supply Chain/Commercial identifies local solution provider
- But,
  - Some challenges may not be part of a typical regulatory scope
    - Alignment with corporate approach
    - Visibility into legislative policy development and industry advocacy
    - Technical/operational insight of the options

How to define hard requirements with fluid regulations?

Global Initiatives Call for Input from Industry

- US Legislative opportunities
  - Food and Drug Administration Safety and Innovation Act of 2012 - Reauthorization of the Prescription Drug User Fee Act
  - Bi-Cameral/Bi-Partisan Congressional Working Group
- Pharmaceutical Security Distribution Alliance
  - Rx-TEC (lot-level tracking) proposal
  - Other commentators Pew Research Center, California, etc.
- Competition between EFPIA and EDQM proposal
  - Resistance from certain parts of industry

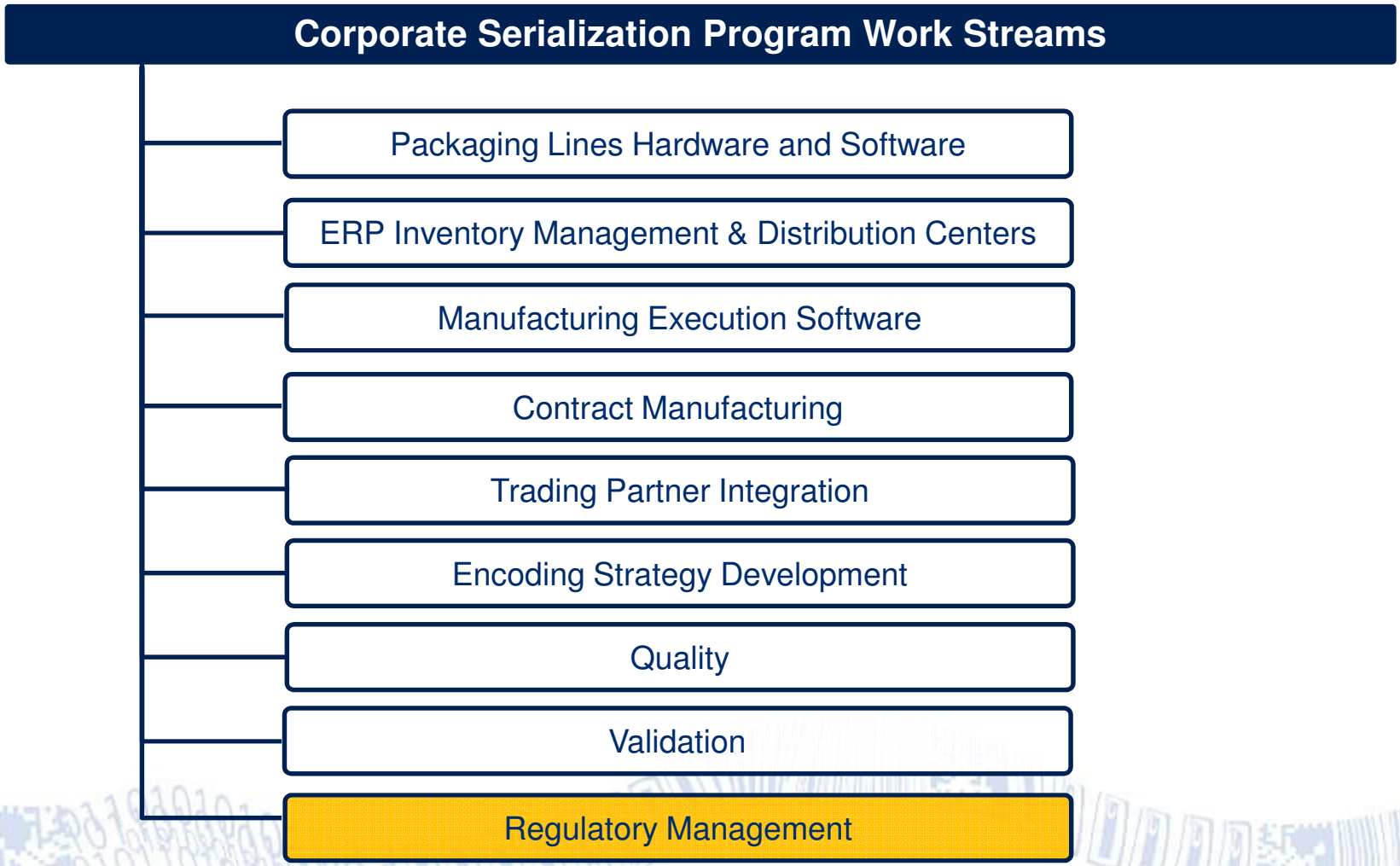
Increased pressure on Management to take a policy position

Supporting Expansion
Now It's Getting Complicated!

- Even an accurate database of requirements has challenges
  - New products
  - New partners
  - New markets
  - Developing requirements
- A database tool cannot account for all the issues
  - Evaluate expansions against corporate plans
  - Determine gaps and issues
  - Opportunities for regulatory change
  - Need for "specialized" solutions

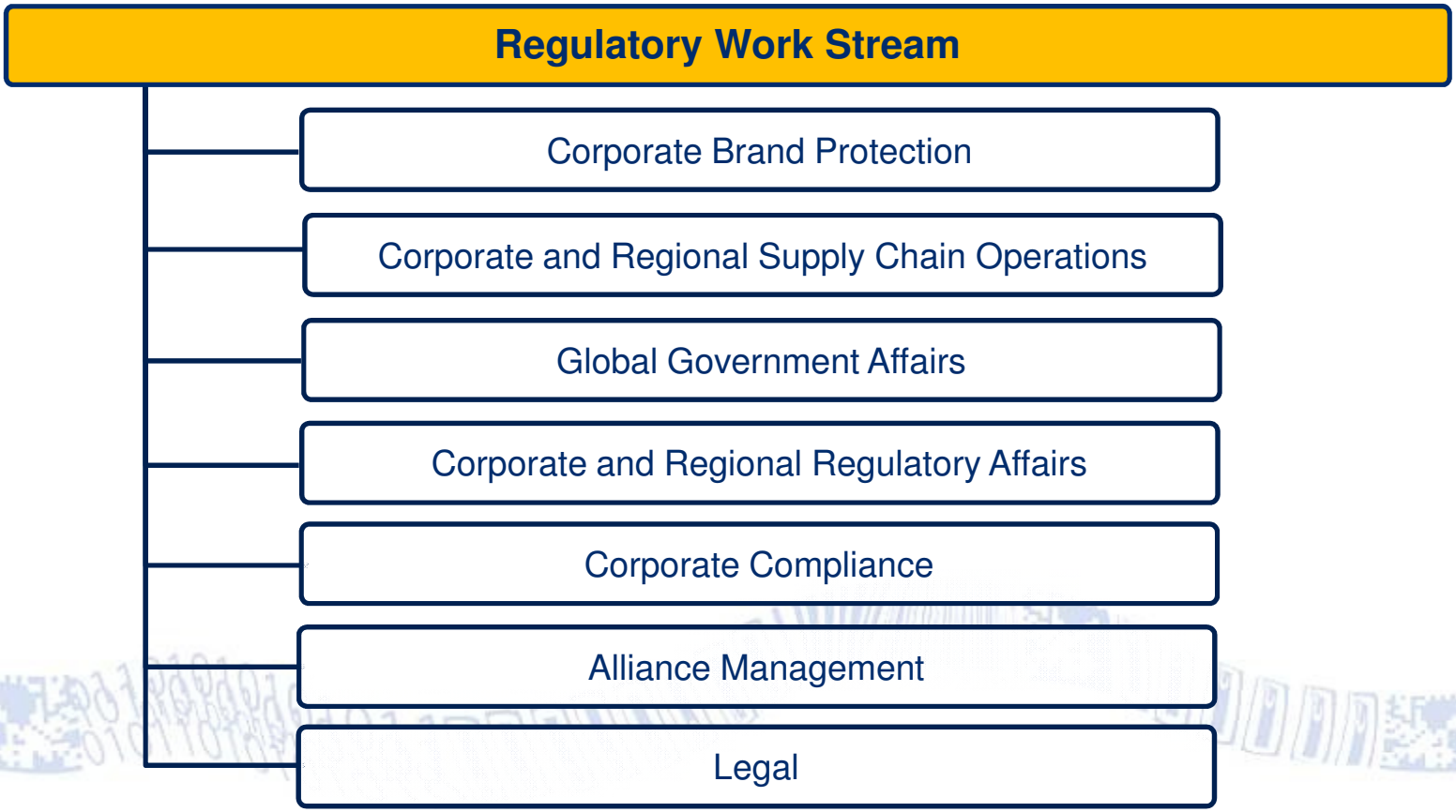
How to define hard requirements in a fluid environment?

This is Well Beyond just Technology

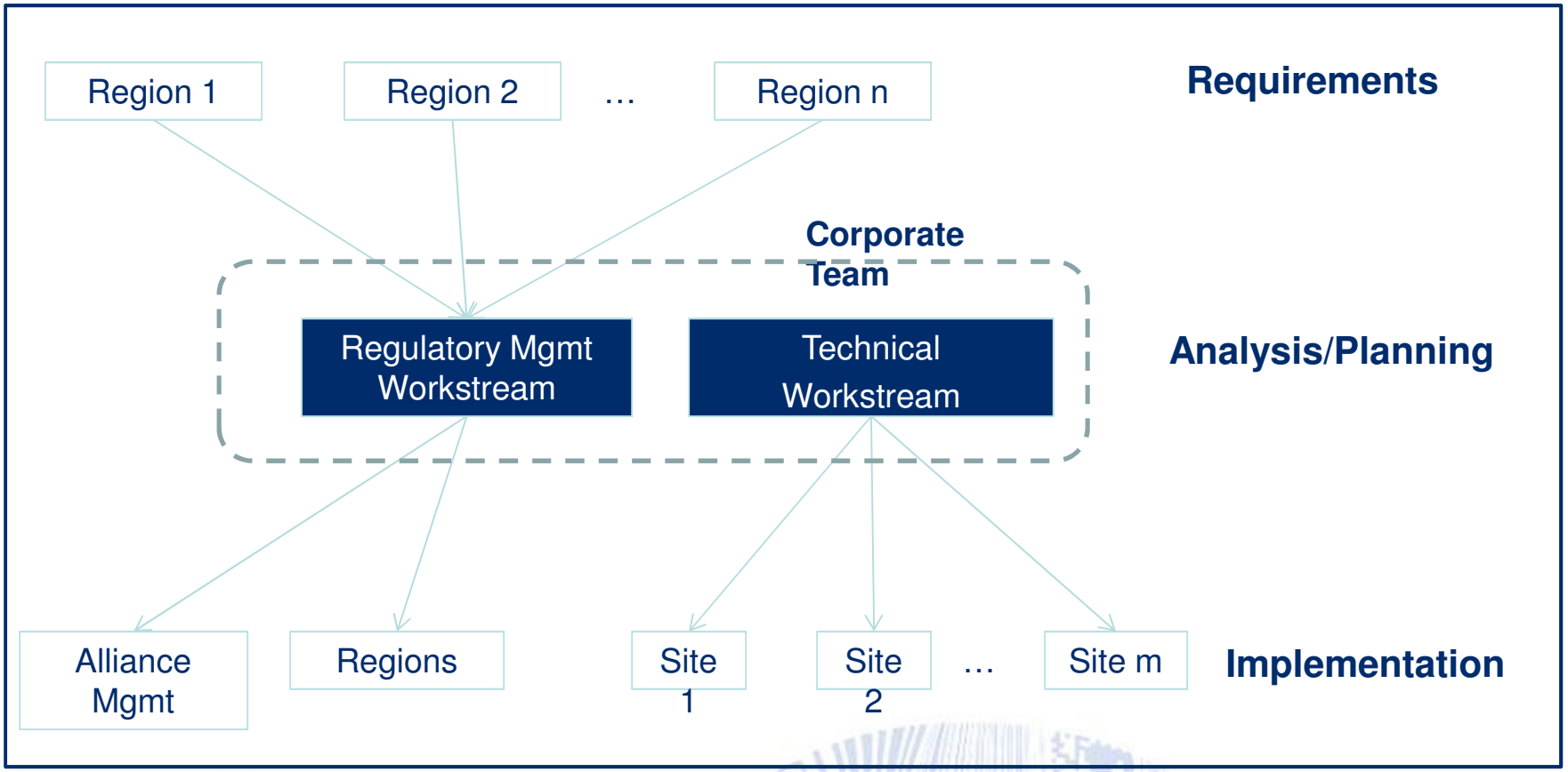


The Regulatory Management Work Stream Assures Global Compliance

- Monitor regulations within Companies expanding footprint
- Analyze for compliance gaps and solutions
- Provide advocacy through industry forums



A Model for Ensuring Global Compliance



Solutions: a balance between requirements, operations and commercial

Questions?

Thanks to GS1 Healthcare

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