Agenda

• Legal classification of 3D Printing
• Current regulation of various types of 3D Printing
• Intellectual Property Right Issues
• Data Protection Aspects
Legal view on 3D Printing

• Production Facility
  • Production facilities for medical devices and medicinal products are regulated
  • EU-Directives and Regulations, national laws, ISO 13485
• Final Product
  • Regulated as medical device, ATMP or other product
• Raw Material
  • Raw material for medical devices and medicinal products are regulated
  • Harvest, storage, transport and use of biological material is regulated
Legal view on 3D Printing

• Production Process
  • Quality system required for manufacturing process of medical devices and medicinal products
  • National competent authorities and Notified Bodies may classify design and production tools as medical devices, e.g. design software

• Personal Data
  • Personal (health) data might be collected, stored and used during manufacturing chain
  • Customization might link product to an individual person
Production Facility

- Production Facility: 3D Printer
- Currently regulated under EU Machinery Directive 2006/42/EC
Raw Material

• Chemical substances regulated under Regulation 1907/2006 (REACH)
• Living cells and tissues regulated under Directive 2004/23/EC
• Special rules apply to medical devices manufactured utilizing animal tissue (Commission Regulation 722/2012)
Final Product

• Can be a medical device or an accessory to a medical device and regulated under Directive 93/42/EEC

• Can be an ATMP and regulated under Regulation 1394/2007
Final Product

• Can be a medicinal product and regulated under Directive 2001/83/EC

• Can be none of the aforementioned categories
  • Pre-op models
  • Tissue models for research, drug discovery
Medical Device Law

• Current position of regulators: custom-made medical devices
• Prescription by physician defines the features of the final product
• Production technique is standardized
ATMP Regulation

- Tissue Engineered Product or a Combined ATMP
- If a product contains viable cells, it is an ATMP even if the principal mode of action is structural
  - Reversal of standard rule for medical device vs medicine
- Unlikely to be a “mere graft” unless cells (or tissues) are
  - minimally manipulated; and
  - used for same essential function
- Could argue that autologous product is not placed on the market
- Could argue that not manufactured within an industrial process
GMP Requirements

• Current ATMP GMP requirements assume a central manufacturing facility
• Unpractical for bedside 3D printing
• National Competent Authorities are risk averse
• Consider “Hospital Use Exemption” rules (especially in Germany and Spain)
  • Does not require trial data
  • Requires GMP “equivalence”
  • Can charge patients for therapy
• ATMP Regulation scheduled for revision
  • Could change autologous and combined ATMPs
Intellectual Property

• Copyrights for
  • Software
  • Software model for device or body part

• Patents for
  • Printing method
  • Final product
  • Printing materials

• Human body itself cannot be a patentable invention
• Elements isolated from the human body or otherwise produced by my technical processes may constitute a patentable invention

• Various competing solutions to attempt to resolve IP issues
Personal Data

- 3D printing involves collection, processing and storing personal health data
- Data controller has regulatory requirements, such as data processing agreement with third parties
- Personal health data might be exported outside the EU
- Some of the existing Guidance Documents by Working Party are relevant for 3D printing
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