



# THE MASSACHUSETTS CRO CMO CLUSTER

## Accelerating Drug Development

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

The Conference Center at Bentley University LaCava Conference Center  
75 Forest Street, LaCava 300, Waltham, MA 02452

March 6, 2012 7:30 AM – 5:30 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 and 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. The downsizing of laboratory space and the increase in the number of virtual companies has become more of the norm 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 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 their biotech startups in a cost efficient manner. 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 are available. 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. 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 have 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 significantly accelerating and reducing the costs for the development of new pharmaceuticals and therapies.

### 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 both virtual and 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.

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:** Biopharmaceutical decision makers interested in learning about the value of outsourcing locally  
**REGISTRATION FEE:** \$75.00 MassBio Members and \$100.00 Non-MassBio Members  
**MASSBIO CONTACT:** Lauren Laidlaw, Director, Innovation Services & Events, lauren.laidlaw@massbio.org, 617.674.5100  
**SYMPOSIUM INFO:** Shelley Amster, Conference Producer, 978-371-5901/978-239-1468, shelley@shelleyco.com  
**TO LEARN MORE:** [www.massbio.org](http://www.massbio.org)  
**TO REGISTER DIRECTLY:** [http://www.massbio.org/events/calendar/1389-ma\\_cro\\_cmo\\_committee\\_symposium\\_accelerating\\_drug/event\\_detail](http://www.massbio.org/events/calendar/1389-ma_cro_cmo_committee_symposium_accelerating_drug/event_detail)

## AGENDA

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- 7:30            **Continental Breakfast**  
**Registration, Networking and Refreshments**
- 8:30            **Welcome Address & Logistical Remarks**  
*Shelley Amster, Principal, ShelleyCO, LLC, CRO/CMO Committee, Conference Co-Chair*
- MA CRO CMO Committee Historic Background**  
*Ed Price, CEO, PCI Synthesis*
- Opening Remarks**  
*Raj Rajur, Ph.D., Founder, President and CEO, Creagen Biosciences, Conference Co-Chair*
- Keynote Presentation**  
*Josef H. von Rickenbach, Chair of the Board, CEO and Founder of PAREXEL International*
- 9:15            **Regulatory Inspection Trends**  
*Karen N. Archdeacon, Compliance Officer, FDA New England District*
- 9:45            **Networking and Refreshment Break in Exhibit Area**
- 10:30          **The Changing Paradigm – Reality from the Front Office**
- Moderator & Panelists**  
*Roger Frechette, Ph.D. Co-Founder & CSO, NE Pharma Associates*  
*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**
- Moderator & Panelists**  
*Norton Peet, Ph.D., Director of Chemistry, Microbiotix, Inc.*  
*Peter H. Glick, Venture Partner, Ampersand Capital Partners*  
*Barbara Fox, Ph.D., CEO, Avaxia Biologics*  
*Ross D. Pettit, Ph.D., VP of Clinical Ops & Outsourcing, AMAG Pharmaceuticals,*  
*Craig M. Sorensen, Ph.D., VP R&D Network Design & Technology Integration, Vertex*  
*Murali Gopalakrishnan, Ph.D., Director of Global External Research, Abbott Laboratories*
- 12:00          **Networking Luncheon Buffet in Exhibit Halls**
- 1:15            **Keynote Presentation - Job Creation in This Economic Climate**  
*Tim Murray, Lieutenant Governor State of Massachusetts (invited)*
- 1:30            **The Evolving VC World & Their Growing Relationships with External Resources**
- Moderator & Panelists**  
*Daniel Behr, MBA, Founder, Access BridgeGap Ventures Access Industries, Inc.*  
*Kevin Bitterman, Principal, Polaris Ventures*  
*Bernat Olle, Ph.D., Principal, PureTech Ventures*  
*Douglas E. Onsi, Managing Director, HealthCare Ventures*



Chris Velis, Principal, Medcap Advisors

2:15 **CRO CMO Innovation Showcase**

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, Akrisis Technologies, LLC

3:00 **Partnerships and Funding Alternative Resources**

**Moderator Panelists**

Doug Banks, Associate Vice President for Economic Development at University of Massachusetts  
Betsy M. Ohlsson-Wilhelm, Ph.D., CEO, SciGro, Inc.  
Martha Farmer, Ph.D., President & CEO, North Shore InnoVentures  
Richard D. Gill, Ph.D., President & CEO, TruTouch Technologies; Advisor, LaunchPad Venture Group  
Pamela Norton, VP, Industry and Program Relations, Massachusetts Life Science Center

3:45 **Closing Remarks**

Scott Gillis, CEO, Onsite Therapeutics, Inc. and Board Member, MassBio Council

4:00 **Program Adjourns. Networking Reception Begins.**



**MassBio Mass CRO-CMO STEERING COMMITTEE**

<p><b>Avecia Biotechnology</b> <b>Averica Discovery</b> <b>Biotrofix, Inc.</b> <b>Blue Sky Biotech, Inc.</b> <b>Blue Stream Labs</b> <b>Cambridge Biomedical</b></p>	<p><b>Ce3inc</b> <b>CreaGen Biosciences</b> <b>Microtest Laboratories, Inc.</b> <b>NSF Pharmalytica</b> <b>ORA Clinical</b> <b>Organix, Inc.</b></p>	<p><b>PCI Synthesis</b> <b>PION INC</b> <b>Pharmalucence, Inc.</b> <b>SBH Sciences</b> <b>TGA Sciences, Inc.</b> <b>ViviSource Laboratories</b> <b>Xtal Biostructures</b></p>
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**SPECIAL THANKS TO OUR OTHER MA CRO CMO EXHIBITORS THAT ARE MAKING THIS EVENT POSSIBLE**

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