

Thank you for your interest in utilizing the cutting edge technology M2D2 has to offer with our lab facilities. Please reference the "Onboarding" step below, which outlines the process to apply as a resident company. Required forms included.





600 Suffolk Street, 2<sup>nd</sup> Flr, Lowell, Ma.

110 Canal Street, 4<sup>th</sup> Flr, Lowell, Ma.

#### M2D2 Onboarding:

- 1. Participation application
- Presentation to M2D2's executive committee (overview of business plan and ability to interact with UMass Lowell and UMass Med School/ hiring of interns, clinical trials, animal studies, use of core research facility <a href="www.uml.edu/crf">www.uml.edu/crf</a>, etc.)
- 3. Proof of insurance per university requirements
- 4. Lab occupancy application and approval, including lab safety training. Link to lab training schedule: https://www.uml.edu/EEM/Training-schedule/Training-Schedule-EHS.aspx
- 5. License agreement signed (the university's version of a lease; outlines terms of agreement, payment information, etc.)

Contact MaryAnn Picard with any questions: maryann picard@uml.edu | (978) 934-3403



### **M2D2 Participation Application**

Name:	
Organization:	
Address:	
Contact Information: e-mail:	Phone:
Website Address:	

#### I. Overview of Product

Please provide a 1 page overview addressing the following topics:

Product Name
Medical Issue Addressed
Technical Description of Device
Current Stage of Product Development

- II. **Medical Significance** Please limit response to 2 pages; include supporting diagrams or documentation in appendix.
  - 1. Describe the health issue or medical problem that the device intends to address and its hoped-for benefit.
  - 2. Describe the device's current status and potential effectiveness in addressing this medical problem. Please attach any supporting work, preliminary data or testing that is relevant in an appendix.
  - 3. Describe the potential advantages and disadvantages of this product over any existing or emerging products.
  - 4. Describe the anticipated medical risks/safety of the device.
  - 5. Note anticipated acceptability or adoption challenges for the medical community, and how these might be addressed.
  - 6. Describe the anticipated biological and/or clinical development required for FDA regulatory submission.

## M2D2 Participation Application

**III. Business Plan** – Please limit response to 2 pages; include supporting diagrams or documentation in appendix.

- 1. Describe the technologies employed in this device and the proof of concept todate, and the current status of development.
- 2. Describe the current status of Intellectual Property associated with this product (e.g., patent status, prior art, licenses).
- 3. Estimate the size, value, and accessibility of your targeted market segment.
- 4. Describe existing products and technologies that might compete with your device (please list their manufacturer, target market & price). Describe the relative advantage of your product from a patient's and healthcare professional's perspective.
- 5. Describe the product's development status (idea, mock-up, working prototype, etc.) and the anticipated engineering development work that is required.
- 6. Describe the anticipated regulatory classification (Class 1, 2, or 3) and path for the product. If Class 2, will clinical trials be required?
- 7. Describe how the device will be marketed, distributed and reimbursed/priced. Estimate the resulting product profitability.

### IV. Research & Business Team – Please limit response to 2 pages.

Please list all members of the research and business team, including their roles on this project, credentials, affiliations, and ownership interest in the project.

V. Desired M2D2 Assistance – Please limit response to 1 page.

# M2D2 Participation Application

Please describe the activities, resources and capabilities desired from M2D2 to help develop the product.

VI. Permission to Share – Please check yes or no. If Yes, please choose your desired companies.

M2D2 offers early access and exposure to the following industry corporate sponsors. Please indicate your permission for M2D2 to share your company's non-confidential information:

No
Yes

Please share my information with the following companies:

Boston Scientific

Johnson & Johnson

#### **M2D2 Client Insurance Requirements**

Within ten (10) business days prior to execution of the Space License and annually thereafter (if applicable), Licensee shall furnish the University with certificates of insurance evidencing the policies listed below. At its sole cost and expense, during the term of this Space License, and during such other times as Licensee occupies the Premises or any part thereof, Licensee must maintain and keep in force the following insurance policies:

- A. Commercial General Liability Insurance including contractual liability coverage, written on an occurrence form with combined limits for personal and bodily injury and death and for property damage of at least two million dollars (\$2,000,000) per occurrence and four million dollars (\$4,000,000) in the aggregate. The insurance policy or policies shall name the University as an additional insured. Licensee shall promptly notify University if such coverage is cancelled, reduced or otherwise materially altered.
- B. Vehicle Liability Insurance covering each vehicle of Licensee entering the Premises with combined limits for bodily injury and property damage of at least one million dollars (\$1,000,000) per accident.
- C. Workers' Compensation Insurance in compliance with applicable Federal and state laws, including Employers Liability Insurance with limits of at least one million dollars (\$1,000,000) per occurrence.
- D. Such other types of insurance and in such amounts as University may, from time to time, require in its reasonable judgment.

One or more certificates of insurance showing insurance coverage as required by the applicant/client.

The insurance coverage required by this Section shall be by standard policies, obtained from financially sound and responsible insurance companies licensed to do business in the Commonwealth of Massachusetts. All insurance maintained by Licensee shall provide that such insurance for the benefit of the University shall be primary and the University's own insurance shall be non-contributing. In the event Licensee fails to obtain any of the insurance coverage required by this section, or if any of the required insurance policies are cancelled, it shall be grounds for immediate termination of this Space License as provided in Section 18(c) of this Agreement.

Need help finding insurance? M2D2's preferred insurance company is Sallop Insurance Kim Ferraro (KFerraro@sallop.com) or Kristin Procopio (KProcopio@sallop.com) would be happy to help you with your M2D2 insurance needs:



Sallop Insurance Company 25 New Chardon Street Boston MA 02114 617-488-6573 www.sallop.com

## M2D2 Application for Occupancy Approval & UMass Lowell Transmittal Checklist

	□ New	v or $\square$ Renewal Application	
	Location Reques	ted: □ 600 Suffolk Street OR □ 110 Canal Street	
		ith all supporting documents for UML review and approval.	
	All Information provided is considered	d confidential and for review and approval for occupancy only.	
Name	of Company:	Date Submitted:	
Name	of Applicant:	Email Address:	
Addre	ss:	Phone:	
	nents Submitted with Application* nature of activities to be conducted	(First three are required and list of materials is dependent d):	
1)	☐ Participation application		
2)  Insurance certificate provided with adequate coverage			
3) $\square$ List of company-owned equipment that will be moved to UML			
•	4) $\square$ List of Chemical and Biological* materials to be used at UML		
5) 🗆 Anticipated move-in date:			
6) $\Box$ If renewal, check here to indicate company/occupant is in good standing with UMass Lowell			
	Accounts Payable	a activities or material used that would require FLIC or OIC	
	a. $\square$ if Kenewai no Change in review	activities or material used that would require EHS or OIC	
		nge in activity or materials used that require EHS or OIC	
-	lete the following sections:  Detailed description of what activities this area/facility):	es will be done in UML facility. (NO live animals may be used in	
В.	<ul> <li>B. Check all applicable for work to be conducted at UML and list ALL materials where requested:  (Please check off and describe types of materials to be used at UML/M2D2 to develop the technology or device.)  Office Space Use Only.  Human Subject Research  UMass Lowell students will be involved in the research  UMass Lowell students will use results to meet academic requirements  Other, explain:</li> </ul>		

# ☐ **Chemicals.** Provide and attach a complete **list of chemical names** and approximate quantities used: THESE TWO QUESTIONS ONLY TO BE COMPLETED BY COMPANIES THAT REQUIRE OR WILL NEED SBL1/BSL2 ☐ Biological materials (blood or other human derived materials in order to develop the product) (Materials allowed only up to Risk Group/BSL2.): Check whether $\square$ BSL1 and/or $\square$ BSL2 Check below ONLY IF YOU HAVE CHECKED BSL1 and/or BSL2 ABOVE. ☐ If BSL1 and/or BSL2, I understand I must submit an IBC Registration and receive approval before any materials are brought to UML. \*Note: For use of Biological materials, an IBC Registration form must be submitted to the Institutional Biosafety Committee (IBC) for review and approval before any materials may be used or moved to UML. This may take up to 6 weeks, depending on the timing of this application. For more information and IBC Registration form, go to http://www.uml.edu/Research/OIC/biological-safety/default.aspx □ I understand and agree to adhere to all regulations associated with shipping and transport of hazardous materials. List all specific types of biological materials to be used and approximate quantities (Any human derived materials such as blood, rDNA, pathogens, infectious agents, toxins, etc.): C. Describe the types of equipment needed in the space: ☐ Biosafety Cabinet ☐ Chemical Fume Hood ☐ Other, specify: D. Describe how you expect to dispose of materials used: $\square$ Sink disposal with Environmental and Emergency Management/Environmental Health and Safety approval ☐ Hazardous waste in bin for pick-up ☐ Regular trash ☐ Other, describe: E. Acknowledgement of requirements by Applicant: I understand that any survey or research work conducted that involves human subjects requires the review and approval of an Institutional Review Board. All licensees/members are responsible for securing appropriate IRB review prior to commencing any research that engages human subjects. (Please initial above) Applicant agrees that all personnel for company will register and complete all required training as relevant to the business activity on the next available training session after receiving move in confirmation (i.e., EHS lab safety training, blood borne pathogens, basic biosafety training, etc). (please initial above) http://www.uml.edu/EEM/Training-schedule/Training-Schedule-EHS.aspx Name and title of individual completing this application. Printed Name & Title Relationship to Company Signature Date

M2D2 Application for Occupancy Approval & UMass Lowell Transmittal Checklist