Building a Serialization Compliance/Advocacy Management System

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Global Product Protection
Amgen Inc. (April 2013)

About Amgen

- World's leading independent biotechnology company, with a mission to serve patients
  - Amgen medicines have reached more than 25 million patients
  - Presence in more than 50 countries
- More than 30 years of pioneering science and vital medicines
- Focus solely on discovering, developing, and making human therapeutics
  - Specializing in innovative medicines for serious illness
  - Pioneer and world leader in protein therapeutic manufacturing
- Broad and deep pipeline of novel product candidates



Marketed Products

EPOGEN (EPOETIN ALFA) RECOMBINANT
NEUPOGEN (FILGRASTIM)
Aranesp (darbepoetin alfa)
Neulasta (pegfilgrastim)
Enbrel etanercept
Sensipar (cinacalcet) Tablets 30mg·60mg·90mg
FIRST-IN-CLASS Mimpara cinacalcet
Vectibix (panitumumab) Injection for IV Infusion
Nplate romiplostim
prolia (denosumab) injection
XGEVA (denosumab)

For additional information about Amgen products, including important safety information, visit www.amgen.com

Building a Serialization System in a Changing Regulatory Environment

Part 1 Tracking, understanding and complying in an evolving regulatory environment

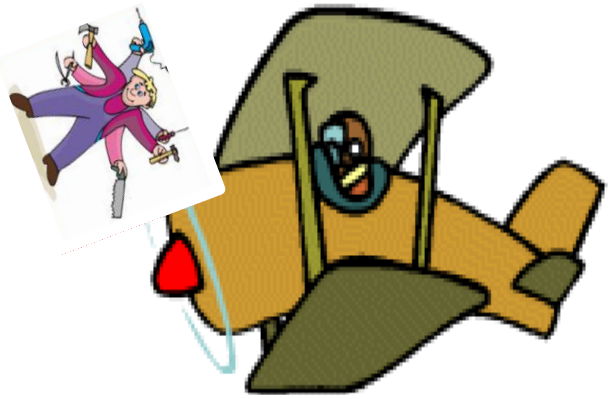
Part 2 Working to influence regulations to promote effective systems

Focus on regulatory issues not on mechanics of serialization

Part 1: Building a Global Serialization Compliance Management System

The Challenge:

- Monitor developing serialization requirements and define compliance solutions, while the company expands globally



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
- 2009, Brazil Casa da Moeda system
- 2010, China Electronic Monitoring of Essential Drugs
- 2011, EU Falsified Medicines Directive
- 2011, Argentina Serialization required by 2012
- 2013, Brazil distributed tracking system

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We have often underestimated the complexity of enabling such a system

Prism of California Implementation This is a Technology Issue, Right?

- Yes,
  - California has defined requirements: Serialization by 2011/15 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 solution”
- But,
  - More there are different systems and timelines
    - Italy, Turkey, China, etc
  - Regulations in formation
    - What do we build for?

We need an enterprise-level solution, but something else, 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 operational requirements going to be compatible with CA?
  - From a product manufacturing/IS perspective—Yes
- We have systems in place for other issues, right?
  - Bollino for Italy, Belgium; 2D Matrix for France

Ok, a Technical Project, with monitoring of requirements

Requirements Continue to Emerge Lining-up Production Capability

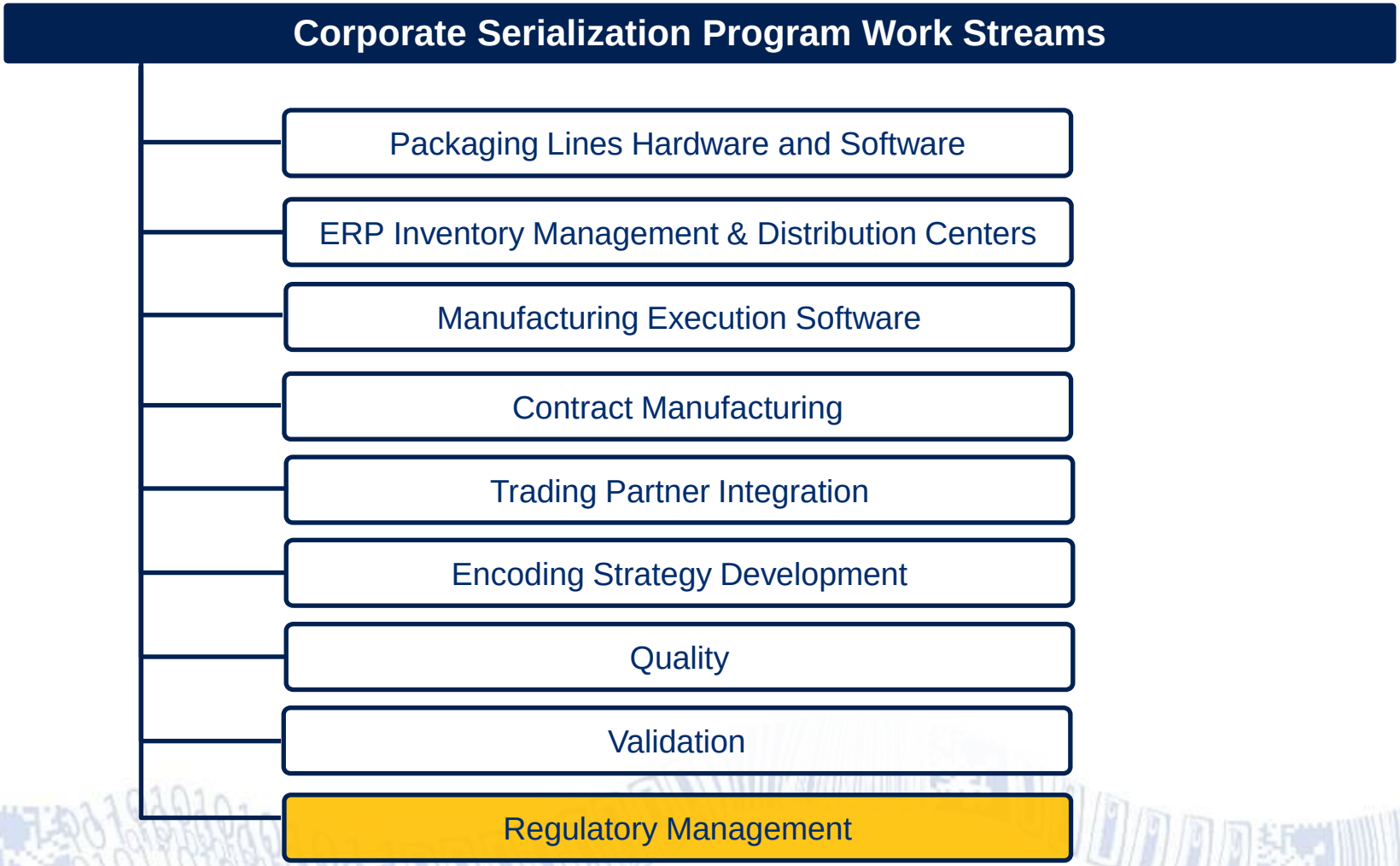
- Emerging/changing requirements
  - Possible legislation by Congress in US—effect on CA planning?
  - EFPIA and EDQM in EU—authentication or track and trace?
  - Additional requirements for China, South Korea, Taiwan, Argentina, India, Brazil, Saudi Arabia
  - Group purchasing organization requests
- Matching production with requirements
  - For each product in each country-production line implementation must meet regulatory timeline
  - Limits on serialization equipment and resources
  - Serialization implementation is just one of many manufacturing requirements
  - Regulatory filings and other compliance requirements too
  - Need to ensure uninterrupted supply of medicine

Be Mindful of Expansion, too

- Need to integrate
  - New products
  - New partners
  - New markets
  - Developing requirements
- A database tool cannot account for all the issues
  - Evaluate expansions against corporate serialization plan
  - Determine gaps and issues
  - Opportunities for regulatory change
  - Need for “specialized” solutions

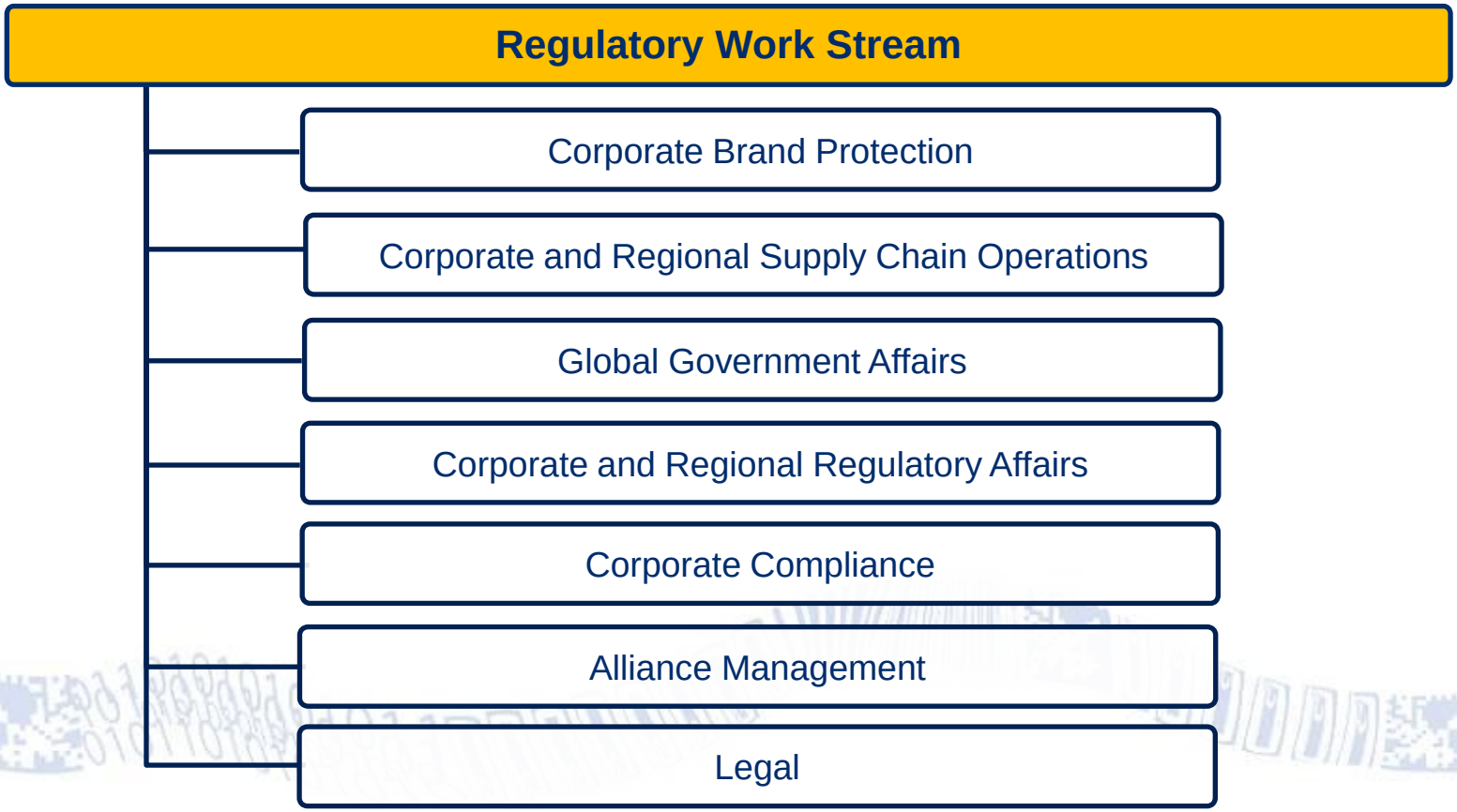
Fitting the pieces together is necessary to assure supply

This is Well Beyond just Technology

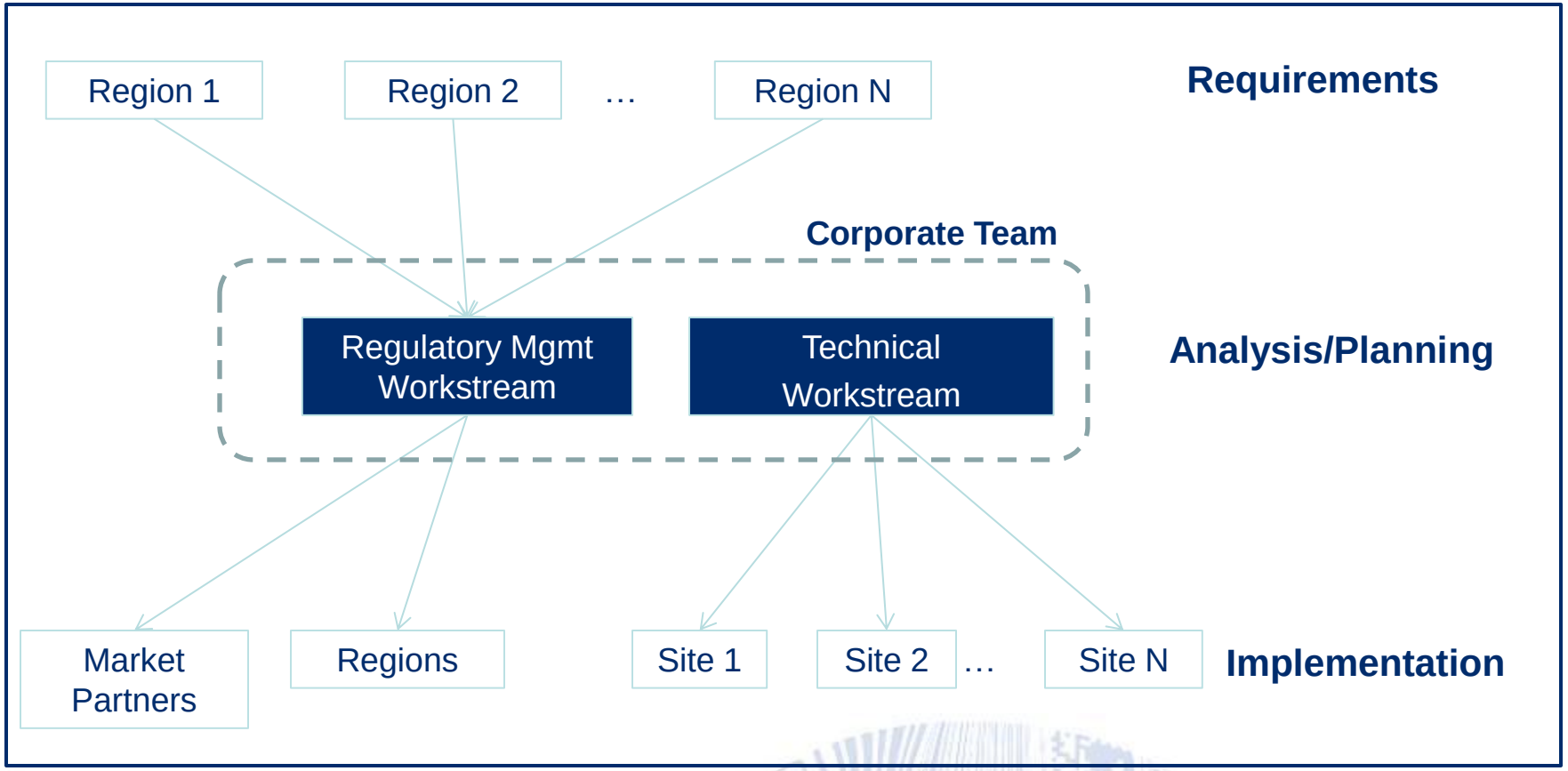


The Regulatory Management Work Stream Assures Global Compliance

- Monitor regulations within Company's expanding footprint
- Analyzes for compliance gaps and solutions
- Provide advocacy through industry forums



A Model for Ensuring Global Compliance



Solution is a balance between requirements, operations and commercial

Part 2: Must Advocate for Realistic, Implementable Requirements

- Support patient safety, criminal enforcement and fraud prevention goals
- Point out the “impossible”
- Drive for manageable interoperability processes
- Adopt timelines compatible with resource and equipment availability
- Avoid requirements that would disrupt the availability of medicines

Pieces must fit in order to land on success

Approaching Effective Dates are Increasing Urgency of Alignment

- Interoperability" (DPMS v. EPCIS) approach
- EFPIA v. EDQM systems
- Non-GS1 system coding
- Excessive duplication in distributed systems
- "Real Time" system response
- Proprietary SMS approaches

Timelines are always an issue of concern

Especially with scarce expertise and equipment

Important for All Stakeholders to Cooperate to Advance Goals

- Regulators-establish achievable, harmonized requirement with broad input
- GS1-establish effective standards as a basis for system design and operations
- Supply chain associations-play active, knowledgeable facilitator role within business and with regulators
- Companies-effective analysis of capabilities, communication of possibilities, and implementation
- Vendors-realistic commitments and cooperation

Idealistic Goals

An iterative process that can lead to real results

An Impressive Example

- Draft Brazil Regulations (progress before our eyes)
  - Rapid communication of requirement and capabilities
  - Engagement of informed industry associations
  - Identification of key requirements
  - Development of sincere approaches as regulatory input
- Iteration continuing in EU and US
- Other opportunities China, Unit Level Marking

We must continue the process to make the leap

Questions?

Thanks to GS1 Healthcare and each of you

Contact Details

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