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Regulatory & Clinical Affairs
Quality Management

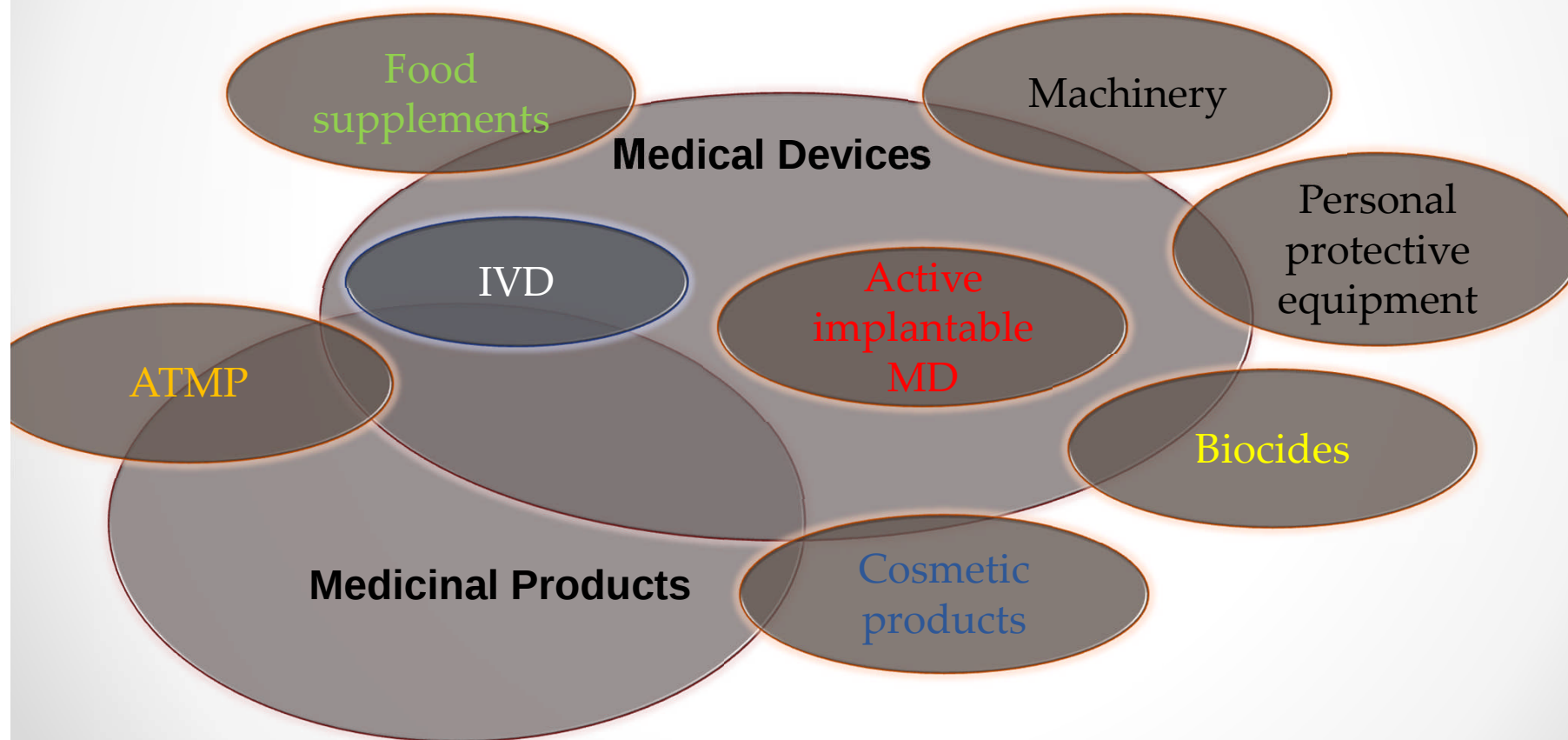
Nano-Tera.ch

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Borderline Issues

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Borderline on what ?



Borderline

1 - What is the intended purpose of your product ?

2 – What is the directive or regulation that applies related to the intended purpose ?

3 – Is the product borderline ?

- **Based on its intended use ???**
- **Based on its technical composition ???**

Some References Europe

Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative:

- http://ec.europa.eu/health/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf

Borderline Manual – classification – device cosmetic, medicinal product :

- http://ec.europa.eu/health/medical-devices/files/wg_minutes_member_lists/borderline_manual_01_en.pdf

Cosmetic products directive:

- <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009R1223&from=EN>

Nano Materials:

- http://elc-eu.org/uploads/news_documents/ELC_updated_position_on_Nanotechnologies_-_22_Nov_2011.pdf
- <http://ejlt.org/article/view/93/158>
- http://scholarworks.umass.edu/cgi/viewcontent.cgi?article=1118&context=dose_response

Some References USA

Borderline cosmetic - drug:

- <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm#Both>

Device – not a device ?:

- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051521.htm>

Combination product :

- <http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm>

Nano Materials:

- <http://www.fda.gov/cosmetics/guidanceregulation/guidancedocuments/ucm300886.htm>
- <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm348890.pdf>
- <http://www.fda.gov/scienceresearch/specialtopics/nanotechnology/ucm309678.htm>

End of part 9. Borderline Issues

Followed by part 10 QSR / ISO 13485 (Pierre-Alain Sommer)