Definition of Manufacturer

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Definition of Manufacturer

Why is GHTF looking at this?

- Why is GHTF looking at this?
- Define the Players?
- Responsibilities
- Key Players
- Manufacturer
- Other Players
- Experience in Europe

Definition of Manufacturer

Why is GHTF looking at this?

- Responsibility for safety for a device
- Many have a role to play

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Why is GHTF looking at this?

- Responsibility for safety for a device
- Many have a role to play

Seller, user, maker, designer, repackager, importer, distributor, regulator, servicing, repair, assembler, clinician, etc.

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Define the players

So you need to define the players

It has to be clear who you are talking about

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Responsibilities

And why do you have to be clear who you are talking about?

Because you will later assign (legal) responsibilities and tasks

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Key Players

Looking at our systems key players are identified:

- Manufacturer
- Authorised Representative
- Distributor
- Importer

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Manufacturer

The Regulator wants to establish easily the one person who takes regulatory responsibility for a medical device that is marketed within its jurisdiction.

Not as easy as you think?

Maker, designer, steriliser, marketer, distributor, logo, final assembler, corporate entity, national sponsor, refurbishing, etc.

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Manufacturer

Finally linked it to the name on the device, that is, what the consumer (the user) sees

"Manufacturer" means any natural or legal person who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies)

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"Authorised Representative" means any natural or legal person established within a country or jurisdiction who has received a mandate from the manufacturer to act on his behalf for specific tasks with regard to the latter's obligations under that country or jurisdiction's legislation

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"Distributor" means any natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user

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"Importer" means any natural or legal person in the supply chain who first makes a medical device, manufactured in another jurisdiction, available in a country or jurisdiction where it is to be marketed

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Experience in Europe

Problems

Manufacturer	OBL Virtual Manufacturing Reprocessing
Authorised Representative	One or more per manufacturer One or more per device What is their exact responsibility
Distributor	Barely mentioned in the text But has a significant role
Importer	Lost in our text Effectively no responsibility

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Thank You For Listening

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