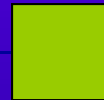
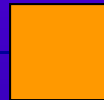
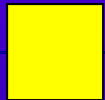


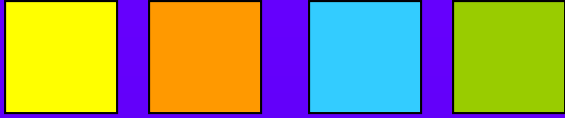
# Micromyx

A Microbiology Services  
Company



Lab Services – Research - Consulting - Regulatory

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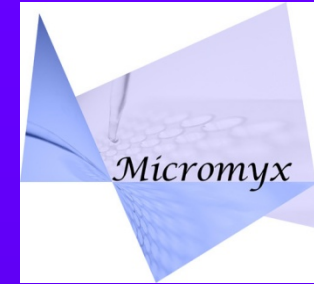
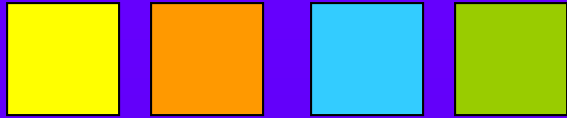


## Company description

Micromyx is a microbiology services company specializing in anti-infective discovery and development for the pharmaceutical, biotechnology, medical device, and animal health industries.

- High quality laboratory services from experts who have successfully gained FDA approval of new antibiotics
- Micromyx will customize the relationship with each client
  - stand-alone assay services to meet the client's specific needs
  - collaborative discovery program for exploratory projects
- GCP, GLP or non-GLP capabilities

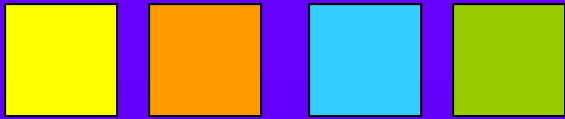
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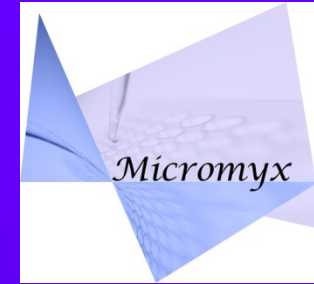
## About Micromyx

- Established in November 2004
- Co-founders Dean Shinabarger (CEO) and Gary Zurenko
- Occupy 5000 sq ft of laboratory and office space in the Southwest Michigan Innovation Center in Kalamazoo, Michigan
- Biosafety Level 2
- Current staff: 9 scientists, 2 executives
- Subcontractors for general consulting, QA and medical writing

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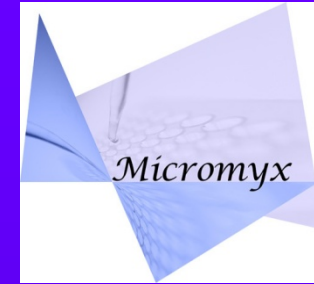
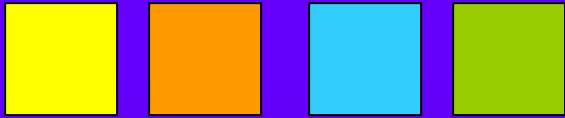
## Management



### *Chief Executive Officer : Dean Shinabarger, Ph.D.*

- 21 years antibacterial research experience including Micromyx, Pfizer, Pharmacia, Upjohn, Procter & Gamble Pharmaceuticals
- Directed biochemistry/molecular biology laboratories in Discovery Research
- Team leader for antibacterial discovery projects
- Elucidated mechanism-of-action and -resistance of oxazolidinones
- Member of Zyvox™ FDA advisory committee team

*Micromyx*

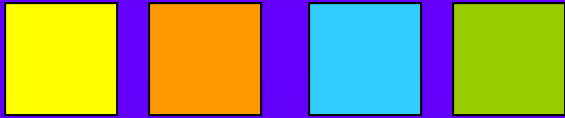


## Management

### *Chief Scientific Officer : Chris Pillar, Ph.D.*

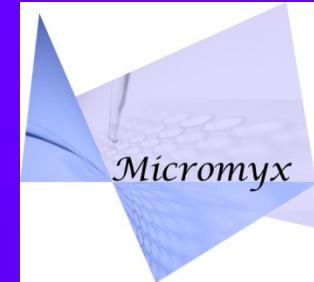
- 7 years preclinical microbiology experience at Eurofins Medinet and Micromyx
- Directs client interactions and supervision of laboratory staff
- Microbiology and molecular biology experience

*Micromyx*



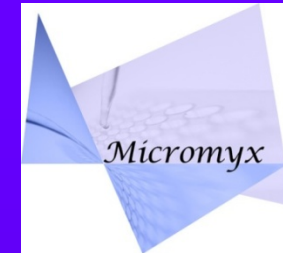
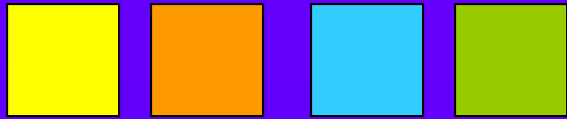
## Key Consultant

Gary Zurenko, M.S. (key consultant)

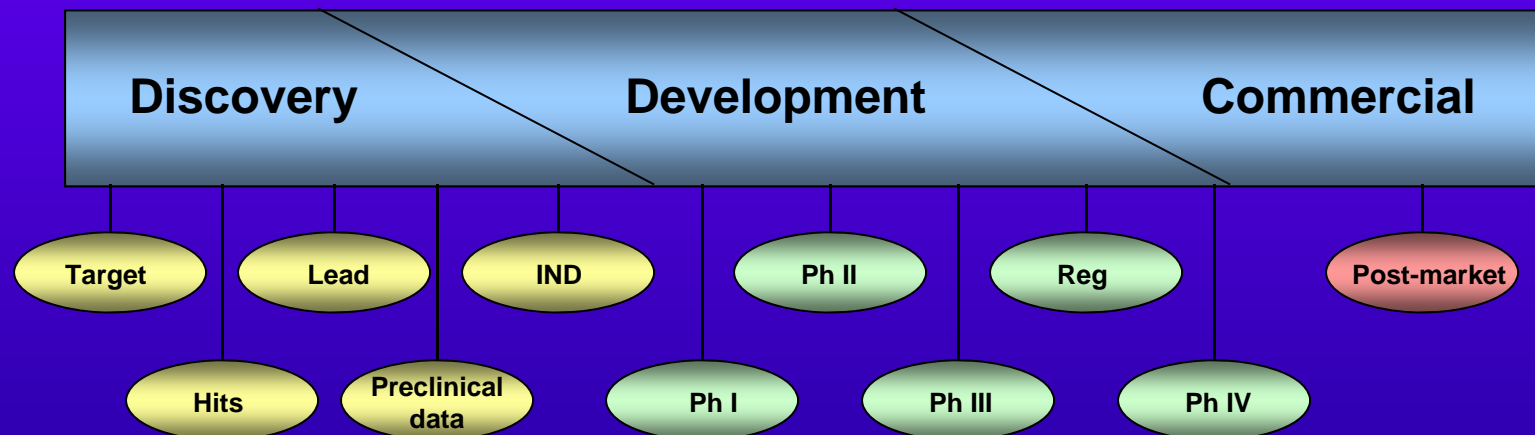


- 39 years antibacterial research experience at Micromyx, Pfizer, Pharmacia, and Upjohn
  - Directed microbiology laboratories in Discovery Research
  - Acted as microbiology consultant for Clinical Development
- Lead microbiologist for Cleocin™ (sNDAs), Vantin™, Zyvox™ *in vitro* studies
- Experienced in FDA filings and MRP process
  - Principal author of microbiology section of Zyvox™ NDA
  - Member of Zyvox™ FDA advisory committee team
- > 20 yr experience with Clinical and Laboratory Standards Institute (currently Voting Member of Veterinary AST Subcommittee)

*Micromyx*

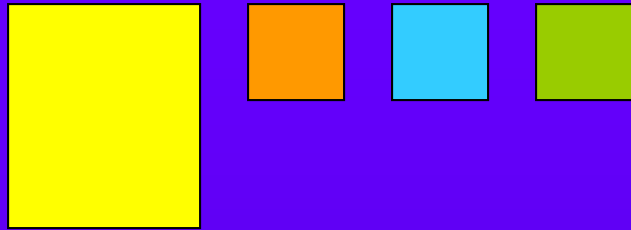
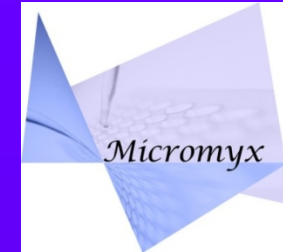


## Micromyx Adds Value Throughout The Antibiotic Discovery and Development Process



Micromyx provides laboratory and consulting services by scientists with documented experience in discovery, development, and product approvals

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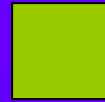
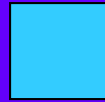
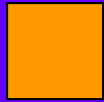
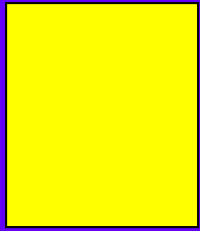
## Lab Services

- Experienced laboratory scientists
- High quality & high capacity laboratory
- Large and diverse culture collection of hospital isolates
- Susceptibility determinations for bacteria, yeasts, and fungi
- Anaerobic microbiology capabilities
- MIC<sub>90</sub> determinations

*Micromyx*

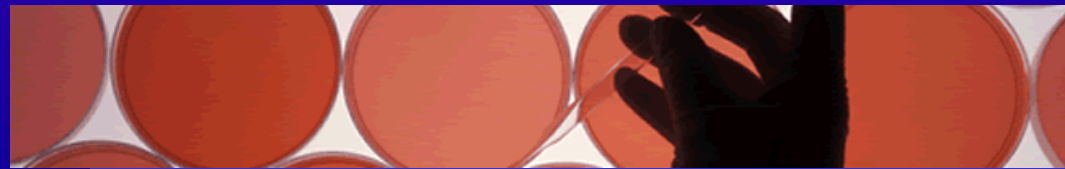


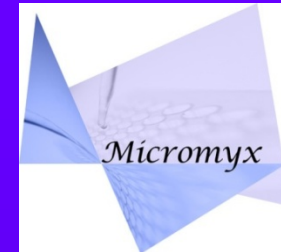
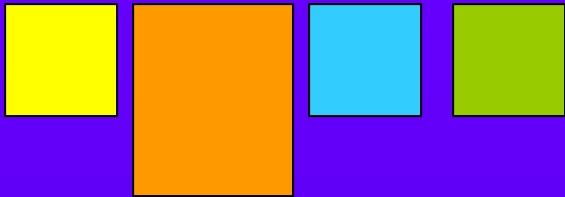




## Lab Services - continued

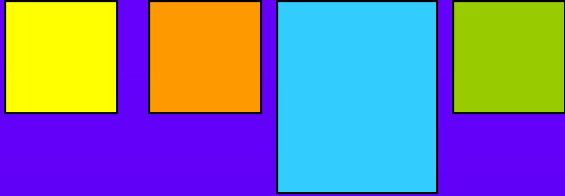
- Bactericidal , fungicidal, sporicidal assessments
  - MBCs/MFCs
  - Time-kill kinetics
  - *C. difficile* spore germination/cidal assessments
- Microbial identification (biochemical- and 16S rRNA-based)
- Drug combination assessments
- Tier I and Tier II QC Studies
- Disk mass determination
- Resistance development assays
- PCR amplification and DNA sequencing of resistance genes
- PFGE of isolates





## Research

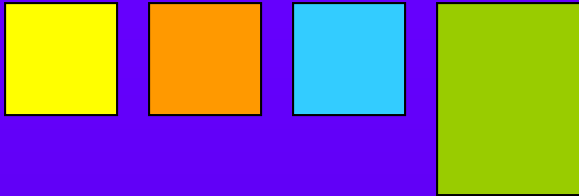
- High-throughput whole cell and/or enzyme screening of compounds
- Mechanistic assessment of new antimicrobial agents
  - Mechanism of action: Macro synthesis; T/T assay
  - Mechanism of resistance
  - Resistance development: Spontaneous mutation; serial passage
- Cloning, expression, and purification of enzymes
- Enzyme assay development and kinetic characterization of inhibition by compounds
- Beta Lactamase Assays



## Consulting

- Extensive experience in antibiotic discovery and development through FDA approval
- Consulting services
  - develop discovery strategy
  - review preclinical data packages
  - provide an opinion regarding product or project
  - due diligence activities
  - identifying other key antimicrobial R&D service providers
    - in vivo efficacy
    - ADME
    - toxicology
      - monitor the activities for the client

*Micromyx*



## Regulatory

- Planning a strategy to generate the data required for FDA or international submissions
- Planning or writing the microbiology section of INDs, NDAs, or international dossiers
- Representing the client at FDA, EMEA (European Medicines Agency), or other regulatory agencies
- Provide guidance regarding CLSI and EUCAST submissions