

Drug Shortage Prevention: A New Model

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Pharmaceutical Industry Association – Puerto Rico
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What will we cover today?

Introduction to the ISPE Drug Shortages Initiative

Evolving drug shortages environment

Regulatory Landscape

Supply & Distribution Resilience

ISPE Drug Shortages Prevention Model

The ISPE Drug Shortages Initiative

SCOPE

Drug shortage prevention opportunities within ISPE areas of expertise

(i.e., technical, quality and regulatory topics)

GOALS

Advance progress in drug shortage prevention through industry guidance and health authority interactions

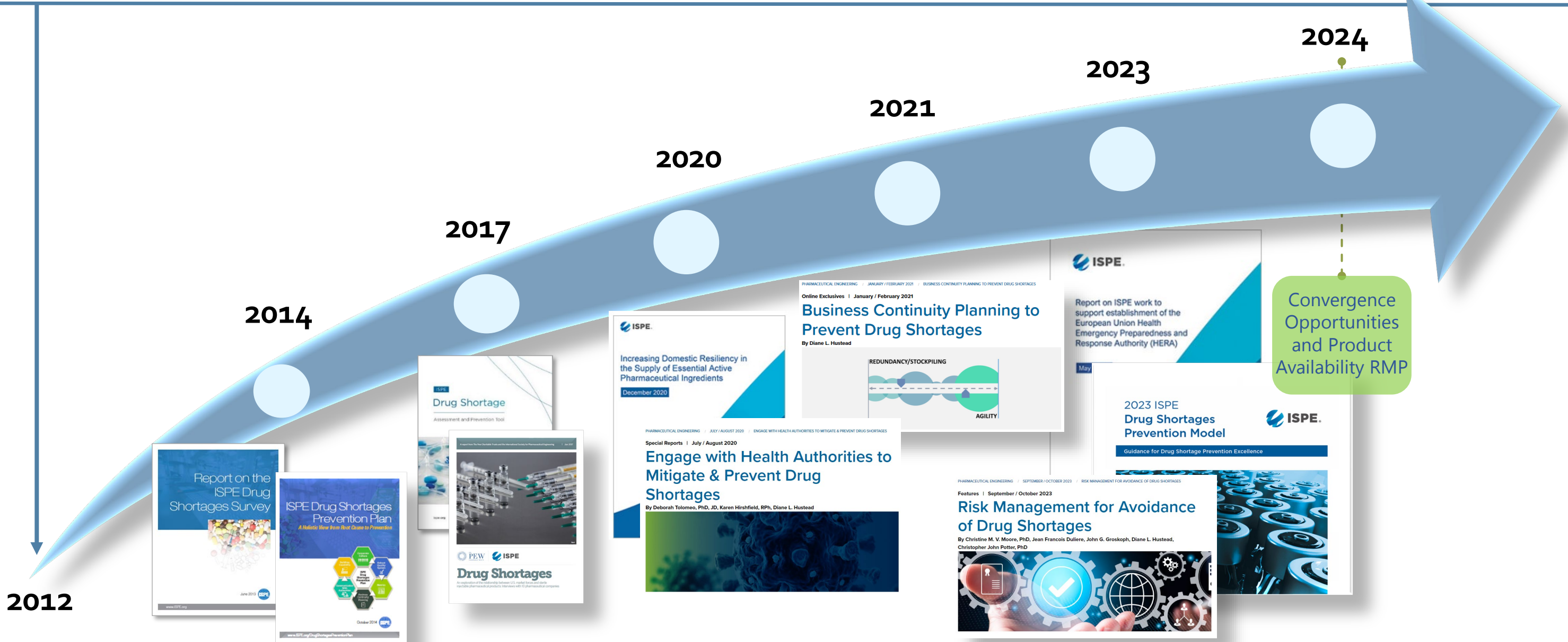
TEAM

- Multidisciplinary
- Passionate
- Global
- Experts

● ● ● global supply chain ● ● complex problem ● ● ●

ISPE Contributions to Drug Shortage Prevention

The longstanding ISPE commitment to drug shortage prevention began in 2012.

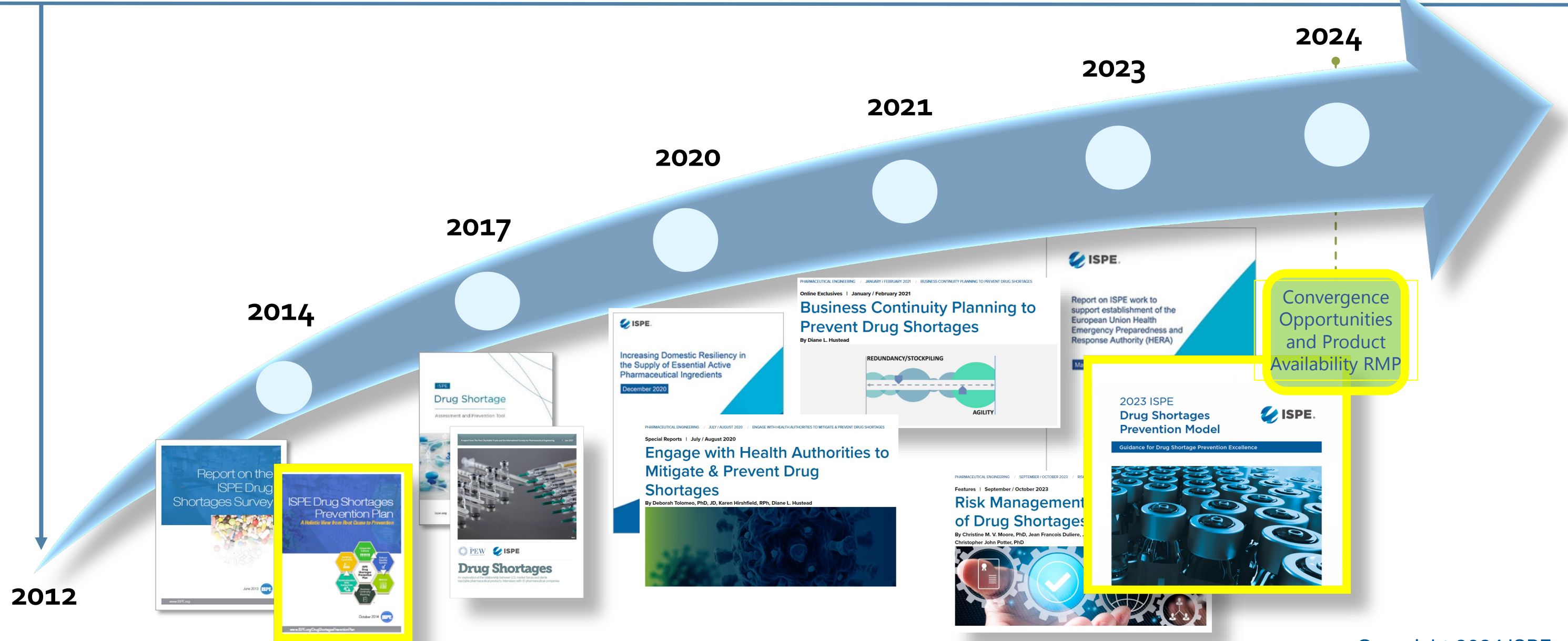


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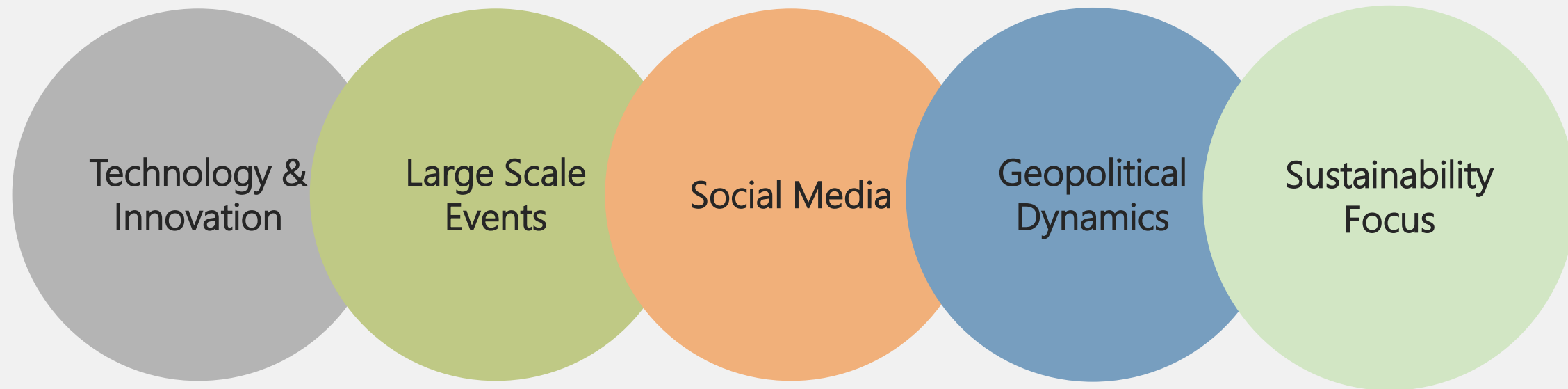
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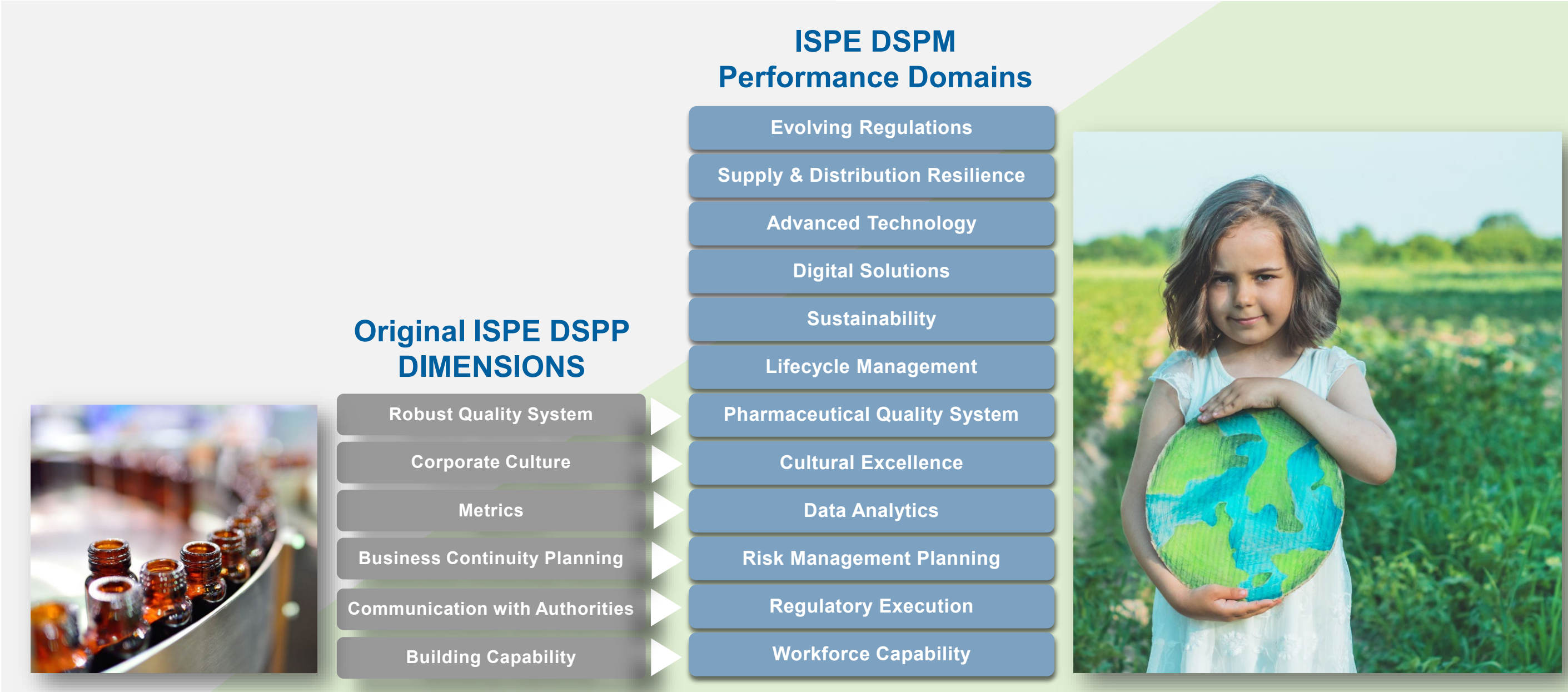
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What has changed?



ISPE Drug Shortages Prevention Model Evolution

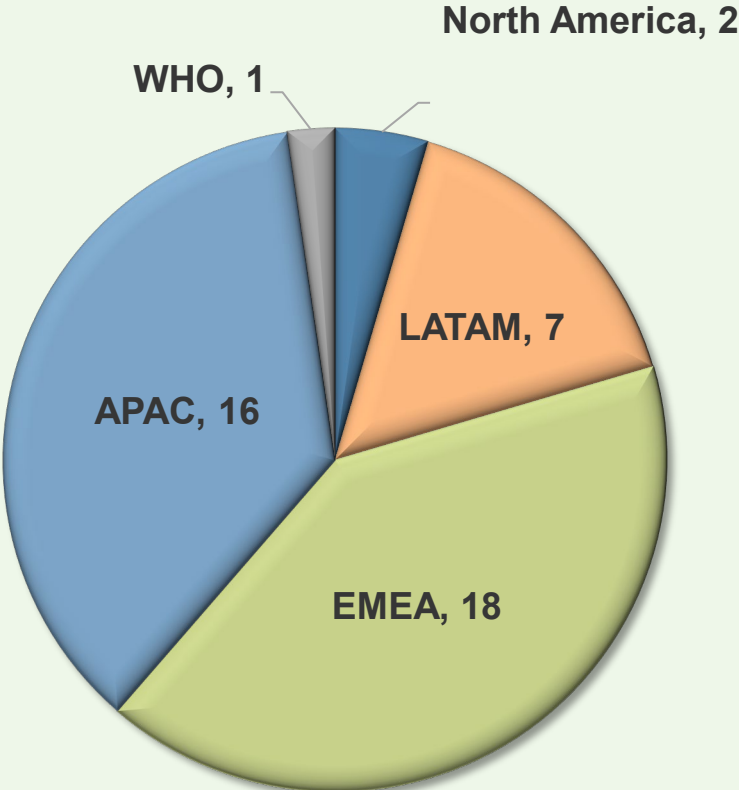


Regulatory Landscape – Global Analysis

Observations

- Few requirements across APAC markets (including China, India)
- Requirements in EU & across NCAs
- Minimal MEA Data (Israel)
- LATAM focus on discontinuation reporting
- Similar reporting timeframes & definitions in North America (US & Canada)

Geographical Overview of Survey Participants



44 Markets

Total Surveyed

~75%

Shortage Reporting
11 Prioritize
22 All Products

~60%

Discontinuation Reporting

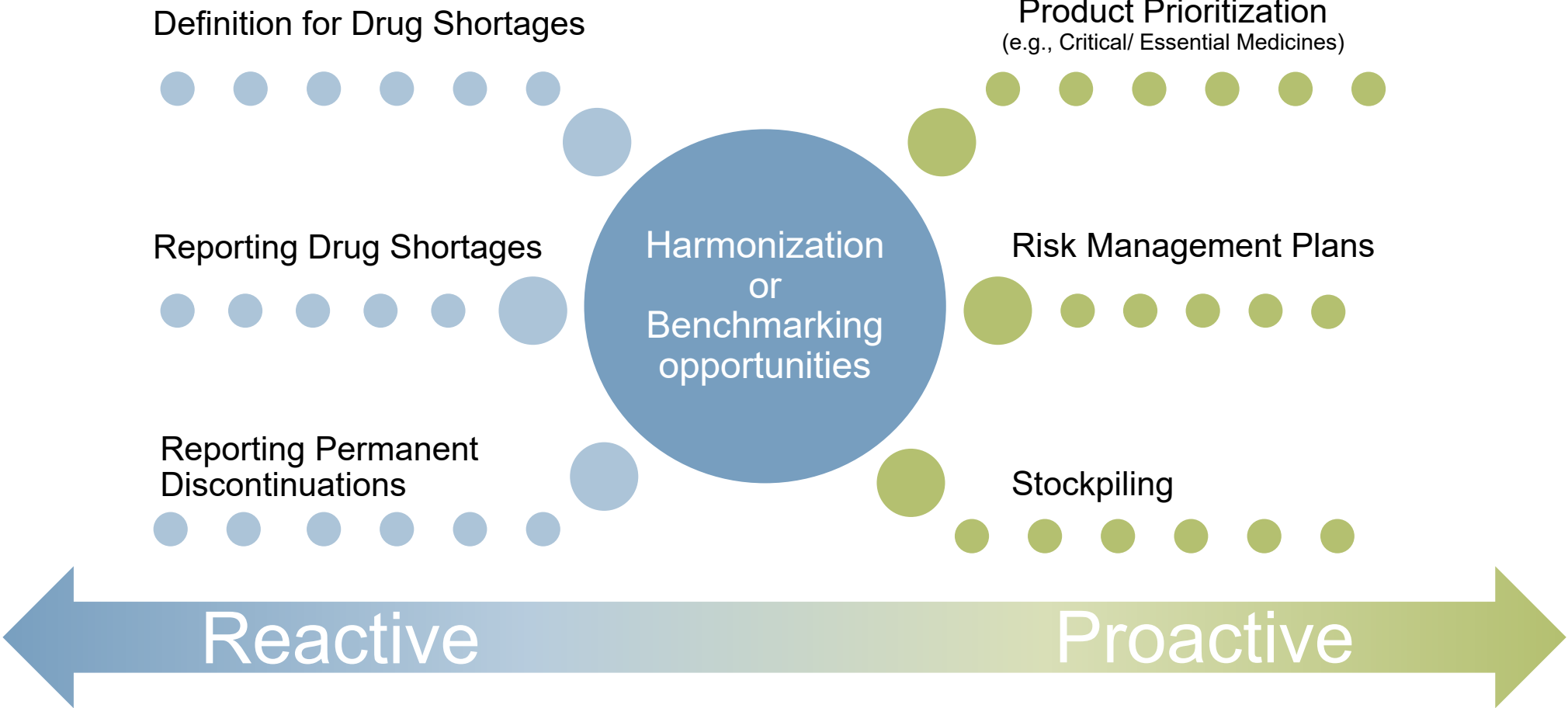
9 Markets

Analyzed regarding
Stockpiling/ Safety Stock

6 Markets

Analyzed regarding
Risk Management Plans

Themes



Conclusions from the Regulatory Landscape Study

Convergence Opportunities Exist

Prioritization is Key to Success

Safety Stock/Stockpiling should be Streamlined and Flexible

Product Availability RMP Practices are in a Transformational Period

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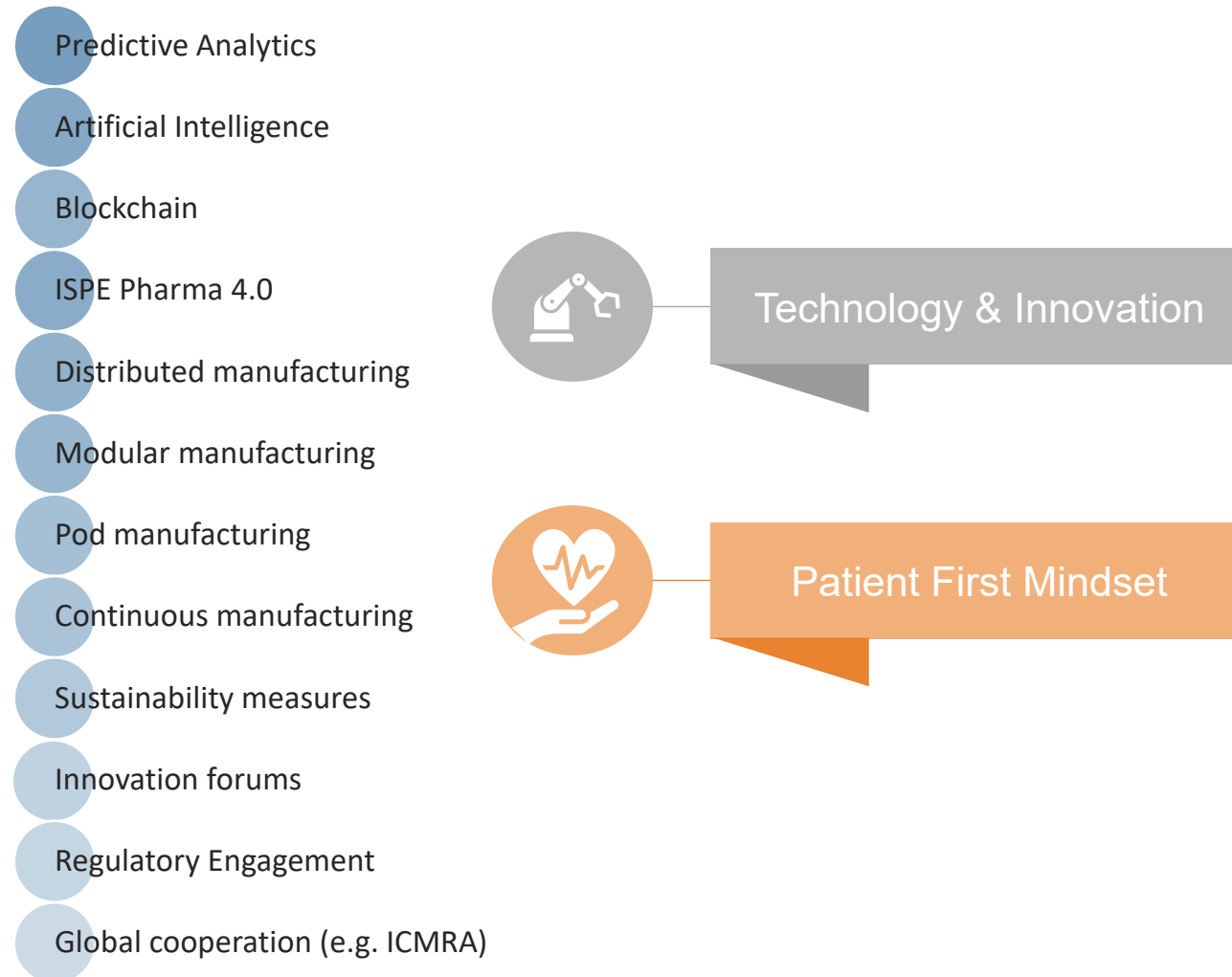
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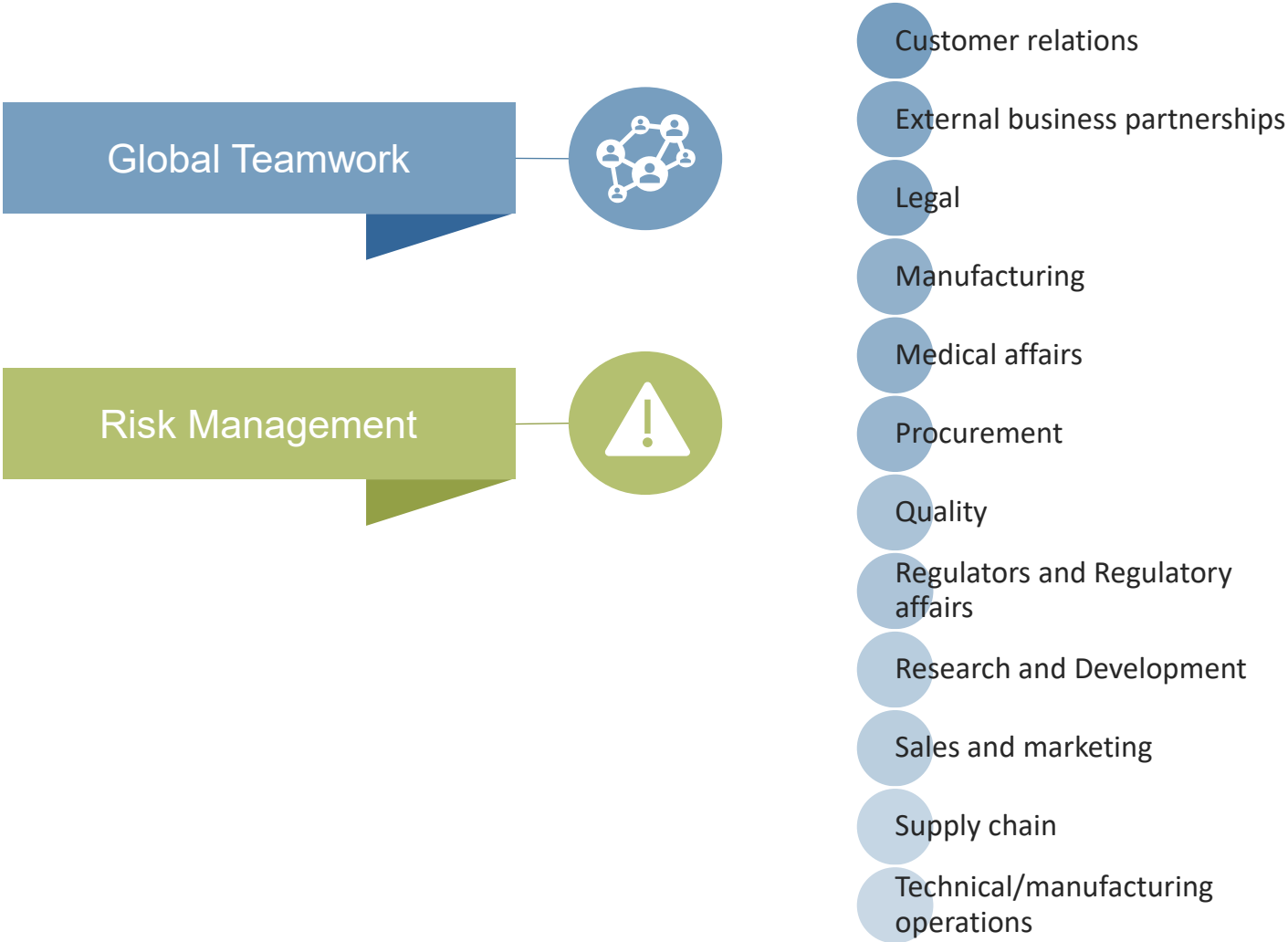
Supply and Distribution Resilience



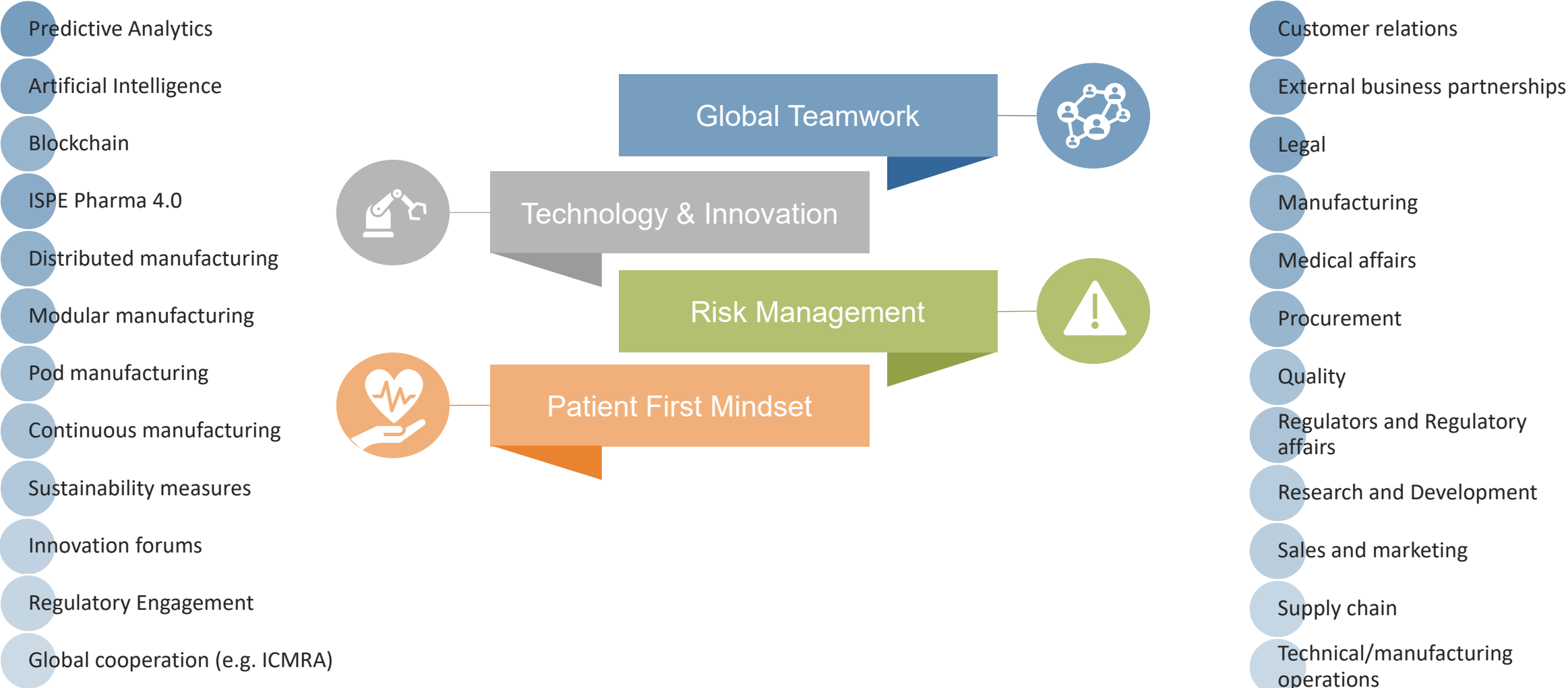
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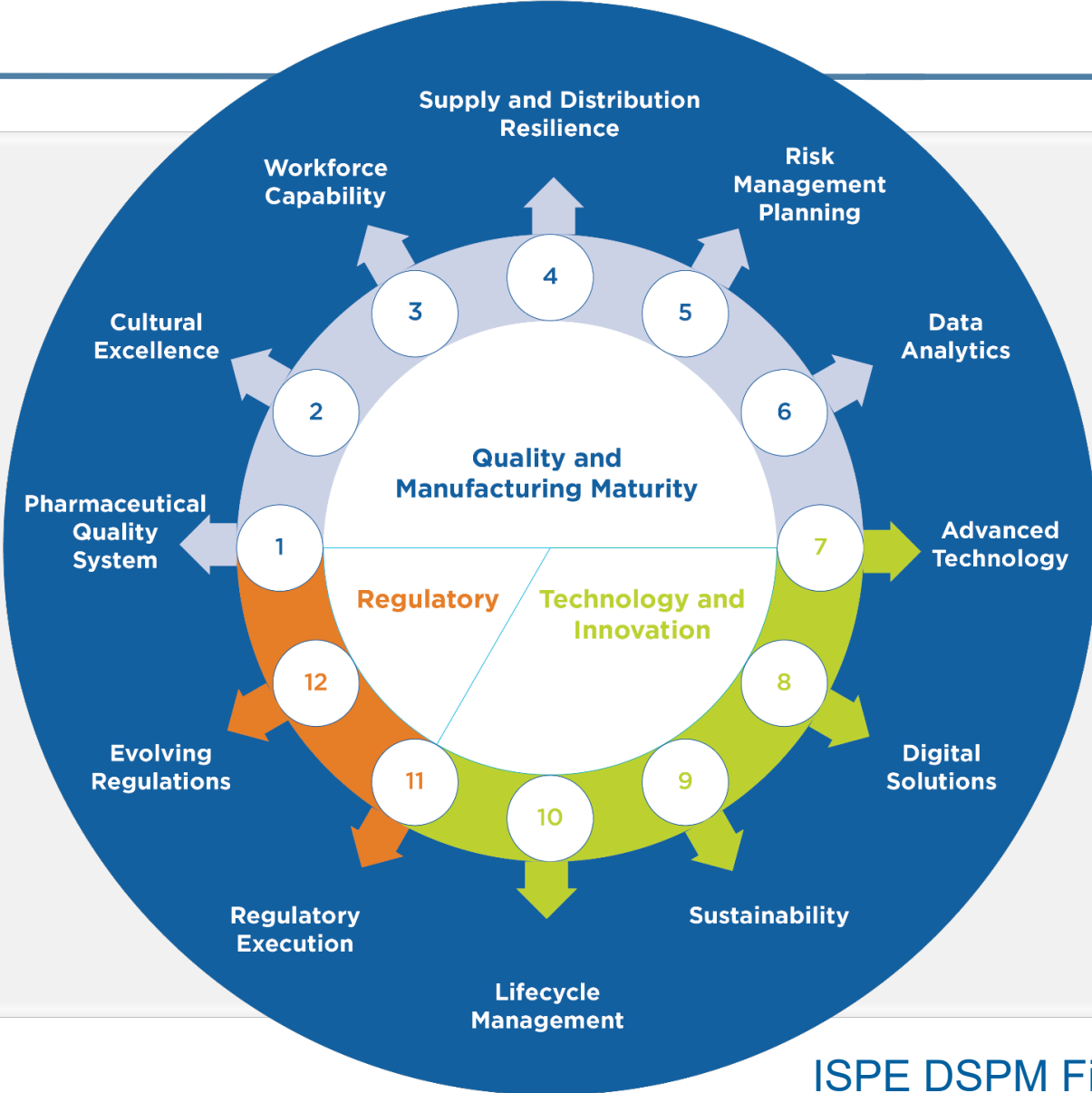
Supply and Distribution Resilience



ISPE Drug Shortages Prevention Model

Guidance for Drug Shortage Prevention Excellence

- ❖ Modernized
- ❖ Global resource
- ❖ Highlights extensive ISPE drug shortage prevention resources
- ❖ Demonstrates the depth and breadth of partnership required for success
- ❖ Illustrates risk management opportunities at organizational, operational, and product-specific levels

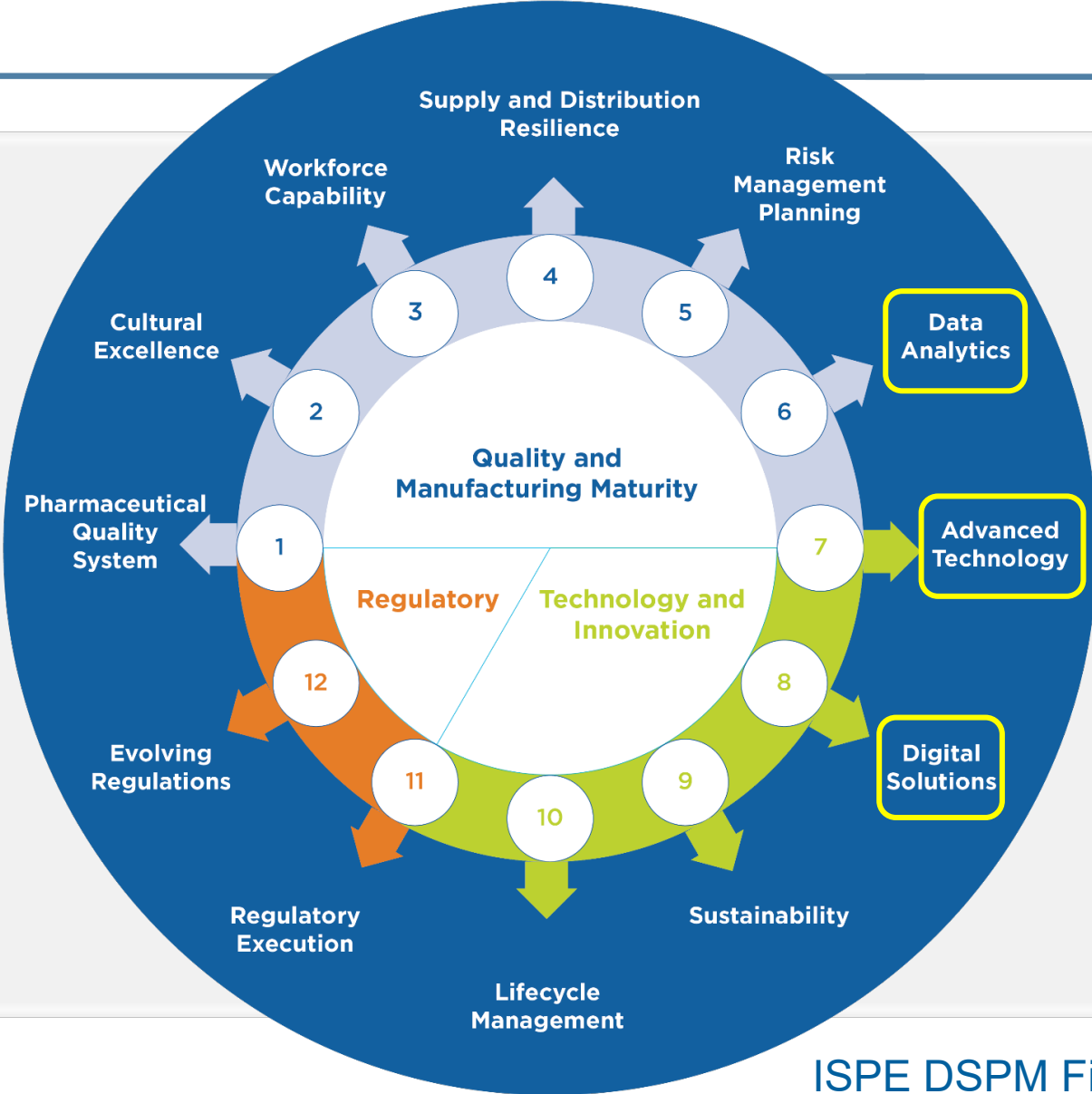


ISPE DSPM Figure 1

ISPE Drug Shortages Prevention Model

Guidance for Drug Shortage Prevention Excellence

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ISPE DSPM Figure 1

Data Analytics: Company-specific data



CAPA Effectiveness



Repeat Deviation Rate



Recall Events



Market Demand Data



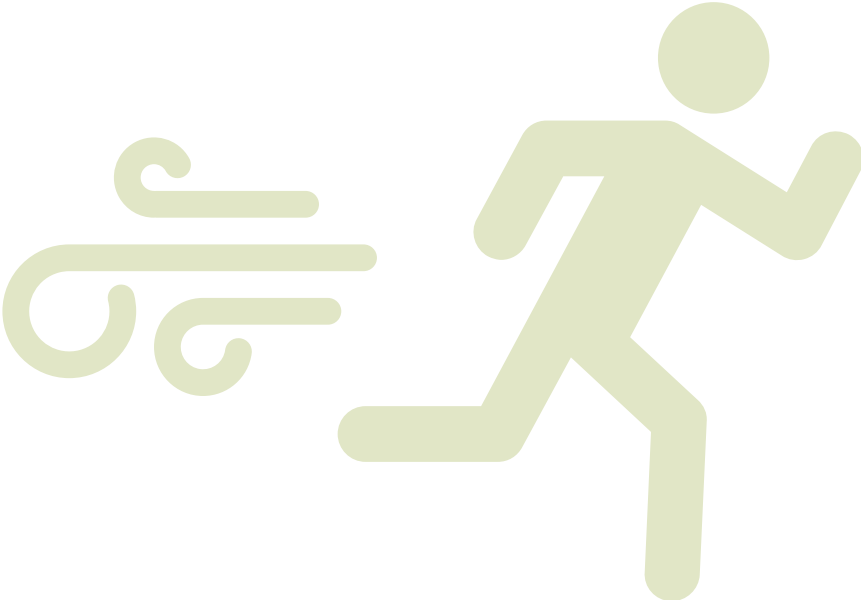
Supply Chain Data

Assess Company-specific data to create best possible outcomes for product availability

Data Analytics: Company-specific data

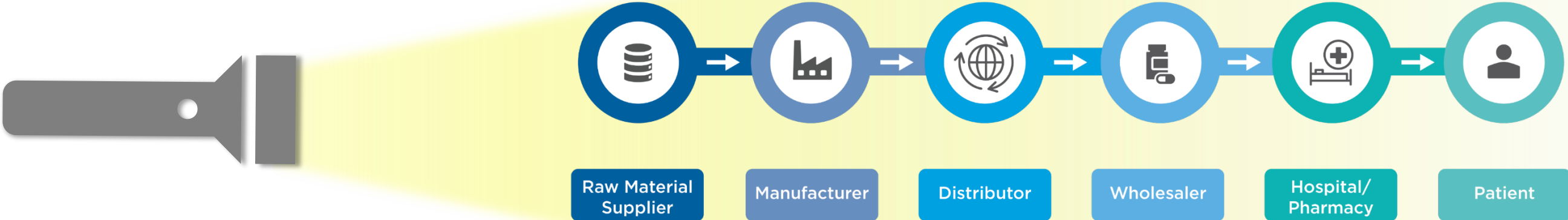
- ✓ CAPA Effectiveness
- ✓ Repeat Deviation Rate
- ✓ Recall Events
- ✓ Market Demand Data
- ✓ Supply Chain Data

Assess Company-specific data to create best possible outcomes for product availability



Data Analytics: Industry-wide data

Many stakeholders are interested in greater transparency of industry-wide supply performance data



Example: [USP Medicine Supply Map](#)

Advanced Technology

Accelerating time to market or return to market



Examples

- ❖ Pod/modular manufacturing
- ❖ Continuous manufacturing
- ❖ New routes for drug substance production

US Example: [Phlow Corporation](#)

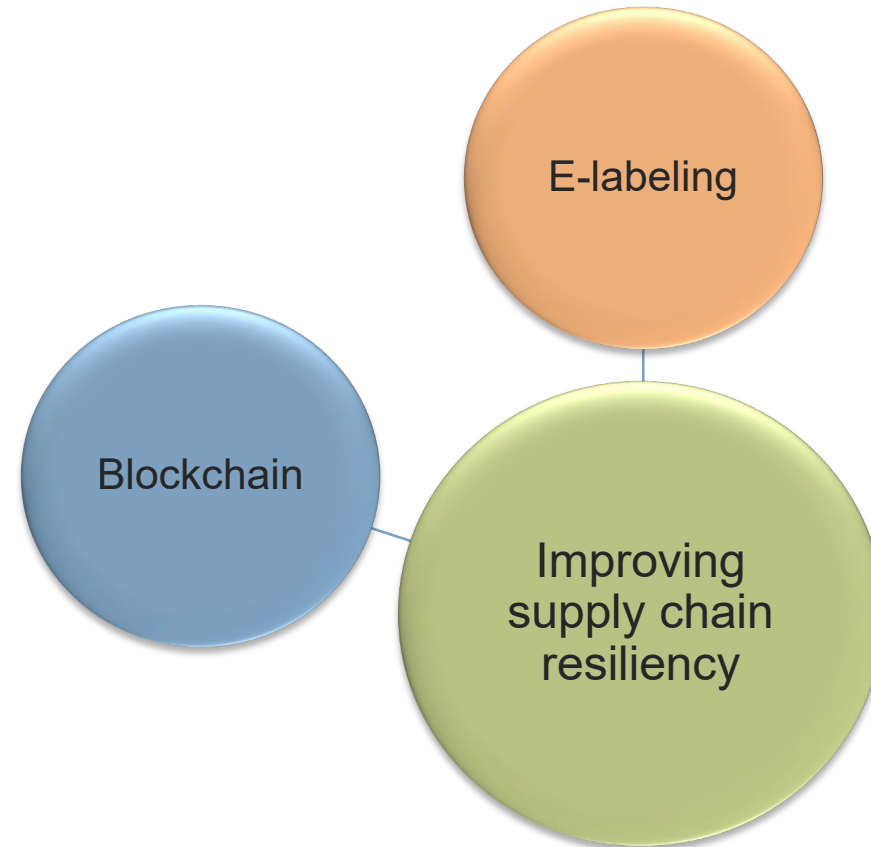
Digital Solutions: Modernizing Resiliency

Adoption of digital solutions in supply resiliency efforts can lead to more efficient and effective operations, better risk management, and improved product availability



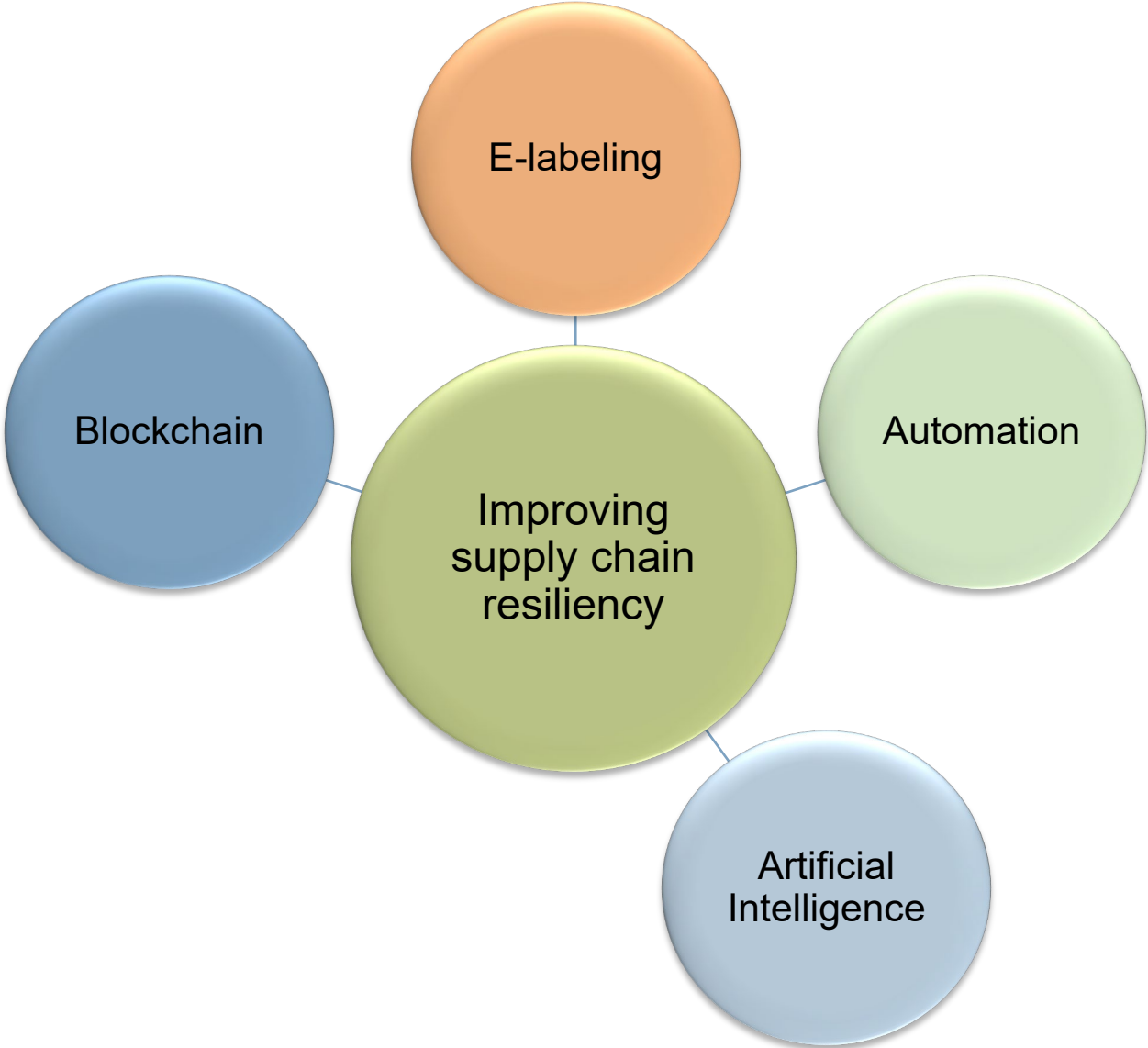
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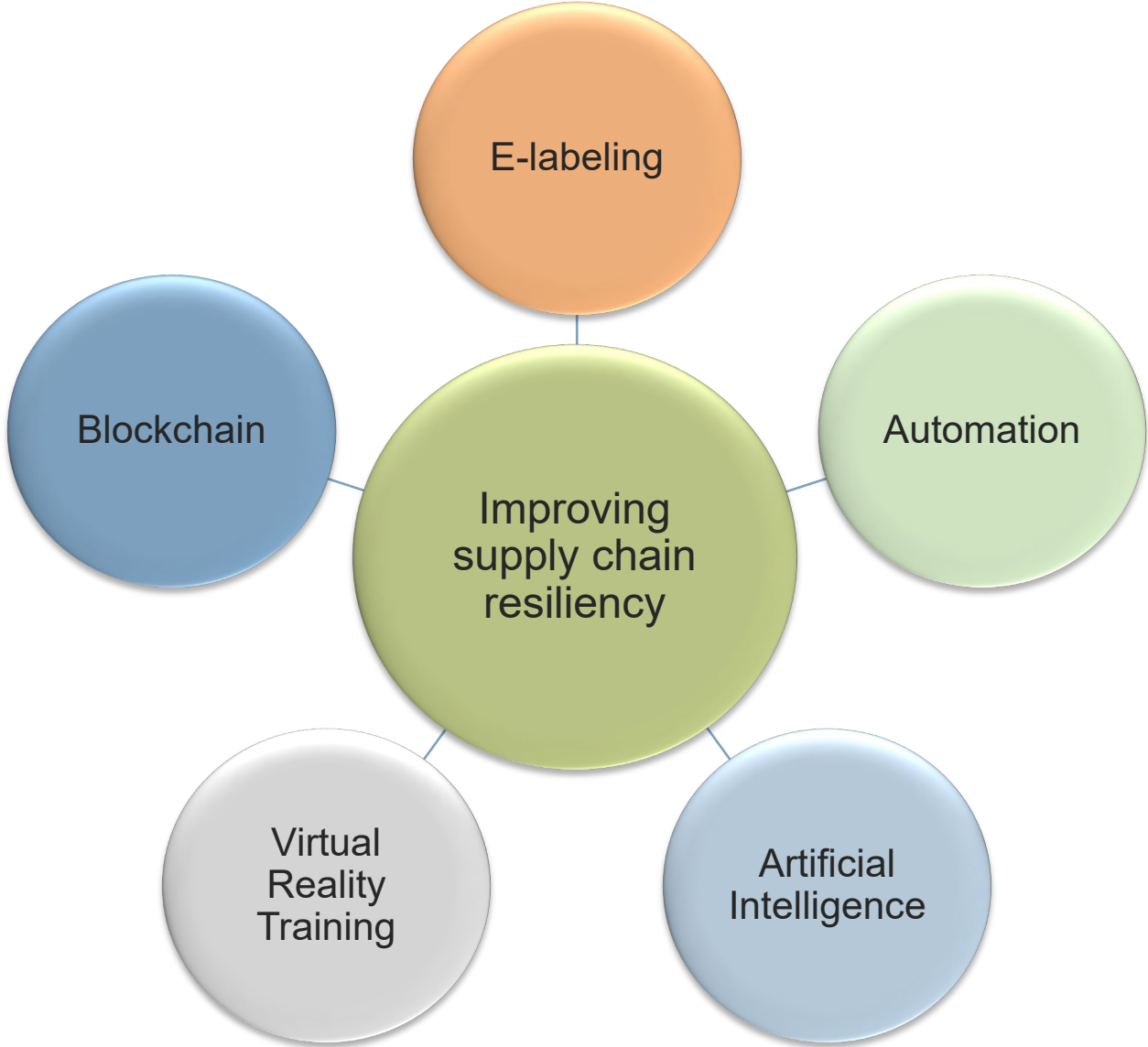
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ISPE Resources:
[GAMP](#) and [Pharma 4.0](#)

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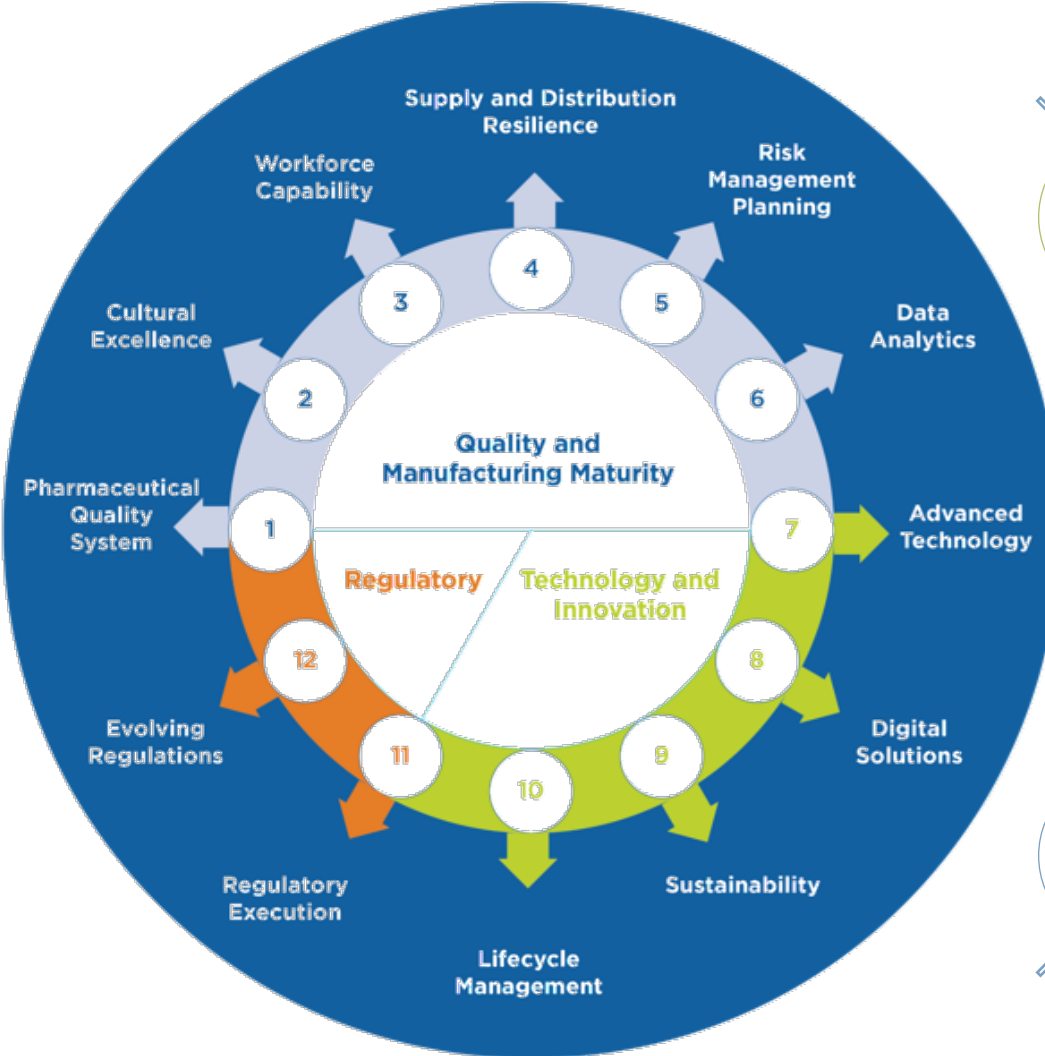
Evolving drug shortages environment

Regulatory Landscape

Supply & Distribution Resilience

ISPE Drug Shortages Prevention Model

How can you help?



- Connect with the ISPE Drug Shortages Initiative Team – [Link for more information](#)
- Follow evolving regulations
- Ask: ‘Can we do better?’
- Utilize ISPE guidance for continual improvement

ISPE Drug shortages initiatives 2024-2025 Priorities

Convergence Opportunities

Product Availability Risk Management
Guidance

Cultural Excellence & Drug Shortage
Prevention

Emerging Leaders Engagement

Continued Support for Regulatory
Landscape (e.g., HERA, Duke Margolis
ReVAMP)

DSPM Assessment and Prevention Tool