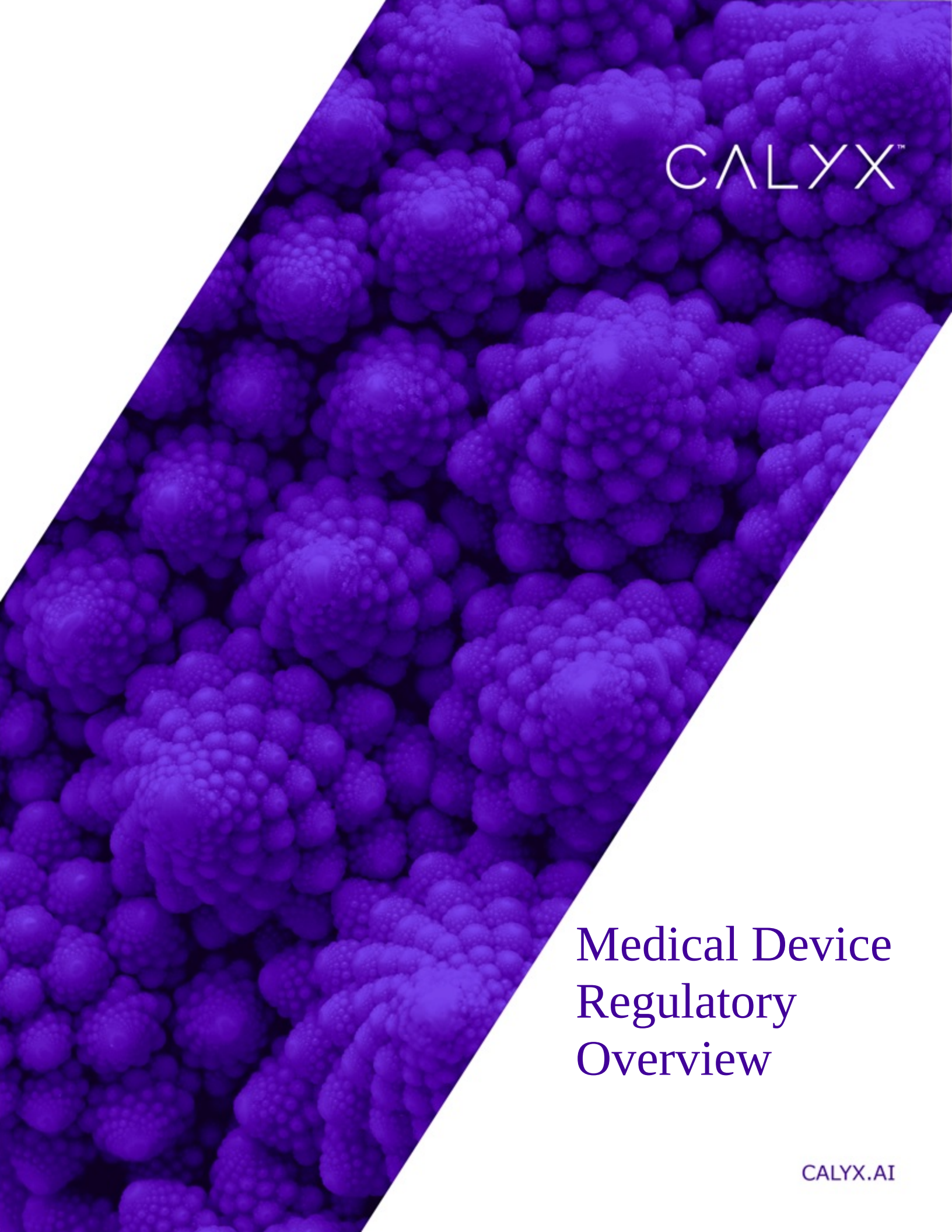

Medical Device Regulatory Overview

CALYX.AI

1 Revision History

When Calyx releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Calyx reviews the Release Notes against each Best Practice to determine any impact to the document:

Impact = Release notes-documented upgrade changes this Best Practice

No Impact = Release notes-documented upgrade changes do not affect this Best Practice

When Release Notes impact Best Practice documentation, Calyx recommends that clients review the entire Release Notes for a full understanding of all changes associated with this Best Practice documentation.

Software Version	Release/ Revision Date	Summary of Change(s)
7.0	02-Aug-21	Creation of Medical Device Regulatory Overview

2 Contents

3 Document Purpose

The purpose of this document is to centralize key Medical Device regulatory information in a central view.

4 Scope

The overview covers key Medical Device definitions, terms, risk classes and owner options.

5 Calyx Definitions

Calyx Definitions	Country	Definition
Medical Device Product Family	Global	The Medical Device Product Family entity represents a data grouping for Products that have the same Intended Use, Indications for Use, Risk Class and essential principles such as design and manufacturing characteristics. (Form, Fit, Function)
Product	Global	Clients may define Medical Device Products in CALYX RIM™ for Registrations in a number of ways: • **Global Model Number (GMN),** which is used for the unique identification of a product model or product family. • **Customer Facing Number (CFN)** or **Stock Keeping Number (SKU)** assigned to a product by the manufacturer for stock keeping purposes and internal operations. • Some companies will use the GMN and CFN interchangeably. • Another alternative is defining Products by the various Presentation and Dimensions As a best practice, a Product Name should contain the same name as the Product Family. The client may complete other Medical Device-specific fields as needed.

6 MD Agency Definitions

MD Agency Definitions	Country	Definition
Component	United States FDA CFR 21CFR820.3	*Component* means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is included as part of the finished, packaged, and labeled device
	Other Options	Some clients define Components by the Global Trade Item Number (GTIN) which represents part numbers. The Global Trade Item Number (GTIN) provides a global supply chain solution by identifying any trade item that may be priced, ordered, or invoiced.
Accessory	United States (FDA Medical Device Accessories Guidance, December 20,2017)	A finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices. Individual accessories may either be classified pursuant to the same regulation as a corresponding parent device, when appropriate, or be regulated independently. **Interpretation**: Generally, refers to a Class I device
	European Union EUR-Lex - 32017R0745 - EN - EUR-Lex (europa.eu)	An Accessory for a medical device means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s) *NB: In Europe an Accessory could potentially not be a medical device.*
Convenience Kit (US) Kit (EU)	United States FDA guidance "Unique Device Identification: Convenience Kits, April 26, 2019.	A convenience kit is "two or more different medical devices packaged together for the convenience of the user" (21 CFR 801.3). FDA interprets this to mean a device that contains two or more different medical devices packaged together and intended to remain packaged together and not to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before being used by an end user

MD Agency Definitions	Country	Definition
		Interpretation: Two or more sterilized medical devices packaged together with package intact upon receipt. Replacement parts may be substituted after use.
	European Union (IVDR Article 2)	A 'kit' means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof **Interpretation**: Two or more devices used for in vitro diagnostic examination.
Medical Procedure Kits (US) Procedure Pack (EU)	United States (FDA guidance "Unique Device Identification: Convenience Kits, April 26, 2019)	A medical procedure kit typically consists of one or more medical devices, packaged together to facilitate a single surgical or medical procedure
	European Union (IVDR Article 2)	A combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose
Drug Device Combination (DDC) (EU) Combination Products (FDA)	EU	For the purpose of this guideline, medicinal products which contain one or more medical devices(s) as an integral part of the composition, as well as medicinal products for which one or more medical device(s) and/or device component(s) are necessary for use of the medicinal product are defined as DDCs. The types of DDCs within the scope of this guideline are medical device(s) and/or device component(s) that are integral to the medicinal product or non-integral (i.e. co-packaged with the medicinal product or referenced in the medicinal product information and obtained separately)
	FDA	A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.
Principal/Ancillary Intended Action (EU)	EU	A medicine that is incorporated within a medical device where the main mode of action is due to the device is called an Ancillary medicinal substance. If the principle intended action of the combination product is achieved by the medicine, the entire product is regulated as a medicinal product.

MD Agency Definitions	Country	Definition
Primary Mode of Action (FDA)	FDA	Primary mode of action is the single mode of action of a combination product that provides the most important therapeutic action of the combination product. The most important therapeutic action is the mode of action expected to make the greatest contribution to the overall intended therapeutic effects of the combination product.

7 Medical Device Risk Classes

Medical Device Risk Classes categorize products based on the complexity of the product and the risk to the patient. The Device Risk Class may impact whether a client will need to create a Registration. Other data points may also be affected.

The table summarizes established categories for the United States and Europe. Risk classifications change per country, and a Class I in the US is not necessarily the same as a Class I Risk Classification in the EU.

Country	Device / Risk Classification	Device Type Examples	Regulatory *Database
United States	Class I, Class II	Convenience Kits Medical procedure Kits Accessories	FURLS website
	Class III	Pacemakers Other complex device w/ high risk	FURLS website
United Kingdom	Class A, B, C, D	General IVDs (in vitro diagnostic devices)	MHRA DORS website
	Class I Class IIa Class IIb Class III	Procedure Packs Custom-Made devices Systems and procedure packs Pacemakers Other complex device w/ high risk	MHRA DORS website
Europe and Northern Ireland	Class A,B,C, D	General IVDs (in vitro diagnostic devices)	EUDAMED database
	Class I Class IIa	Procedure Packs Custom-Made devices	EUDAMED database

	Class IIb Class III	Systems and procedure packs Pacemakers Other complex device w/ high risk	

*** Regulatory Database Notes:**

FURLS: [FDA] Unified Registration and Listing System (online submission system)

MHRA DORS: Medicines and Healthcare products Regulatory Agency (MHRA) Devices Online Registration System (DORS) (United Kingdom Medical Device tracking system)

EUDAMED: European Databank for Medical Devices (database used to monitor the safety and performance of medical devices distributed in Europe)

8 Application Owner Options

Clients should use the *Application* > *Application Owner* field to track their ownership status as it relates to the Med Device Convenience/Procedure kits. The ownership designation may affect the kit data tracked in RIM.

Screens	Fields	Recommended Data: New MD Product or Kit
Client owns and markets single Medical Device	The client manufacturers, registers, packages, markets, and maintains compliance for all elements of the Medical Device Product As Product creators, they must adhere to all Medical Device regulatory requirements AND As Assemblers, they must prove compliance with GMP: Good Manufacturing Processes and may be the target of an audit or site inspection.	**Product Family**: All BP Fields **Product**: All BP Fields **Component**: All BP Fields **Application:** All BP Fields **Event:** All BP Fields **Sequence**: All BP Fields **Registration**: All BP Fields **Product Detail Set**: Optional
Client Manufactures and Assembles Kit Products	The client manufacturers, registers, packages, markets, and maintains compliance for all elements of the MD Convenience & Procedure Kit. As Product creators, they must adhere to all Medical Device regulatory requirements AND As Assemblers, they must prove compliance with GMP: Good Manufacturing Processes	**Product Family**: For each standalone Product **Product**: All BP Fields **Component**: All BP Fields **Application:** All BP Fields • National or EU Applications when product is marketed as a standalone product

Screens	Fields	Recommended Data: New MD Product or Kit
	and may be the target of an audit or site inspection.	• Kit Applications when multiple Products are marketed together as a Kit **Event:** All BP Fields **Sequence**: All BP Fields **Registration**: All BP Fields • National Registrations for standalone products • Kit Registration that includes all Products in the Kit **Product Detail Set**: Optional
Client Manufacturers some, but not all, Kit items, then Assembles Kit	A company may assemble kits that contain their own and 3rd party vendor products. As Product creators, the client must adhere to all Medical Device regulatory requirements AND As Kit Assemblers, the client must prove compliance with GMP: Good Manufacturing Processes and may be the target of an audit or site inspection.	**Product Family**: All BP Fields for all Product Families **Product**: All BP Fields for all Products **3rd Party vendor Products:** represented as Packaging in the PDS **Component**: All BP Fields for all Components **Application:** • National or EU Applications when client-owned product is marketed as a standalone product • No Applications for 3rd Party vendor Products • Kit Application that includes all Products **Event**: All BP Fields **Sequence:** All BP Fields **Registration**: • National Registrations for standalone, client-owned products • Kit Registration **Product Detail Set**: Develop Packaging details to represent 3rd Party Vendor products

Screens	Fields	Recommended Data: New MD Product or Kit
Client Assembles Other Manufacturer's Products into a Kit	Using approved and marketed Products made by other companies, an Assembler creates a kit to the specifications of the company that has hired them. Assemblers must prove compliance with GMP: Good Manufacturing Processes and may be the target of an audit or site inspection.	**Product Family for all Kits**: All BP Fields **Product**: Each Product represents a marketed Kit **Component**: None **Application**: For the Kit Product **Event:** All BP Fields **Sequence:** All BP Fields **Registration**: Kit Registration **Product Detail Set**: None
Authorised Representative (EU)	Authorised representative' is a natural or legal person within the [European] Union who accepted a written mandate from a non-EU manufacturer to register and manage their product(s) in the European Union. **Note:** Many Authorised Representatives can access Product Owner's RIM system	**Product Family**: For each standalone Product **Product**: All BP Fields **Component**: All BP Fields **Application:** All BP Fields • National or EU Applications when product is marketed as a standalone product • Kit Applications when multiple Products are marketed together as a Kit **Event:** All BP Fields **Sequence**: All BP Fields **Registration**: All BP Fields • National Registrations for standalone products • Kit Registration that includes all Products in the Kit **Product Detail Set**: Optional