MassBio’s fourth annual CRO/CMO Symposium will shed a spotlight on the strength and success of the CRO and CMO communities in the Commonwealth and beyond, with a focus on industry trends and the momentum of outsourcing locally.

The Symposium will be held Friday, Nov. 13 and focus on the theme “Fast Forward: Leveraging Strategic Partners to Accelerate Drug Development.” This event draws more than 300 industry leaders to discuss and evaluate the best alternatives that have evolved in shortening time to market.

Fairmount Partners’ Michael Martorelli will present the morning keynote, “Piloting Your Strategic Options,” outlining the current state of outsourcing in the industry and setting the stage for the day’s discussions.

Harvard Business School’s Willy Shih will present the closing keynote, entitled “Competing on Capabilities: Is Outsourcing Always the Right Model?” Shih is known for his work on American economic competitiveness.

The Symposium will also feature panel discussions, industry-vendor case studies, new technology showcases, hot topic roundtable discussions and a networking reception. The Exhibit Hall will feature nearly 50 strategic partners from Massachusetts and around the globe, including representatives from California-based CROs and CMOs presented in partnership with BVS and Biocom.

Registration is open. For more information, visit MassBio.org.

MassBio CRO/CMO Symposium will focus on industry trends
What better way to kick off the fall than to join together with hundreds of industry leaders, investors and business development teams from around the world at BioPharm America? Thank you to all who participated. We were thrilled to once again team up with EBD Group to host this event in Boston.

Inside this edition you will see a snapshot of the industry, which shows that biopharma and biopharma manufacturing employment growth across the state is outpacing other leading clusters and national averages. In 2014, we saw the highest annual growth rate since 2008. And we have seen that momentum continue. MassBio’s job listing site reached an all-time high in 2015, averaging 2,000 listings per day. That is something to celebrate.

To help foster an environment for companies to grow and thrive in Massachusetts, I am excited to announce that MassBioEd will be building a job trends and forecasting tool and sharing the information with hiring managers and academic institutions. The initiative is headed by Peter Abair, MassBioEd’s new Executive Director. Peter has served us well over the years as the Director of Economic and Global Affairs and I have no doubt he will pull from his experience in that arena in his new role at MassBioEd. The students in this state are our future workforce and it is only natural there should be a bridge between education and economic development, and no one understands that better than Peter.

As we look ahead, I encourage you to join us for our second annual Patient Advocacy Summit and the fourth annual CRO/CMO Symposium. The Patient Advocacy Summit, which will be held on Oct. 27, will bring industry leaders together with other stakeholders to examine ways in which life sciences companies can more fully incorporate the patient voice into the work they do. The CRO/CMO Symposium, scheduled for Nov. 13, will shine a spotlight on the strength and success of the CRO and CMO communities in the Commonwealth. I look forward to seeing many of you there.

Best wishes for a productive and innovative fall.

Robert K. Coughlin is President & CEO of MassBio.
POLICY UPDATE

It was an unusually busy summer on Capitol Hill and Beacon Hill as policymakers took up issues important to the industry. Here is a recap:

BEACON HILL

The Legislature wrapped up its Fiscal Year 2016 Budget debate at the end of July with two days of voting to override roughly 87 vetoes and restore about $97 million in spending to the fiscal 2016 budget cut by Governor Baker. Provisions were included to study potential cost savings for prescription medications including, but not limited to, the feasibility of joining a Medicaid multistate prescription drug bulk purchase consortium and pursuing new supplemental rebates from prescription drug manufacturers, as well as prescription drug take-back initiatives.

MassBio will continue to participate in the task forces and commissions set up by the Legislature to study these issues.

We are also gearing up for the fall hearing cycle, which will include a hearing on Senate bill #1048, a bill written and pushed forward by the insurance plans to confuse the conversation about healthcare costs and outcomes, and to raise the administrative burden on biotech companies. MassBio is working with members to educate policymakers about the bill and will testify in opposition when the hearing is held.

CAPITOL HILL

On July 10, the House of Representatives passed the 21st Century Cures Act on a bipartisan vote of 344-77. The bill seeks to speed developments in new medical treatments through streamlining approval processes for medical device manufacturers and drug developers and includes about $8.7 billion in new NIH medical research dollars and $550 million for the FDA. The Senate Health, Education, Labor, and Pensions (HELP) Committee is currently working on their version of a “Cures” initiative, and MassBio continues to work with our delegation to move these ideas forward.

July also saw continued debate on patent reform legislation, although ultimately no bill came to the House floor. MassBio, in partnership with BIO, continues to push for major reform of the Patent and Trademark Office’s (PTO) Inter Partes Review (IPR) process for challenging patents. We expect continued discussion and debate on patent reform this fall.

MassBio thanks Senator Elizabeth Warren, who coordinated a visit by Acting FDA Commissioner Dr. Stephen Ostroff and several members of his agency to Boston. Commissioner Ostroff met with MassBio member company CEOs to discuss ways to improve FDA-industry interactions.

Q & A WITH RONNY MOSSTON

Ronny Mosston is the Vice President of Patient Advocacy and Public Affairs at OvaScience, a global life sciences company dedicated to improving fertility for women around the world and a pioneer in the patient advocacy field. She serves on the Steering Committee for MassBio’s upcoming Patient Advocacy Summit, which will be held on October 27 in Cambridge. The Summit aims to improve how industry and patient organizations work together to accelerate scientific and drug development to improve the lives of patients.

Q: How does OvaScience ensure the patient is at the center of the work that you do?

From the inception of the company, our strategy was to meet with and learn from the patient and advocacy leaders and incorporate their priorities into all stages of the company. We continue to invite patients and leading advocates to share their experiences with the company and continue to engage at each milestone of our growth.

This summer we launched a first-of-its-kind educational forum for the fertility community focused on the overlooked area of egg health. The unbranded site— www.egghealth.com—provides information and resources solely for the patients’ educational benefit.

Q: Where do you see the patient advocacy field in the future?

My personal hope is that working in patient advocacy in industry is recognized and promoted as an exciting and important professional option for those seeking a career in life sciences. Companies at all stages of development have begun to invest in and value a career path in advocacy to align goals cross functionally with other critical, strategic functions. For those of us in the profession, it is our responsibility to serve as ambassadors and teachers to support the next generation of patient advocates.


Q: What is your advice for life sciences companies that want to engage in patient advocacy initiatives?

A strong commitment from the CEO and leadership team in the early stages and throughout the growth of a company is essential to building a sustainable, comprehensive and respected patient advocacy strategy. It is most effective when tied to corporate and functional goals and is valued as a top priority throughout the organization. There is an increasing trend from leading companies and regulatory bodies to include patient reported outcomes as a critical data point in all stages of the company’s development, including clinical trial design, recruitment and progression. Organizations that earn respect and support from the patient community map out short and long term internal and external opportunities to include the voice of the patient to accelerate the organization forward.

Q: What is your advice for life sciences companies that want to engage in patient advocacy initiatives?

A strong commitment from the CEO and leadership team in the early stages and throughout the growth of a company is essential to building a sustainable, comprehensive and respected patient advocacy strategy. It is most effective when tied to corporate and functional goals and is valued as a top priority throughout the organization. There is an increasing trend from leading companies and regulatory bodies to include patient reported outcomes as a critical data point in all stages of the company’s development, including clinical trial design, recruitment and progression. Organizations that earn respect and support from the patient community map out short and long term internal and external opportunities to include the voice of the patient to accelerate the organization forward.

Massachusetts biopharma employment grew by 4.9% in 2014, the highest annual growth rate for the Massachusetts industry since 2008, according to an annual industry report published by MassBio.


Massachusetts also continues to far surpass the nation in biopharma manufacturing employment growth. In the last 10 years, Massachusetts biopharma manufacturing employment has grown by 28.4% to 9,989 jobs statewide. In the same time period, the United States lost 3,520 biopharma manufacturing jobs, a 2.2% decrease.

“As the Massachusetts life sciences industry continues to grow, there is both the need and the opportunity to increase our capacity for advanced manufacturing,” said Robert K. Coughlin, President & CEO of MassBio. “We look forward to continuing to work with Governor Charlie Baker and his administration as well as our partners in academia to support an ecosystem that fosters manufacturing growth, which will, in turn, be an economic driver for the Commonwealth.”

Positions for open biopharma industry positions of MassBio’s online job board are matching up, with an average daily number of listings above 2,000 jobs in 2015. MassBio.org is not a comprehensive listing of all jobs available in the industry in Massachusetts but given its significant volume, it does provide a statistically strong sampling in determining job hiring trends.

Massachusetts continues to lead the nation in biotechnology R&D jobs, a segment of the larger industry employment, with more than 29,997 positions in 2014, and maintained its position as the leader in biotech R&D as defined by industry concentration. The industry’s economic impact as measured by MA-based payroll topped $7.29 billion.

Ventures investments in Massachusetts rose to a record $1.8 billion in 2014 and 2015 on is on track to another banner year. In the first two quarters of 2015, Massachusetts biotechnology companies have received more than $1 billion in financing.

The data shows some slowed growth in one area—seed-stage funding for Massachusetts companies. The average amount of seed-stage funding for the five years through 2014 was lower than the five year period preceding (2009-2013). While not an immediate cause for alarm, MassBio continues to monitor such limited funding as an indicator of the industry’s long-term growth potential.

“On average, the Massachusetts cluster is built on a foundation of technologies spawning out from academic institutions and medical centers and a strong early-stage research community,” Coughlin said. “We need to ensure they evolve very early ideas toward the funding necessary to move to the next phase of testing whether they could become our next generation of treatments and cures.”

In response to growing concern regarding transportation in Eastern Massachusetts, this year’s Snapshot also includes commuter survey responses collected by MassBio. The survey suggests that the use of the T and commuter rail as means of commuting are substantially more satisfied with their commuters than those who drive or use the commuter rail. More than 70% of commuter rail users are dissatisfied with their commutes. MassBio will continue to advocate for improvements to public transportation and the infrastructure necessary to fuel the industry for growth well into the future.

Additional highlights from the report include:
- Massachusetts-headquartered companies have a total of 1,491 candidates at some stage of R&D. Oncology candidates continue to make up 37% of that pipeline.
- Systemic anti-infectives, central nervous system, and musculoskeletal/therapeutic areas are other strong areas of research.
- Massachusetts accounts for 11% of the U.S.-based drug development pipeline. Massachusetts-headquartered companies account for 5.5% of the global biologics pipeline.
- With 17 IPOs in 2014, Massachusetts almost doubled its previous biotech/pharma annual IPO record of 9 (2013). Thus far in 2015, nine additional Massachusetts biotech companies have had IPOs.
- The top 4 NIH-funded independent hospitals (and 8 of the top 14) in the U.S. in 2014 are in Boston.
- On an NIH-funding per capita basis, Massachusetts continues to far exceed other NIH recipient states. Only California receives more total NIH funding.

Since 2007, 8 million square feet of commercial lab space has been added to inventory in Massachusetts. Approximately 1.8 million square feet of additional lab space is under construction.

The estimated average salary in the biopharma industry is $120,628.

Massachusetts-headquartered companies have had 1,491 drug candidates in the pipeline at some stage of R&D. Oncology drug candidates make up 37% of that pipeline.

The estimated average salary in the biopharma industry is $120,628.

Massachusetts-headquartered companies have had 1,491 drug candidates in the pipeline at some stage of R&D. Oncology drug candidates make up 37% of that pipeline.

So far in 2015, there has been a daily average of 2,000 open biopharma industry positions on MassBio’s online job board.
Peter Abair has been named MassBioEd’s new Executive Director. He will be focusing on collecting job data and analyzing trends this fall.

MassBio’s Impact 2020 report identified a challenge for companies as they grow and thrive in Massachusetts—data on and access to the right workforce.

MassBio’s job listings site reached an all-time high so far in 2015, averaging well over 2,000 listings per day. Anecdotally, industry employers are reporting difficulty in hiring for a variety of positions. Such reports raise concerns that our traditionally strong pipeline of high quality workers is under strain.

Specifically, Impact 2020 found both companies and universities face challenges in workforce development and training due to the lack of a reliable, ongoing source of data on job demand in the life sciences industry.

That’s where the MassBioEd Foundation comes in. Beginning this fall, MassBioEd will build a job trends and forecasting tool, collecting data from MassBio member companies, analyzing the trends, and sharing with hiring managers and academic institutions.

“Our goal is for the MassBioEd Foundation to be the universally accepted source for information on industry job trends, providing a needed resource for educators, employers, and job seekers,” said Peter Abair, MassBioEd’s new Executive Director.

MassBioEd will continue to strengthen its widely-recognized, signature BioTeach program which provides training and mentorship for public high school science teachers on lab-based lessons in the life sciences as well as Career Exploration Days at local biotech and pharma companies. The new job trends and forecasting capacity builds upon MassBioEd’s educational programming foundation by providing a clear understanding of what jobs are trending strongly, what skills are associated with those positions, and what job opportunities will be available in the future.

MassBioEd will roll out initial reporting in December 2015, including three-month and three-year job trends by category as well as required skill sets, experience levels, and degree levels. By mid-2016, the reporting will be web-based and augmented with more in-depth required job skills information as well as job forecasting. This new service has received strong support from industry and financial support from MassBio.

“We are proud to support MassBioEd’s new job forecasting initiative,” stated MassBio President & CEO Robert K. Coughlin. “We believe it will serve as a valuable resource for the continued development of the booming life sciences industry in Massachusetts.”

The service is in line with MassBioEd’s central mission, which aspires to engage teachers, inspire students and guide the life sciences workforce.

“Our aim is to be a trusted guide to educators, industry, and prospective industry employees,” stated Abair. “We want to demystify the pathway from the classroom to the workforce.”

MassBio’s 21st Annual Golf Classic was held on Sept. 11 at Pinehills Golf Club in Plymouth. The event raised more than $100,000 for MassBioEd and its signature BioTeach program. Former Patriots captain and offensive lineman Dan Connolly was on hand to lend his support, while Peter Abair enjoyed the day in his new role as Executive Director of the Foundation.

MassBio President & CEO Robert K. Coughlin (far left), Airgas Northeast Region President Kent Carter (second from left) and MassBioEd Executive Director Peter Abair (far right) congratulated one of the winning teams—a foursome from Stericycle Inc. that included John Jepsen, Rick Salmonsen, Paul Jepsen and Terry Helmetag.

Thank you to our event sponsors

Industry professionals braved a rainy morning on the course to support biotech education.

Golfers met former Patriots lineman Dan Connolly, third from left, and spoke with MassBioEd’s Executive Director Peter Abair, second from right, about the impact their donations will have on biotech education.
**THERE IS POWER IN NUMBERS!**

By aggregating the purchasing power of the member companies within MassBio, the MassBio Purchasing Consortium allows members to have a strong presence in the marketplace so they can bring more to their bottom lines. These case studies show savings actually achieved by MassBio members.

MassBio continuously evaluates the needs of member companies and the existing contracts to ensure the best value.


---

**CHECK OUT THE SAVINGS ACTUALLY ACHIEVED BY MASSBIO MEMBERS**

<table>
<thead>
<tr>
<th>Small Biotech</th>
<th>Associate Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employees: 30</td>
<td>Employees: 200</td>
</tr>
<tr>
<td>Items Purchased:</td>
<td></td>
</tr>
<tr>
<td>* Lab Gases</td>
<td>* Office Supplies</td>
</tr>
<tr>
<td>* Lab Supplies</td>
<td></td>
</tr>
<tr>
<td>* Hazardous Waste Management</td>
<td></td>
</tr>
<tr>
<td>* Office Supplies</td>
<td></td>
</tr>
</tbody>
</table>

| Est. List Price: | $187,539 | Est. List Price: | $36,085 |
| Consortium Spend: | $123,075 | Consortium Spend: | $21,651 |
| Est. Savings: | $64,464   | Est. Savings: | $14,434  |
| +Year-End Rebate: | $3,564  | +Year-End Rebate: | $324    |

**Bottom Line Savings:** $63,556  
**Bottom Line Savings:** $7,008

---

**WORLD’S INDUSTRY LEADERS GATHER, COLLABORATE**

BioPharm America 2015 drew more than 850 life sciences professionals from 524 companies and 27 countries around the world and saw 2,274 one-to-one partnering meetings. MassBio, in partnership with EBD Group, the leading partnering firm for the life sciences industry, hosted BioPharm America September 15-17 at the Boston Marriott Copley Place.

“The impressive showing of life sciences executives from around the world is indicative of how vital Massachusetts is to the industry,” said Robert K. Coughlin, President & CEO of MassBio. “The partnering meetings are a valuable opportunity to foster collaborations that will deliver cures for patients.”

The conference kicked off with an Opening Plenary entitled “Giving up the corporate jet and going back to the trenches: Insights from biotech disrupters” featuring four former pharma executives who are now running small biotech companies.

The seasoned panelists shared the triumphs and tribulations of moving from a large pharma to a small biotech but overwhelmingly said the risk is worth the reward. Jeremy Levin, former Teva Pharmaceuticals CEO and current Chairman & CEO of Ovid Therapeutics, highlighted the incredible impact of meeting with patients “eyeball to eyeball” and getting the opportunity to truly know your employees. His fellow panelists agreed and addressed the importance of cultivating an invigorating culture that motivates employees to perform at the highest level.

Tuesday afternoon began with an Executive Discussion, “Rare Diseases: The new norm?” Panelists focused on the potential for disruptive innovation within industry and academia partnerships, the FDA, and incorporating patients in the design of clinical trials. Ilan Ganot, founder and CEO of Solid Biosciences and the father of a child with Duchenne Muscular Dystrophy, stressed the importance of listening to the patient. “Patients really know the disease. We like to think we know, but they really know. If you can find a way to work with patients, it’s a great formula to be successful,” he said.

New this year was the Biotech Startup Day sponsored by Johnson & Johnson Innovation. After a series of panel discussions on funding opportunities and strategy, 20+ budding entrepreneurs had four minutes each to pitch their companies to a panel of experts and compete for a prize. Proteorex Therapeutics Inc. came out on top for their innovative technology and services to support drug discovery. Founder & CEO Aman Iqbal and his team won the use of a bench at one of Johnson & Johnson Innovation’s JLABS managed locations for three months and six months of mentorship from a Johnson & Johnson Innovation team member.

Other panels throughout the conference covered hot topics such as regenerative medicine, externalizing R&D, biomarkers, precision medicine, digital health, and big data. BioPharm America will return to Boston September 13-15, 2016.
BY MEAGHAN CASEY

When Bud Pickard, a dairy farmer in upstate New York, started to feel rundown and achy six years ago, he attributed it to the demands of his job. He was working 12 to 16 hours a day, and physical pains were not out of the ordinary.

But when his physician suggested a total body scan, the results suggested bone cancer—not the diagnosis Pickard wanted to hear just 10 days before Christmas. He was referred to an oncologist for a second opinion and that eventually brought him to Dr. Daniel DeAngelo, Clinical Director of Adult Leukemia Services in the Center for Hematologic Oncology at Dana-Farber Cancer Institute.

DeAngelo ordered a bone marrow biopsy, which revealed the dense accumulation of mast cells—immune cells that produce a variety of mediators, such as histamine, that are important in the body’s allergic responses. Though Pickard’s bones were strong, he had lost 60 percent of his bone marrow. He was then diagnosed with systemic mastocytosis, a disorder in which mast cells are abnormally increased in multiple organs including the bone marrow, skin, gastrointestinal tract, liver and spleen. By this time, Pickard was feeling bloated, had lost weight and both his liver and spleen were enlarged.

Fortunately, DeAngelo had teamed up with Dr. Cem Akin, an allergist and immunologist who leads the Mastocytosis Center at Brigham and Women’s Hospital, a first-of-its-kind center that provides expert multidisciplinary evaluation and treatment for patients from across the country.

“Many cases of mastocytosis are missed, especially early in the disease, leading to a delay in critical treatment,” said Akin.

DeAngelo was the lead investigator on a clinical trial of midostaurin, an investigational therapy designed to inhibit multiple kinases, including one triggered by a genetic mutation found in most patients with systemic mastocytosis.

Pickard began taking midostaurin in March 2013 and has had success with the drug. His liver and spleen have returned to normal and he has had no side effects.

While stories like Pickard’s show the promise of new targeted therapies in development, the unmet need for systemic mastocytosis, particularly for patients with aggressive disease, remains high. There are still no approved therapies to target the mutated gene found in more than 94 percent of systemic mastocytosis patients. In aggressive cases, the disease compromises organ function and average survival is only three to five years from the time of diagnosis.

Cambridge-based Blueprint Medicines is developing a highly targeted drug for those patients. In September 2015, the company received FDA approval to begin a Phase 1 clinical trial of the drug, called BLU-285, for the treatment of advanced systemic mastocytosis and expects to enroll approximately 60 patients with advanced systemic mastocytosis in the clinical trial.

“BLU-285 is a potent and selective inhibitor of the KIT D816V mutation, the primary driver of disease in more than 94 percent of systemic mastocytosis patients,” said Jeffrey Albers, CEO of Blueprint Medicines. “We’re thrilled to be advancing this drug into clinical trials. All of us at Blueprint Medicines are motivated by the goal of making a difference for patients. We aim to do that by using our deep understanding of the genetic blueprint of cancer and other diseases driven by the abnormal activation of kinases to craft highly selective medicines.”

Pickard, now 73, is in the process of moving to Paxton, Mass. He has been living in Fonda, N.Y. since 1989, maintaining his farm. He is the father of four and credits the support of his wife, Cynthia, and his children for helping him through the worst of the disease. Since his diagnosis, he has returned to Boston every three months and is looking forward to a closer commute to the hospitals. “I can’t say enough about the doctors in Boston,” Pickard said. “I’ve been so fortunate to have had their care.”