



NAVIGATING GROWING PAINS FOR BIOPHARMACEUTICAL COMPANIES EXPERIENCING RAPID GROWTH

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Jeffrey Mackay, Vice President, Facilities, Real Estate and Supply Chain, Foundation Medicine

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ISPE Product Show 2019
Track 2: Innovation in Facility Design

LEARNING OBJECTIVES:

RECOGNIZE PITFALLS DURING TIMES OF (POTENTIAL) EXPLOSIVE GROWTH

OVERVIEW

PRESENTERS' BIO

INDUSTRY GROWTH

GROWTH DRIVERS

STRATEGY DURING UNCERTAINTY

CASE STUDIES AND LESSONS LEARNED

THANK YOU AND SUMMARY

Q & A

Introduction to Presenters



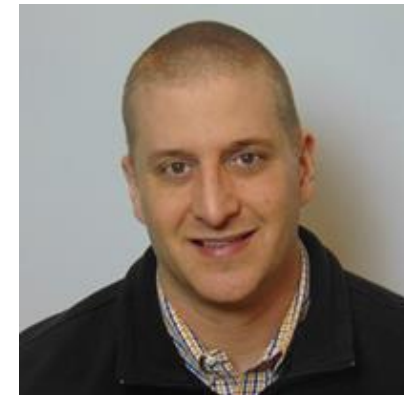
Patrick Gallagher
Moderator, President & CEO,
Hereva Consultants



Charles Pappalardo
Vice President,
Global Operations and Real Estate,
Vertex Pharmaceuticals



Ed Dondero
Director of Real Estate & Planning,
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Jeffrey Mackay
Vice President, Facilities,
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Biopharmaceuticals Industry: a Snapshot

Global Biotech/Biopharma

- 3rd fastest growing industry, growth rate at 7.4% ¹

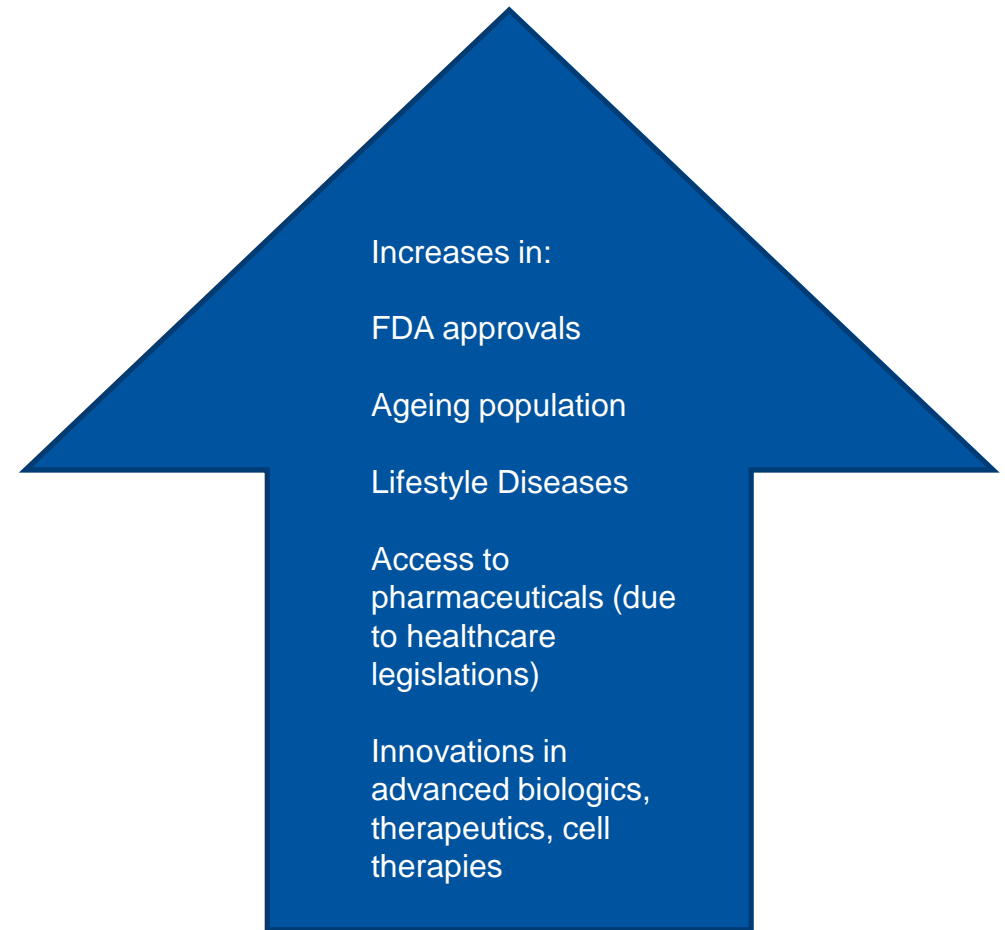
US Biopharma Industry

- Accounts for a third of the global market ²
- U.S. firms conduct over half the world's R&D in pharmaceuticals
\$1.3 trillion in economic output
- \$558 billion in revenue from biopharmaceutical businesses and \$659 billion from suppliers and worker spending.
- One of the world's most supportive domestic environments for the development and commercialization of pharmaceuticals with minimal market barriers
- Attracts the majority of global venture capital investments in start-up biopharmaceutical enterprises

¹ World Finance, <https://www.worldfinance.com/markets/top-5-of-the-fastest-growing-industries-in-the-world>

² Select USA, <https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states>

Growth Drivers



Biopharmaceuticals Industry in Massachusetts

Massachusetts State of Biopharma



Kendall Square 1969 and 2016
Source: MIT Technology Review

Biopharmaceuticals Industry in Massachusetts

Massachusetts State of Biopharma



Seaport 1980 and 2016

Source: Seaport Then image by Bob Dean/The Boston Globe via Getty Images, Seaport Now image by David L. Ryan/The Boston Globe via Getty Images

Biopharmaceuticals Industry in Massachusetts

Massachusetts State of Biopharma

- Top pharma hub in US
- 100+ pharma companies in Cambridge
- Pharma jobs grew 28% over 10 years ³
- Commercial lab space:
 - 2009 = 17 M sf
 - 2018 = 29 M sf
 - 71% Increase in past 10 years



Biopharmaceutical Sector's Contribution to Massachusetts's Economy



ECONOMIC OUTPUT

\$79.2B

Total Value of Goods and Services Supported by Biopharmaceutical Sector



EMPLOYEE PRODUCTIVITY

\$567,003

Per Employee in Direct Biopharmaceutical Sector Jobs

vs

\$178,739

Per Employee Across All Massachusetts Job Sectors



REVENUE GENERATED

\$6.2B

Total State and Federal Taxes Paid



AVERAGE COMPENSATION

\$156,027

Per Employee in Direct Jobs in the Biopharmaceutical Sector

vs

\$71,883

Per Employee Across All Massachusetts Jobs

[PhRMA.org/Economic-Impact](https://phrma.org/Economic-Impact)

³ [2018 Industry Snapshot, MassBio](#)

The Growth Drivers

Q: In your experience, what are the most common drivers for facilities expansion?

- FDA Approvals
- Time to Market: Demand for commercialization
- Product Demand
- Innovations in R & D
- VC Industry – Domestic and Foreign
- Acquisition and Mergers



Strategy During Uncertainty

Discussion Outline

Navigate Pendulum Swings

Operating Through Expansions

Compliance Issues

Institute Changes in Maturing Company

Strategy During Uncertainty

Navigate Pendulum Swings

- Funding Changes
- Master Plan vs Business Plan
 - Real Estate Needs and Capital
 - Info exchange between silos
- FDA Approvals
- Manufacturing
- Risks
- Technology Changes

"DO WHAT YOU FEEL IN
YOUR HEART TO BE RIGHT
- FOR YOU'LL BE
CRITICIZED ANYWAY.
YOU'LL BE DAMNED IF YOU
DO, AND DAMNED IF YOU
DON'T."

ELEANOR ROOSEVELT

Strategy Under Uncertainty

Navigate Pendulum Swings

Operating Through Expansions

- Resource control
- Inventory AND PROCUREMENT/CONTRACTS
- Compliance
- Keep Users happy (TALENT RETENTION)
- NO disruptions to daily operations



Strategy Under Uncertainty

Navigate Pendulum Swings
Operating Through Expansions

Compliance Issues:

- Risks
- Planning
- Prioritizing



Strategy Under Uncertainty

Navigate Pendulum Swings

Operate Through Expansions

Compliance Issues

Institute Changes in Maturing Company:

- Culture
- SOPs
- Operational Procedures



"Our competitor has increased production rates and revenue by 40% by installing state-of-the-art control systems and adding global distribution."

Case Studies & Lessons Learned

In Process Case Study

Charles Pappalardo

Managing through accelerated organic growth coupled with fast tracked Business Development activity

- Long range planning informs asset needs requirements but are uncertain
- Fast paced business development activity and new business bolt-ons make the challenge greater
- New asset/facility lead time of plus 24 months increases the complexity of the puzzle
- Breaking work place paradigms eliminating offices and moving to open space concepts
- Building GXP space for technology that has not yet been developed....
- Assembling a plan to solve for the above in the midst of leadership change

Strategy to Solve

Charles Pappalardo

- *Balanced approach to meeting each need*
- *Design for scalability, flexibility and most importantly, optionality*
- *Promote the concept of “reasonable accommodations”*
- *Use the reality Cambridge/Boston Lab market to drive less conservative decisions*
- *Incorporate detailed contingency plans around GXP work activity*
- *Ensure integrated and well balanced project teams – from the get go!*

Case Study

Ed Dondero

- ***Align real estate goals with new corporate vision***
 - *Establishment of new company strategic goals*
 - *Plan for the multiple new products with a 24 month period*
 - *New CEO and HR and R&D heads*
- ***Background***
 - Biogen had recently moved its corporate headquarters and most G&A functions to Weston, however, in 2010 it was about to embark on its most dynamic period in the company's 25 year history. A new management team was hired to meet the need of potentially launching five new products in a span of 24 months and change the culture of Biogen. All established norms were evaluated including organizational structure, how products are developed and lastly how people work.

Case Study

Ed Dondero

- ***What are we solving for:***

- To meet the demand for the five new products the MA based office headcount would grow from 1,500 to 2,000 over five years – Real Estate
- Would the existing workplace setting align with the image Biogen wants to portray and the way people will work in the future – Space Planning

- ***Real Estate***

- Remain in existing buildings in Cambridge and Weston and add an additional 150,000 SF at either location
- Consolidate all office and lab based functions in Cambridge
- Move all operations to a new site, e.g. Assemble Row – Somerville

- ***Workplace Setting***

- Conversion of existing office standard (150 SF offices on outside walls and 8x8 high walled workstations) to total open office plan

Case Study

Jeff Mackay

- ***How to manage extreme growth in a company without a mature REFM Function***
 - *2X growth in 18 months, 4x growth in 4 years*
- ***Managing the expectations and risks for a short, medium and long-term strategy***
- **“Threading a Needle” on Real Estate decisions in an unfavorable market**
 - Minimize long-term lease obligations
 - Minimize capital investment
 - Minimize geographic footprint
- *Implementing alternative workplace solutions in a company trying to attract talent*
- *Mitigating Risk to core business operations in sub-optimal facilities*

Lessons Learned

Jeff Mackay

- ***Understand your organizations appetite and preconceived notions about changing the work environment***
- ***Design space for flexibility***
 - *Rapid changes in business can make inflexible workplaces obsolete before they are even completed*
 - *Plan for what you could do; not what you know you will do*
- ***Educate C-Suite on the complexity and timelines for securing and brining new space on-line***
 - *Options with pro's, con's, timelines, budget and risk*
- ***Never stop the planning process***
- ***In some cases even the most well thought out plans can't satisfy the changing business requirements***
- ***Accept that in many cases you will have to accept the best of bad options***

Presenters Bios



Patrick Gallagher,
President & CEO,
Hereva Consultants

Founder and CEO of Hereva Consultants, Patrick is a seasoned professional with over 25 years of experience in the construction industry. Primarily working in the research and technology sectors, he has spent the past 18 years specializing in client representation and project management services, focusing on the Biotechnology sector. Patrick understands the requirements of facilities services, the importance of maintaining operations, fast response and internal customer service balanced with company policy – all while keeping the client's financial goals and corporate values at the forefront.

Education: Bachelors of Science (Hons) — Cost Management of Building Engineering Services, UK; BTec Higher National Diploma – Building Engineering Services (Commercial), UK; BTec National Diploma – Building Engineering Services (Commercial), UK



Charles Pappalardo
VP, Global Operations
& Real Estate,
Vertex Pharmaceuticals

Chuck maintains over 25 years of experience within the science and technology sector being immediately involved in global real estate, large scale capital projects, facilities engineering and management, global environment, health and safety, corporate security and related technical and operational support functions. He possesses extensive knowledge in developing science and technology facilities from the ground up having been involved in all stages of the process: developing and managing successful project teams in the planning, construction, delivery and validation of multiple large scale facilities worldwide. Chuck's current responsibilities at Vertex include oversight over the company's facility global assets including Planning, Construction, Operations, Security, EHS, Business Continuity and Real Estate. Chuck is a member in the International Society of Pharmaceutical Engineers (ISPE), International Facilities Managers Association (IFMA) and CORNET.

Chuck is a graduate of both Norwich University and Umass Lowell obtaining both undergraduate and graduate degrees in Engineering Technology and Environmental Science. Chairman, Seaport Transportation Management Association

Presenters Bios



Ed Dondero,
Director of Real Estate
& Planning, Biogen

Ed has had over thirty years of experience in the biomedical field while also working for Tufts University and Shire Pharmaceuticals. His responsibilities have included the management of small and large lab, office and manufacturing projects, energy management and the supervision of an operation and maintenance staff. Presently his duties are the oversight and administration of global real estate and master space planning functions.

Education: BS in Construction Management from Wentworth Institute of Technology and an MBA from Bentley College



Jeffrey Mackay, MBA, FMP
Vice President, Facilities,
Real Estate and Supply Chain,
Foundation Medicine

Jeff is the Vice President of Facilities, Real Estate and Supply Chain at Foundation Medicine. In this capacity, Jeff is responsible for real estate, facilities management, lab asset management, security, and EH&S at all of FMI's facilities in MA, CA, NC and Germany. Additionally, Jeff is responsible for FMI's global supply chain. Prior to Foundation Medicine, Jeff served as the Senior Director of Global Operations at Vertex Pharmaceuticals. Previous roles also includes consulting for Real Estate and FM functions across the Pharmaceutical, Healthcare and Higher Education sectors. His clients included Johnson and Johnson, Genentech, Kaiser Permanente and Unilever. Jeff has also held leadership roles in FM and Real Estate for Pfizer, Medtronic and AIG.

Jeff holds a B.A from Brandeis University and an MBA from Suffolk University. He has earned the Facilities Management Professional designation from IFMA as well as a Six Sigma Greenbelt

Ed Dondero,
Director of Real Estate
& Planning, Biogen

Q & A