Workshop: Traceability zwischen MDR, Knowledge Units und Dokumenten

Business Pain

Benannte Stellen

- Von aktuell knapp 60 sind bislang 7 für die MDR zugelassen.

- 80 bis 90% der Zeit wird benötigt um Informationen in Techfiles zu suchen.
  - Mehraufwand bei Benannten Stellen
  - Verzögerung von Marktzulassungen

- Neue Firmen können nur beschränkt aufgenommen werden oder gar nicht.

Inverkehrbringer

- Workload erhöht sich durch die MDR
  - Workload bleibt höher, es ist nicht nur ein peak
  - Reduktion R&D Team, Aufstockung Regulatory Team
  - Bestehende Produkte rentieren sich z.T. nicht mehr

- Ohne Benannte Stelle gibt es das Produkt nicht mehr am Markt.

Patienten

- Versorgungsrisiko - Produkte verschwinden vom Markt

Verschwendung, die man angehen kann…

Zu hohe Komplexität

Mehr machen als nötig

Informationsfluss blockiert

Inkonsistente Informationen

Hoher Workload / Überlastung

Informationen nicht finden

Fehler spät im Prozess erkennen

CE Zulassung wegen Mängel abgelehnt

Warten / Verzögerungen

. . .

Nacharbeit am TechFile

Regulatory als Innovator

Knowledge Units

Informationseinheiten unterstützen eine effiziente digitale Transformation von Medical TechFiles.

… etwa 1/3 der Informationseinheiten werden in mehreren Prozessen benötigt

Beispiel

Re-Use in vielen Dokumenten

Koordinationsbedarf mit vielen verschiedenen Organisationseinheiten

Aktueller Status

Aufbau einer KU (Draft)

Attribute einer offiziell freigegebenen KU

KUID	Centrally assigned ID for this type of knowledge unit. ID shall be without semantics
Name	Human readable name for the knowledge unit
Public	Planned // draft // agreed // released // under change // blocked
Reference	GHTF/SG1/N70:2011, MDR Artikel 2 (12), ISO 14971, IEC 60601-1:2013,…
Single / Composite KU	KU may contain other KUs (thus it is composite KU)
Derived KUs	Sub-KUs that compose the information for this KU. (e.g. Intended Purpose: Medical Purpose, Patient Population, User Group, Conditions of Use)
Effected Documents	Documentation that requires such knowledge unit information (e.g. UEF, RMF, PMSR,…)
Source of origin	Source where the information comes from (e.g. Techfile chapter 1.1 (a))

Zusätzliche Firmen spezifische Attribute

Status	Depending on company policy (open, draft, approved, released, under change, blocked)
Status comment	e.g. missmatch is under clarification between Usability Departement and Product Management
Validity	e.g. review before next yearly update of risk benefit analysis at dd.mm.yyyy
Applicable for	e.g. products, product families, variants of products
Content	Actual content of the KU

Medical Devices Regulation 2017/745, Annex II

KU — Draft / Agreed / Defined

Additionally required Documentation (Draft, tbd)

Documentation columns: Animal Study Test Reports · Biocompatibility & Toxicology Test Reports · Cleaning & Disinfection Validation Report · Clinical Evaluation Plan · Clinical Evaluation Report · Clinical Investigation File · Declaration of Conformity · Device Specifications · Instruction Manual - Sterilization · Instructions for Use · Intended Purpose · List of applicable Standards · Literature Review Plan · Literature Review Review · Manufacturer Sterilization Process Description · MDR GSPR Checklist · Non-clinical Publications · Other Labelling and Promotional Material · Patient File Stickers/Cards & Implant Registration Cards · Patient Labelling Documents · Physician Labelling Documents · PMCF Plan · PMCF Report

1. Device description and specification, including variants and accessories

1.1 Device description and specification

Annex II clause	KU Draft (keyword)	Documentation marks
(a) product or trade name and a general description of the device including its intended purpose and intended users:	Product name	
	Device description	
	Intende purpose intended users	Clinical Investigation File (x); Intended Purpose (x); List of applicable Standards (x); PMCF Report (x) — *Beispiel Intended Purpose*
(b) the Basic UDI-DI as referred to in Part C of Annex VI assigned by the manufacturer to the device in question, as soon as identification of this device becomes based on a UDI system, or otherwise a clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability:	Basic UDI-DI	
	Identification	
(c) the intended patient population and medical conditions to be diagnosed, treated and/or monitored and other considerations such as patient selection criteria, indications, contra-indications, warnings:	Intended patient population	
	medical conditions	
	patient selection criteria	
	indications	
	contra-indications	
	warnings	
(d) principles of operation of the device and its mode of action, scientifically demonstrated if necessary:	principles of operation	
	mode of action	
(e) the rationale for the qualification of the product as a device:	rational of classification	
(f) the risk class of the device and the justification for the classification rule(s) applied in accordance with Annex VIII:	risk class	
(g) an explanation of any novel features :	novel features	
(h) a description of the accessories for a device, other devices and other products that are not devices, which are intended to be used in combination with it:	accessories	
(i) a description or complete list of the various configurations/variants of the device that are intended to be made available on the market:	configurations	
(j) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality and, where relevant, its qualitative and quantitative composition. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams:	key functional elements	
(k) a description of the raw materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids:	contact raw materials	
	indirect	

Knowledge Units
im Ecosystem

Normen

Meddev

Eudamed

Common Specifications →

Nationale Stellen →

Benannte Stellen ↔

Knowledge Units

→ Tool Anbieter

→ Inverkehrbringer

→ Supplier & Subcontractors

- Release Management
- Configuration Management
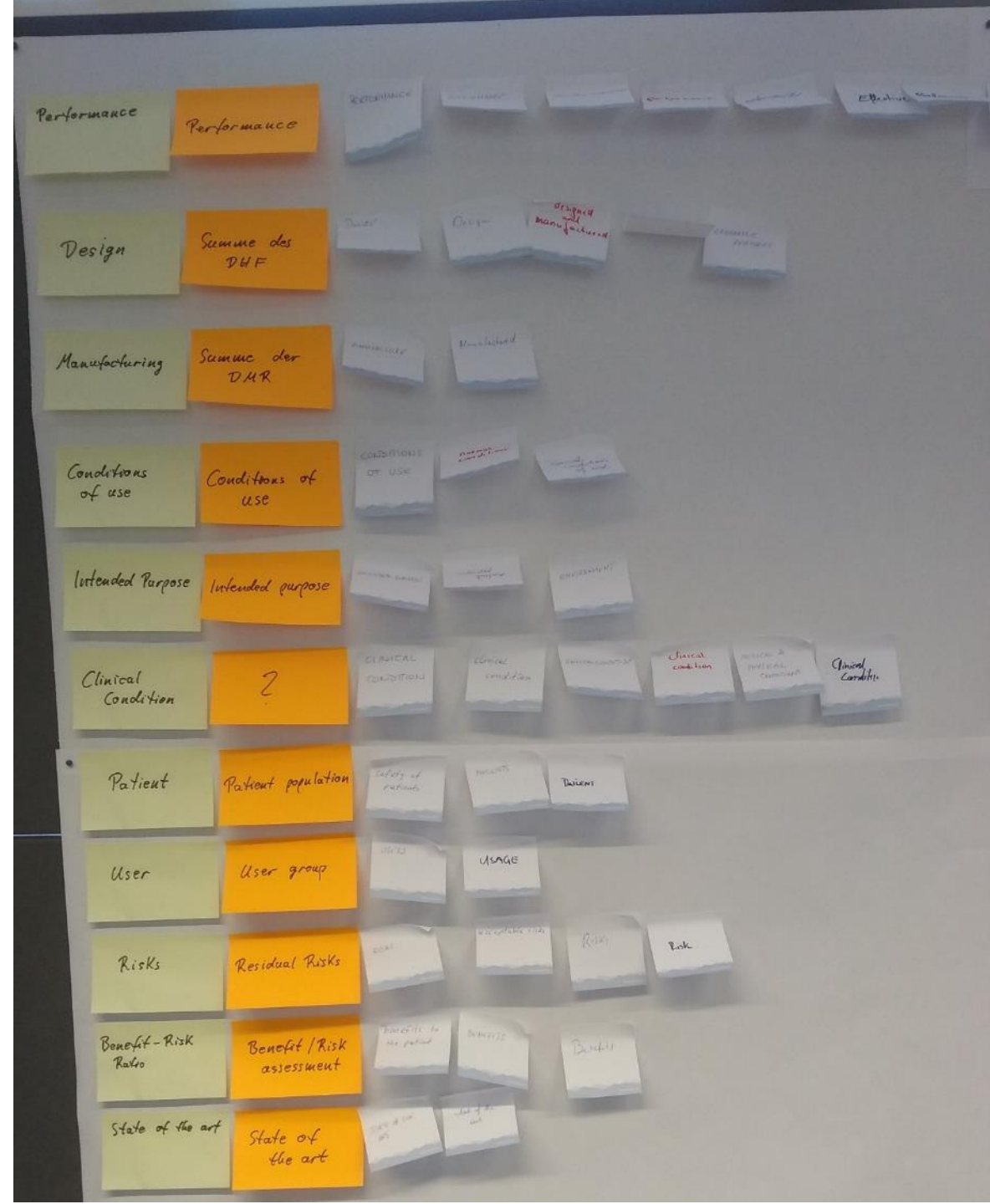- Usage guidance & support
- …

Workshop

Gruppenarbeit

- Gruppen von 3-5 Personen

- Knowledge Units identifizieren

- Sammlung & Diskussion der Ergebnisse

- Knowledge Unit Beispiel

  - Aufbau einer KU

  - Dokumente, welche diese KU nutzen

- Besprechung von Nutzen & Herausforderungen

Welche KUs finden wir in der GS&PR?

1	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

Welche KUs finden wir in der GS&PR?

5	In eliminating or reducing risks related to use error, the manufacturer shall:
	(a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
	(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

Erkenntnisse der ersten Übung

Beobachtungen

- KUs werden von Personen unterschiedlich benannt

- die Anzahl an erkannten KUs ist ebenfalls verschieden

Erkenntnisse:

- Es ist also wichtig eine allgemein gültige Identifikation und Benennung von KU zu erhalten

Inhalte und betroffene Dokumente einer KU

Beispiel KU: «User»

Erkenntnisse der zweiten Übung

Beobachtungen

- Das Verständnis zum Inhalt einer KU wird unterschiedlich gesehen

- KUs können in vielen verschiedenen Dokumenten benötigt sein

- KUs werden in den Unternehmen von vielen verschieden Gruppen benötigt
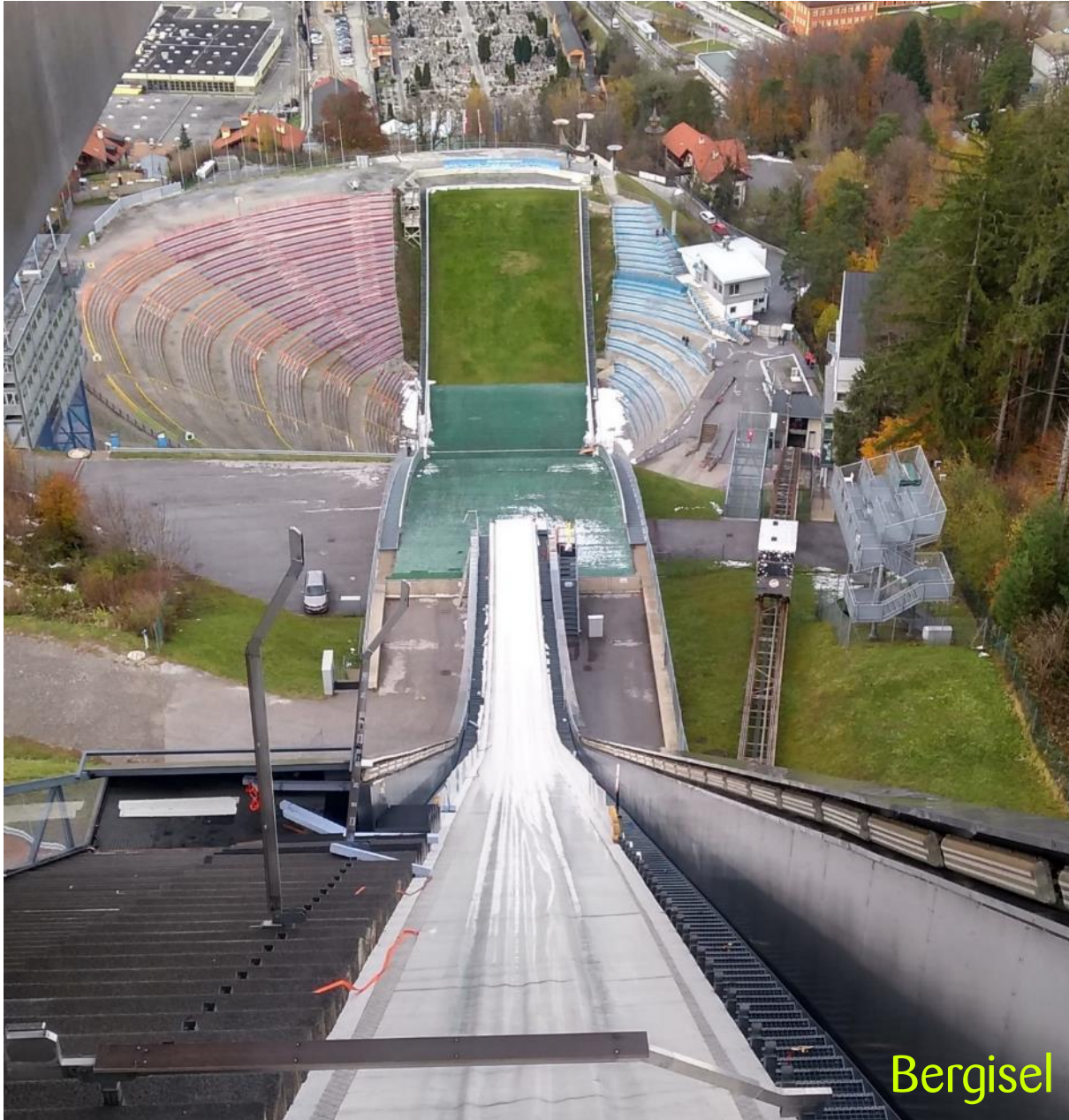
Erkenntnisse:

- Es ist also wichtig eine allgemein gültige Definition und Benennung von KU zu erhalten

- Definition und Benennung sollte von offiziellen Behörden oder Benannte Stellen kommen.

- Etliche Verschwendungen können dadurch vermieden werden.

Nutzen und Herausforderungen …

Bergisel

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