


25th Anniversary ISPE Boston Area Chapter Product Show

The Horizon for Pharmaceutical Manufacturing - ISPE is Ready

Joseph C. Famulare, Past Chairman of the Board, ISPE
VP, Global Head Compliance and External Collaborations, Washington, DC
October 5, 2016



Genentech
A Member of the Roche Group

What is New In Washington, DC



I AM

- Republican
- Democrat
- Headed to Happy Hour

JOIN US INSIDE!
MON - FRI
4-7PM



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What is Happening In Your Region

- Massachusetts accounts for 13% of the U.S.-based drug development pipeline. Massachusetts-headquartered companies account for 5.9% of the global pipeline.
- So far in 2016, there have been 7 Massachusetts biotech IPOs.
- The top 4 NIH-funded independent hospitals (and 7 of the top 15) in the U.S. in 2015 are in Boston.
- On an NIH-funding per capita basis, Massachusetts continues to far exceed other leading NIH-recipient states. Only California receives more total NIH funding.
- Since 2007, 9 million square feet of commercial lab space has been added to inventory in Massachusetts.
- Massachusetts-headquartered companies have developed therapies that focus on patient populations of more than 250 million in the U.S. and more than 1.8 billion around the world.

Ref: <http://files.massbio.org/file/2016-MassBio-Industry-Snapshot.pdf>



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The Horizon for Pharmaceutical Manufacturing

- Accelerated Development Programs
- Regulatory Harmonization and Convergence
- Emerging Markets
- Access to Medicines
- Global Supply Chains
- New Treatment Regimes
 - Gene and Cell Therapies
 - Cancer Vaccines
- Drug Shortages
- Data Integrity
- Meeting Multiple Requirements
- CMC Post Approval Changes
- Multiple Inspections from HA's worldwide
- Supply Chain Traceability and Security
- Factories and Processes to deliver medicines efficiently and effectively



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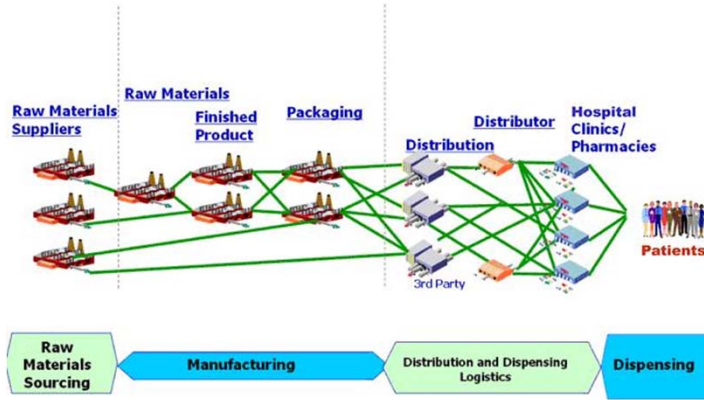
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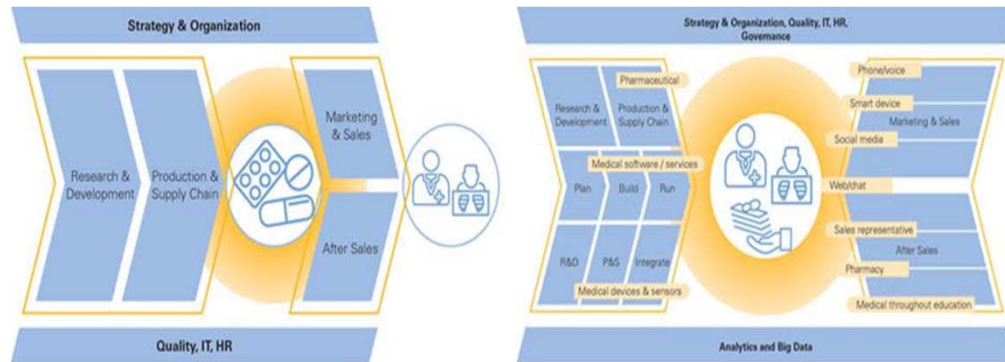
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Supply Chain 101

Pharmaceutical Supply Chain



Pharma's Evolution in Supply Chain



Digital Health: Does Pharma Need To Change Its Business Model To Meet A World's Grip on it?

By Joanne Shorrock

February 24, 2016



Major Initiatives, Programs – Toward Solutions

- RCC - working with regulators worldwide
- PQLI - responding to technical harmonization efforts
- Quality Metrics
- Drug Shortages
- Data Integrity
- Biotechnology
- COPs
- GAMP  ISPE | GAMP
ISPE, the Sponsors of GAMP®
Celebrating 25 Years
- Continuous Manufacturing, Facility of the Future, and more.....



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2016 ISPE in Review

- Continued Leadership in the Drug Shortage Initiative globally
- Quality Metrics Initiative Continues to Lead the Way with Data Driven approaches.



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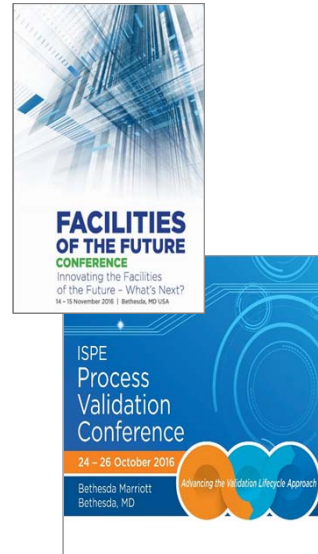
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2016 ISPE in Review

- Facilities of the Future and Continuous Manufacturing
- Product Quality Lifecycle Initiative



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2016 ISPE in Review

- Biotechnology Strategy and
- Continued Regulatory Interaction



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ISPE Achieving Progress

- Engaged Volunteer Leaders
- Local Chapter, Affiliate, and Membership Engagement
- Engaged Leadership from the Board of Directors
- Strong Talented ISPE Staff
- International Presence
- Diversity – Young Professionals, Women in Pharma...
- Engagement with Regulatory Partners
- Patient Focus – The Hallmark of ISPE Culture



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Looking Ahead

ISPE Strategic Plan

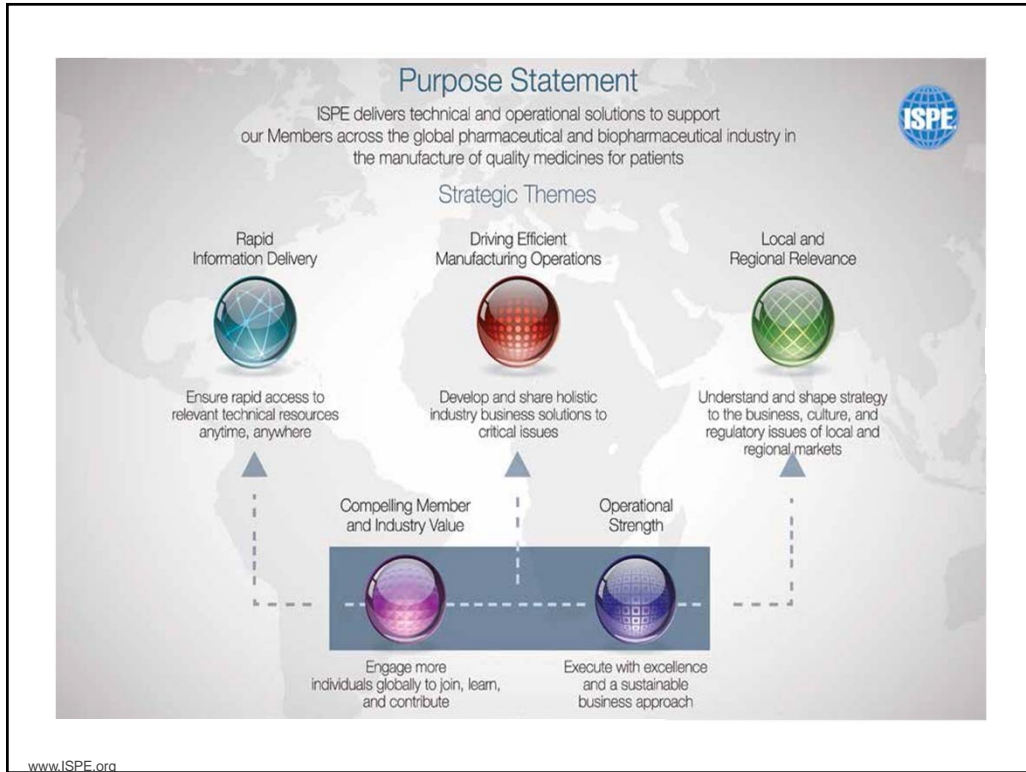


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How Will We Get There?

- Your Input, Your Participation
 - Regulatory Harmonization Convergence
 - “Engineering” Solutions
 - Innovative Approaches
 - Strong Chapter Affiliate Engagement
- How Will It Help
 - Practical training on current topics
 - Being in front of emerging topics
 - Ability to take back



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