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Medical Products Support Services

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Medical Products Support Services was launched in May 2014, to assist engineers, physicians, scientists, and other faculty investigators who are working to bring medical products out of their laboratories and progress their inventions/discoveries toward the marketplace.

MPSS is located within the Vanderbilt Center for Technology Transfer and Commercialization. The CTTC provides professional commercialization services to the Vanderbilt community.

MPSS *Services*

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The MPSS team service to Vanderbilt investigators through two programs:

- ❑ **The Medical Products Development and Commercialization Program (MPDCP)**

- MPDCP assists with all types of medical product development, diagnostics, pharmaceuticals and devices.

- ❑ **The Medical Device Regulatory Affairs Program (MDRAP)**

- MDRAP focuses on providing help regarding medical device regulation. MDRAP provides a range of services including discussion of regulatory strategies, discussion of device classification, application submissions, and communication with the Vanderbilt IRB and the FDA.

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Consult with MPSS may begin any time during the during the development process of a product.

Most often MPSS is consulted in the earlier stages of research and product evaluation.

MPSS *Services*

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The MPSS service is free

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MPDCP PROGRAM

Center for Technology Transfer and Commercialization

MEDICAL

PRODUCTS

DEVELOPMENT

COMMERCIALIZATION

PROGRAM

MPDCP

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MPDCP focuses on *supporting the development effort by providing early feedback*. This includes pointing investigators towards considerations for prototyping, testing, sourcing supplies, identifying potential manufacturing concerns, consideration of the strategies for commercialization, advice for potential startup company.

MPDCP can provide a statement of support for grant purposes.

[In addition to MPDCP feedback, the CTTC licensing team is available to discuss further details on invention disclosures, patents, seeking licensing with a company, and protection of intellectual property.]

MPDCP PROGRAM *ANSWERS*

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- Where to begin the process? Is the device/agent/invention FDA regulated? Is an IDE required?
- What guidance and standards are available or applicable?
- What testing would need to be considered to use a prototype device in a clinical trial?
- What are the potential costs? What are the timelines that need to be considered? Is a grant or other funding involved?
- Are there any other products on the market that are comparable?
- Have potential stakeholders been identified?
- What are the considerations for developing a regulatory strategy?
- How should the device be described? (Class of device, claims, funds, study population, where will the device be used, or drug or IVD used)

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MDRAP Program

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MEDICAL DEVICE REGULATORY AFFAIRS PROGRAM

MDRAP *Guidance*

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MDRAP offers guidance on IRB and FDA perspectives & processes for investigational devices

- Find relevant FDA guidance documents and standards for specific device types (e.g., appropriate cleaning protocols for multiple patient use devices, safe use of lasers, In Vitro Diagnostics, MMA, Clinical and Patient Decision Software)

- MDRAP reviews the IRB and FDA Applications to identify any areas that may be deficient in description for the FDA or IRB. There are common deficiencies found in IRB and IDE FDA Applications.

MDRAP *IRB*

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- The IRB notifies MDRAP when there is an investigator-initiated device study submitted that will be using an investigational device.
- We (MDRAP) provide a supplementary review to the IRB regarding the regulatory status of the device.
- We facilitate the IRB review, by providing a written review and the Committee can reference our input as needed.
- We do not provide recommendations for approval or disapproval of IRB studies (this remains responsibility of the IRB).

MDRAP *Services*

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Offer Regulatory Consultation for investigator-initiated device research– regulated medical device or not?

Determined by the definition of device under section 201(h) FD&C Act

Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is:
1. An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
2. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
3. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
4. intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and
which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

The term "device" does not include software functions excluded pursuant to section 520(o).

MDRAP *Software Function*

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The 21st Century Cures Act amended the "device" definition under the FD&C Act to exclude specific kinds of medical and decision support software from FDA's jurisdiction (section 520(o)).

The intended use or function determines if it can be excluded.

Examples of excluded software functions are:

Software intended for administrative support of a health care facility (e.g., billing, admitting)

Software intended for maintaining or encouraging a healthy lifestyle

Software intended to serve as electronic patient record (the equivalent of paper medical chart)

Software (previously regulated as a class III medical device), such as Medical Device Data Systems (inter-communication between hardware and software), medical image storage devices, medical image communications devices, and laboratory information systems.

"Policy for Device Software Functions and Mobile Medical Apps, 2019"

MDRAP *CDS*

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Excluded functions –
software for clinical decision support-
with 4 specified criteria.

Briefly, the criteria,

- Not intended to acquire, process or analyze
- Intended for displaying, analyzing or printing medical information about a patient or other medical information
- Intended for supporting or providing recommendation to health care professional
- Intended for purpose of enabling HCP to independently review the basis for such recommendation that such software presents- so the HCP does not primarily rely on the recommendations.

Draft Guidance "Clinical Decision Support Software, 2019"

MDRAP *FDA Discretion*

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Enforcement Discretion

The FDA states,

if the device poses low risk to patients or it is important in advancing digital health, the regulation of the software function will be at the discretion of the FDA for whether they will enforce compliance with the device regulatory controls.

MDRAP *Software*

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FDA guidance addresses many kinds of software

- Software as a Medical Device (SaMD)
- Software in a Medical Device (SiMD)
- Multiple function device products

Final note on software:

- FDA's existing oversight approach considers functionality of the software rather than the platform.
- The FDA intends to apply its regulatory oversight to only those software functions that are medical devices and whose functionality could pose a risk to a patient's safety if the device were to not function as intended.

MDRAP *SERVICES*

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MDRAP will provide a written statement for whether a device function meets the definition of a medical device.

These statements are usually made through review of the IRB application, however, if the Investigator requires a statement independent of IRB review– we can provide.

MDRAP *21 CFR 812*

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21 CFR PART 812 Code of Federal Regulation for Investigational Device Exemption (IDE)

There are three applicable regulatory determinations that can be made for an investigational device.

- non-significant risk
(Abbreviated IDE bestowed by IRB);
- significant risk
(FDA IDE Application is required); or
- exemption from IDE
(If Exemption is met – a risk determination is not required.)

Guidance on device risk determination

Who is required to make a risk determination?

(PI first – then the IRB – finally FDA if necessary)

How it is risk determined?

(risk of device + procedures associated with use)

What determines the risk?

(depends on the potential for serious adverse device effect)

Are there steps that can be introduced to mitigate the risk of a device?

Under regulation 21 CFR 812.3(m), an SR device means an investigational device that:

Is intended as an implant and **presents a potential for serious risk to the health, safety, or welfare of a subject**;

Is purported or represented to be for use supporting or sustaining human life **and presents** a **potential for serious risk to the health, safety, or welfare of a subject;**

Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health **and presents a potential for serious risk to the health, safety, or welfare of a subject;** or

Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

What is a Nonsignificant Risk Device Study? A NSR device study is one that does not meet the definition for an SR device study.

MDRAP *IRB*

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There needs to be an explanation supporting the Investigator's risk determination in the IRB Application.

- Has a rationale for the risk determination been provided?
- Has a risk analysis been done?
- Has the benefit/risk for use of the device been explained?

MDRAP *FDA Submission*

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Assistance & Guidance on the Q-Submission Program –which is the process FDA had developed to allow the Investigator to get early FDA feedback before an official application is submitted to the FDA.

Pre-Submission (IDE, Amendments, Supplements)

Offer our attendance to teleconference meetings with the FDA

Assistance with development and submission (eCopy) for FDA applications

Assist with finding predicate devices – referencing this can provide a list of standards that was required for a similar device and what must meet before it is approved.

MDRAP *Investigator initiated research*

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Facilitate FDA communication

(Locating contact, review of the Pre-submission (Pre-sub IDE) and IDE -Early Feasibility Study Applications, Request for Risk Determination)

Facilitate FDA regulatory documentation

Maintain templates on StarBRITE website for IDE documents, template protocol specific for devices, provide tools for conducting risk assessment, and we can make available templates supporting design control documentation – a requirement for the IDE.

Investigator Initiated Device Research Handbook

(StarBRITE/eSMART Login > Regulatory Resources/Support > IDE Support)

MDRAP

Investigator Initiated Device Research Handbook

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Investigator Initiated Device Research Handbook
(StarBRITE/eSMART Login > Regulatory Resources/Support > IDE Support)

This Handbook describes:

- Describes the basics for the Sponsor-Investigator conducting device research
- The determination of significant risk vs nonsignificant risk
- Requirements for study documents
- Manufacturing the investigational device
- Introduction to Design Control (21 CFR 820.30) and the Vanderbilt Quality Management System (which can contribute to the determination of risk)
- Intro to Device Development Strategy (stakeholder, market, IRB submission)
- Device Classification/Classification Panels/Product Codes)
- Regulatory Pathways (Abbreviated IDE, Pre-Submission IDE (Q-Sub), IDE. 510(k), or possibly De Novo (513(f((2). The PMA development resources likely not available for academia.)
- Devices of particular interest (early feasibility studies and first in human studies, IVD, software, Device Software functions (Mobile Apps, Mobile Medical Applications).
- Medical Device Data System (hardware or software intended to transfer, store, convert formats) The classification of MDDS depends on function which guides Agency enforcement

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CTTC
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Who we are

Launched in May 2014, Medical Products Support Services assists engineers, physicians, scientists, and other faculty investigators who are working to bring innovative medical products out of their laboratories, and progress them toward the marketplace.

MPSS is part of Vanderbilt's Center for Technology Transfer and Commercialization (CTTC).

The MPSS team provides free assistance to Vanderbilt investigators in two areas: the Medical Device Regulatory Affairs Program (MDRAP), and the Medical Products Development and Commercialization Program (MPDCP).

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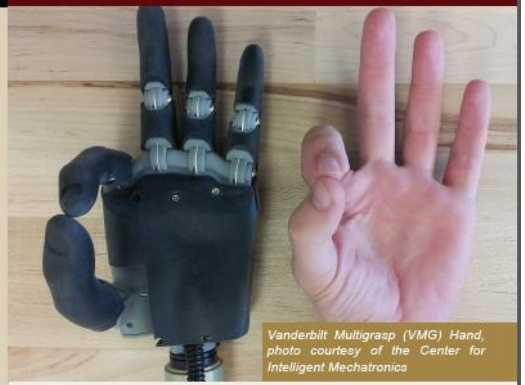
Learn more at www.cttc.co/mpss



Vanderbilt Multigrasp (VMG) Hand, photo courtesy of the Center for Intelligent Mechatronics

What we do

~ Regulatory consultation for early medical device development
~ Guidance on IRB and FDA perspectives & processes
~ Device risk assessments and IDE determination
~ Facilitation of IRB & FDA communication for regulatory strategies
~ Assist with FDA submissions (pre-sub, IDE etc.)
~ Education and training of faculty, staff and students
~ Provide guidance for pre-clinical data to support a clinical study application
~ Assist with regulatory documentation, templates and tools
~ Individualized consultation for your pharmaceutical, medical device, or diagnostic product
~ Provide design control support to build FDA design documentation
~ Early product development planning and commercialization pathways
~ Planning preclinical testing to enable clinical investigations
~ Align academic product testing with FDA and CMS expectations
~ Provide assistance with prototyping, contract manufacturing & testing
~ Facilitate trans-institutional collaboration
~ Provide design control support
~ Support grants as advisors or co-investigators
~ Manufacturing documentation, support and scaling for commercial distribution
~ Support of new ventures based on VU medical product innovations