



THE MASSACHUSETTS CRO CMO CLUSTER

Accelerating Drug Development

A One Day Symposium Presented by Massachusetts Biotechnology Council's
Massachusetts CRO CMO Committee

The Conference Center at Bentley University LaCava Conference Center

March 6, 2012 7:30 AM – 4:00 PM

INTRODUCTION

Time to market has always been and will always be a critical element in the success of biotechnology companies. In this new era of heightened regulatory scrutiny, limited funding sources, and the development of new and innovative business models, the traditional process for developing and commercializing new therapeutics continues to evolve. The trend to leverage internal resources by augmenting them with outsourced scientific, technical and manufacturing assets continue to grow. As a more virtual business model or firms building less full service laboratories has become more of the rule rather than the exception, the industry has responded with a growing community of Contract Research and Manufacturing Organizations. Outsourcing allows companies to acquire highly specialized expertise and manufacturing assets only when they need it. This spreads the total cost amongst a larger number of firms without each one individually carrying the associated fixed costs and overhead required by supporting these capabilities in house. Outsourcing opportunities now are available from contract research, through clinical trial management and into full commercial production. Early adopters have tested and developed a set of Best Practices optimizing each process that will be discussed at the conference.

Massachusetts has become a center of excellence for innovation in drug development. Prolonged development costs are pushing investors to build less and push their portfolio companies to outsource more to increase productivity. Many entrepreneurs are exploring the virtual business model as an alternative strategy for building a biotech startup. Massachusetts is thus benefiting from increasing numbers of biotech firms that are moving to the bay state because they have found, in fact, a full range of high quality technical service companies. Collaborations and the associated business arrangements being created between the members of these two sectors of the community are profound. The Massachusetts CRO/CMO Committee of the Massachusetts Biotechnology Council has organized this program to share the success of these relationships. Several therapeutic and diagnostic companies and their partnering CRO/CMO's will share their experiences on how together, they are leveraging their internal resources by outsourcing every aspect of a therapeutics development from discovery services all the way through commercial manufacturing.

The Massachusetts CRO/CMO cluster is unrivaled anywhere in the USA or the world. No other life science center cluster boasts such a plethora of technical service providers. The Massachusetts CRO/CMO community has become a leading source of employment and is playing a major part in developing new pharmaceuticals across a broad range of therapeutic classes. Ease of access, operational efficiency and the unmatched level of technical expertise has many companies selecting the Massachusetts cluster versus sending work overseas. The Massachusetts CRO/CMO cluster is proving that the greater efficiencies created through real time communication, and increasing access to specialized expertise is actually accelerating and reducing the costs for the development of new pharmaceuticals and therapies is right in the USA.

THE SYMPOSIUM DESCRIPTION AND OBJECTIVES

The goal of this symposium is to allow attendees to evaluate the best alternatives that have evolved in shortening time to market. A series of case studies, interactive panel discussions, and networking sessions provide ample time to explore the various techniques and approaches being used by virtual to established companies. The program includes case studies by start-ups early stage and large pharmaceutical companies doing breakthrough work in discovery, development, and manufacturing that are utilizing the valuable external resources provided by local CRO/CMO firms.

An exhibition area allows direct contact with companies that provide services from research to commercial manufacturing. The Massachusetts CRO/CMO Cluster provides the scientific external resources required to support a virtual and semi virtual company from conception through commercialization. The technical members of these external resource firms are significant contributor to the engine behind the amazing 'MA CRO CMO Cluster.'

Attendees will learn from the drivers in the front offices of many of the regions biopharmaceutical and biotech firms on how through technical outsourcing, they catalyzed their respective businesses to drive the "New Industrial Revolution" by taking their life science businesses into the 21st Century faster and better.

TARGET AUDIENCE:
REGISTRATION FEE:
TO REGISTER:
MASSBIO COUNCIL:
FORSPONSORSHIP:

Biopharmaceutical decision makers interested in learning about the value of outsourcing locally.
\$75.00 MassBio Members and \$100.00 Non-MassBio Members
Go to www.massbio.org
Lauren Laidlaw, lauren.laidlaw@massbio.org
Shelley Amster, shelley@shelleyco.com



AGENDA

- 7:30 **Registration, Networking and Refreshments**
- 8:30 **Welcome & Logistical Remarks**
Shelley Amster, CRO/CMO Committee, Co-Chair, and Conference Producer
- Kick-Off Address**
Raj Rajur, Ph.D., Founder, President and CEO, Creagen Biosciences and Co-Chair
- 8:45 **Keynote Presentation**
- Introduction**
Ed Price, CEO, PCI Synthesis, MassBio MA CRO/CMO Steering Committee, Co-Chair
Josef H. von Rickenbach, Chair of the Board, CEO and Founder of Paraxel International
- 9:30 **Regulatory Trends in Inspections of Outsourcing Firms**
Michele Noe, MBA, Senior Regulatory Operations Officer, FDA
- 10:00 **Networking and Refreshment Break in Exhibit Area**
- 10:30 **The Changing Paradigm – The Reality from the Front Office
Case Presentations and Interactive Panel Conversation**
- Introduction**
Scott Gillis, CEO and MassBio Council Board Member
- Moderator**
Roger Frechette, Ph.D. Co-Founder & CSO, NE Pharma Associates
- Panelists**
Peter Lanciano, CEO, Neotropix
Yael Schwartz, Ph.D., CEO & President, Hygeia Therapeutics
Walter Olgier, CEO, Acetylon
Leslie Williams, President & CEO, ImmusanT, Inc.
- 11:15 **Collaboration Drives R & D - Working Together
Case Presentations and Interactive Panel Discussion**
- Introduction**
Steering Committee Member
- Moderator**
Peter Glick, Principal, Ampersand Ventures
- Barbara Fox, Ph.D., CEO, Avaxia Biologics*
Ross D. Pettit, Ph.D., VP of Clinical Ops & Outsourcing, AMAG Pharmaceuticals,
Craig M. Sorensen, PhD, VP R&D Network Design & Technology Integration, Vertex
Larry A. Blankstein, PhD, Senior Director Clinical Research, Genzyme
Murali Gopalakrishnan, Ph.D., Director of Global External Research, Abbott Laboratories
- 12:00 **Networking Luncheon Buffet**

- 1:15 **Keynote Presentation**
- Introduction**
 Al Coreia, VP, Cambridge BioMedical
- Job Creation in This Economic Climate**
 Deval Patrick, Governor of Massachusetts or Tim Murray, Lieutenant Governor State of Massachusetts (invited)
- 1:45 **Shifting Risk, Alternative Funding Options**
- Part I - How the Venture World is Evolving - The Key Role 'Local' Outsourcing Relationships Are Playing**
- Introduction**
 Steering Committee Member
- Moderator & Panelists**
 David White, Consultant, Third Rock Venture
 Kevin Bitterman, Principal, Polaris Ventures
 Daniel Behr, MBA, Founder, Access BridgeGap Ventures Access Industries, Inc.
 Douglas E. Onsi, Managing Director, HealthCare Ventures
 Chris Velis, Principal, Medcap Advisors
- 2:15 **Part II - CRO CMO Innovation Showcase**
- Introduction**
 Steering Committee Member Introduction
- Marc Bazin, CEO and CO-Founder, HepatoChem*
 Deborah J. Moshinsky, Ph.D., President and CSO, Cell Assay Innovations, LLC
 Joel Berniac, PhD, MBA, President, CEO/Co-Founder, Akrivis Technologies, LLC
- 2:45 **Partnering Alternatives Funding and External Resources**
- Introduction**
 Doug Banks, MHT, Editor
- Moderator & Panelists:**
 Betsy M. Ohlsson-Wilhelm, Ph.D., CEO, SciGro, Inc.
 Martha Farmer, Ph.D., Executive Director, NorthShore Innovation Center
 Richard D. Gill, Ph.D., President & CEO, TruTouch Technologies, LaunchPad Venture Group
 Pamela Norton, VP of Industry and Program Relations, Massachusetts Life Science Center
- 3:15 **Networking and Refreshment Break**
- 3:45- 4:00 **What Lies Ahead**
- Introduction**
 Balaji Bhyravbhatla, Ph.D., CEO, XTAL BioStructures, Co-Chair Steering Committee
- Closing Remarks**
 Imran Nasrullah, M.S., J.D., CL, Chief Business Officer, MassBio Council
- 4:00 **Program Adjourns & Networking Reception Continues**



ORGANIZATION STEERING COMMITTEE

Avecia Biotechnology
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