LEADING REGENERATION

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Snapshot of a journey into the MDR

Experiences & Lessons Learnt

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Personal profile

Chantal Benz

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Geistlich Pharma AG

Main responsiblity about EU/EFTA
Expert in MDR implementation

Point of contact in RA for manufacturing and packaging, GSPR, standard handling, change assessments, TD submissions

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Geistlich at a glance

Our product portfolio

BU Dental
(Dentistry, Oral and Maxillofacial Surgery)

BU Medical
(Sports Medicine, Spine Surgery, Wound Care & Infectiology)

Medical Devices Class III

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TD = Technical Documentation

Experiences in planning of TD submissions

Structure in submission planning

- Stagger TD submissions:
  Similarity in products & TD contents

→

- Relief in terms of time bottlenecks and handling issues at Mfr. & NB
- Embedding of Lessons Learnt & adjustments based on deficiencies

- Planning ahead of time frames for review at NB
- Close exchange & coordination with NB

- Complete overview of all planned TD submissions and their dates

→ Projects at NB created (far) in advance

Experiences in planning of TD submissions

Factors influencing planning reliability

- Bottlenecks in availability of experts at NB
  (clinical, biocompatibility, etc.)
- Specific consultations at authorities
  (Expert Panel)
  (animal origin, medical)
- Duration of review at certification body
- Internal availability of Subject Experts
  (questions during review might cause deficiencies, deficiency reports)

- Planning of time buffer
- Close planning with NB:
  Demand and schedule realistic timelines
  Proactively ask for deadlines
- Regular update to internal stakeholders

→ Reducing probability of time issues

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Experiences in planning of TD submissions

Organisational structure

- Designation of responsible Submission Lead(s):
  - Overview of all timelines of TD submission(s)
  - Central contact point for exchange with NB
  - Main responsibility for deficiencies handling
  - Coordination of Subject Experts
  - Internal communication center

- Designation of responsible Subject Experts:
  - Reponsibility for respective content in TD
  - Answering of questions and deficiencies

Experiences in planning of TD submissions

Phase Out Legacy Devices (no MDR certification planned)

- Cost/Effort-Sales Analyses
  (incl. Lifecycle Management)

→ Business case for need of products

Calculation of maintenance of Technical File
(financial and human resources)

- Consequences of Phase Out in EU/EFTA on other countries
  (early communication to stakeholders in the market)

Q&A to implementation of Regulation (EU) 2023/607

- Sales planning of existing stock
  (26th May 2024 in regard to requirements set out in Regulation (EU) 2023/607)

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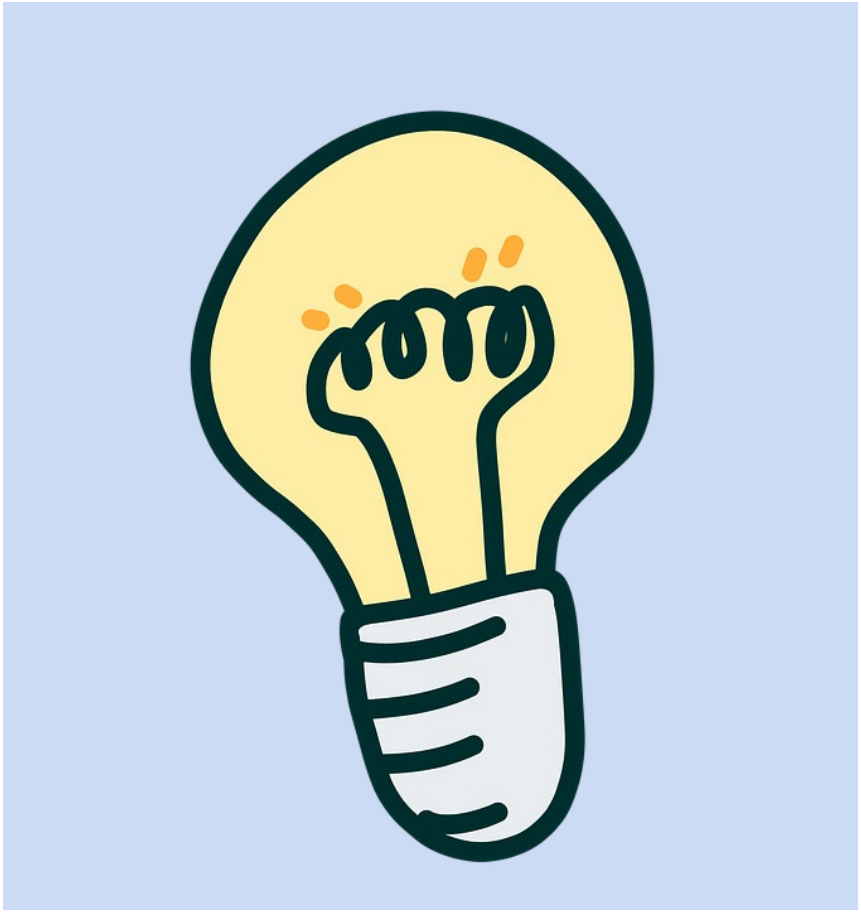
Lessons Learnt

Focal points in the review of the TD

- Fresh evaluation of TD for Legacy Devices
  (although MDCG 2022-14)
- Clinical evidence and claims
- IFU and SSCP
- Packaging
- Proper Process Validations:
  Sufficient description of worst case products



Lessons Learnt

Concerning TD submissions

- Fix TD structure / chapter order
- Deficiency Reports:
  - Early clarification with NB
  - Challenging of deficiencies

- Ask questions
- Adherence of review timeframes

- Take into consideration solved deficiencies in further TD
- Constructive escalation culture:
  Mutual understanding between MUST of NB and CAN of Mfr.
- Mfr. and NB TOGETHER through MDR transition:
  Honesty, openess, transparency on both sides

Handling of product changes during MDR transition

1. Challenging of internally requested changes:
   Importance and urgency?
2. Classification of changes (non-substantial / substantial, non-significant / significant)
3. Implementation:
   - Clarification of dependencies (priorities concerning content and time)
   - Different scenarios:
     - Shifting after the MDR-certification
     - Embedding into the MDR-certification
     - Accelerating:
       - Change Notification under MDD if possible
       - Consider fast track for change review at NB

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Handling of product changes during MDR transition

- Explanation of priorities and dependencies internally and to NB

- Close coordination
- Transparent communication to avoid bottlenecks / consequences for Mfr.

- Increased complexity

Overview essential

Handling of product changes during MDR transition

- Possible impact from changes under MDD during MDR transition on TD assessments

  - Time delay
  - On hold setting of assessment modules
  - Risks on reopening of assessment modules

- Priorisation and planning of change submissions in advance
- Consider fast track for change review at NB

Experiences in planning of Phase Out of Legacy Devices and Phase In of MDR-compliant devices

Basis: Different REF (MDD- vs. MDR-compliant Medical Devices)
Patient Implant Card already introduced for all products

- Change Request: Define actions and making measures traceable
- Sales Planning 
  - Product amount needed to perform conversion from MDD- to MDR-compliant devices
  - No sales stock necessary (extended timelines set out in Regulation (EU) 2023/607)
- Labelling and administrative measures: Define time point/batch to convert
- Update internal EUDAMED master data sheets
- Market / stakeholders to inform (transition period)

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Thank you for your attention

Questions

The Regeneration Company