

B I O L I N K

August 2015



Member News

[MPI Research, Exemplar Genetics Collaboration First to Validate New Animal Model of Atherosclerosis](#)

[Detroit-Based Asterand Buys Memphis-Based Biobank](#)

[Arboretum Ventures files with SEC to raise \\$215 million](#)

Members, submit your company news for inclusion in MichBio's website, biolink, and more.

MichBio Events

September 9-10
[Cutting Edge / Drug Discovery & Development in Michigan](#)

September 25

On the Road with Stephen Rapundalo

July has been busy! I've been working diligently with Michael Kruczek at [DCG](#) to pull together all the data gathered as part of the Michigan Bio-Industry Strategic Roadmap 2015 initiative.



The Roadmap work product will be unveiled at the first-ever [Michigan Bio-Industry Growth Summit](#) set for the afternoon of Tuesday, December 8 in Lansing - SAVE THE DATE!

I did manage to squeeze in some visits this past month. David McGuire and I met up with a few of the companies domiciled at the [Michigan Life Sciences Innovation Center](#) (MSLIC) - [DeNovo Sciences](#), Vinazine, miLead Consulting, Biocrede, and Stonebridge Coatings Laboratory. [\[Read more 'On the Road'\]](#)



Cutting Edge / Drug Discovery & Development in Michigan

September 9-10, 2015

Presented by MichBio &
the University Research Corridor

[BioConnections
Investment
Opportunity with
Sandbox Industries](#)

December 8

[Michigan Bio-Industry
Growth Summit](#)

[View more events
online.](#)

Featured Events

September 15

[Wayne State's BEST
Program Orientation](#)

September 16

[BioArbor: The Good,
the Bad and the Ugly of
Startups](#)

September 16

[Medical Main Street's
INNO-VENTION
Reception](#)

September 28

[MSU Science Connect
for Grad Students,
Postdocs, and
Employers](#)

October 5-7

[AdvaMed - members
save](#)

October 7-8

[MD&M Philadelphia -
members save](#)

[View more online or
submit your member
company's event](#) for
inclusion in MichBio's
website, *biolink* , and
more.



**Online registration
ends Monday,
September 7**

One week until the first symposium
dedicated to drug R&D activities at the state's
research universities! Please join us in East
Lansing. [\[See full agenda and register here\]](#)



**Michigan
Bio-Industry
Roadmap 2015**

SAVE THE DATE!

**Michigan Bio-Industry Growth
Summit: Roadmap for Success**

December 8, 2015

Lansing, MI

This half-day event will present recommendations
from the Roadmap, a strategic plan for growing
Michigan's biosciences industry. The statewide
effort is lead by MichBio, Business Leaders for
Michigan, and the University Research Corridor.

[\[More\]](#)



**Network for
Medical Device
Eval**

A national coordinated
registries network that
monitors medical devices after they are made
commercially available would make it easier for
stakeholders to use data from disparate sources,
according a new report commissioned by FDA.

[\[More\]](#)

**FDA Issues Guidance on
Biosimilars Naming (Sort of)**

The FDA proposes distinct non-proprietary names

MichBio Premium Members

Gold



Silver



Bronze



for biologic and biosimilar drug products to prevent unintended substitution of non-interchangeable therapies, aid in post-market tracking and monitoring. [\[More\]](#)

New Legislative Solution Proposed for LDTs

The Association of Molecular Pathology proposed a legislative solution to modernize the Clinical Laboratory Improvement Amendments. [\[More\]](#)

Refuse to Accept Policy for 510(k)s

The FDA's Center for Devices and Radiological Health issued a revised version of the guidance document that will go into effect on October 1, 2015. [\[More\]](#)

FDA Releases White Paper on Speed of Drug Discovery, Development

The white paper briefly describes "the state of scientific knowledge and its effect on drug development in four key disease areas other than cancer and HIV/AIDS:" Alzheimer's disease, diabetes, rare diseases, and hepatitis C. [\[More\]](#)

Combination Products Regulatory Fairness Act Introduced

A bill was introduced in the U.S. Senate last month is intended to streamline device/drug combination registrations at FDA by letting the agency rely on prior PMAs and approved drug findings to help support new product approvals. [\[More\]](#)

Other Regulatory News

Short briefs on device export fees, GUDID, PDUFA, guidance for rare disease and botanical drug development, modifications to the exempted devices list, more. [\[Full list\]](#)

Patron

Boston
Scientific



Funding Opportunities

View the [July 2015](#) and [August 2015](#) Bioscience Grant Reports , compiled by [G2G Consulting](#).

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