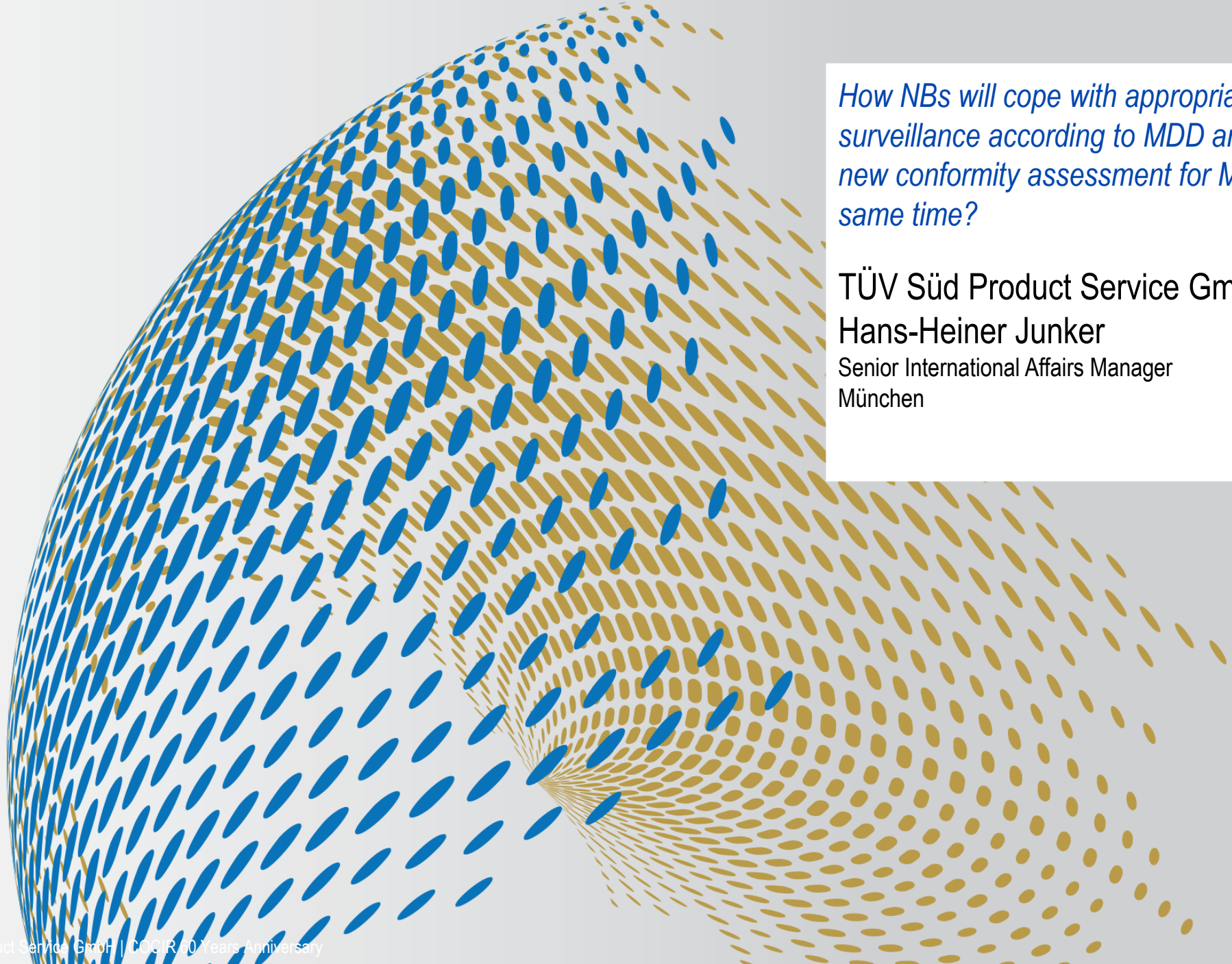

How NBs will cope with appropriate surveillance according to MDD and new conformity assessment for MDR at same time?

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Mehr Wert.
Mehr Vertrauen.

Add value.
Inspire trust.

One – out of many - Challenge

Challenge

Transition from MDD to MDR

- Old QM System
- Combination of old and new system

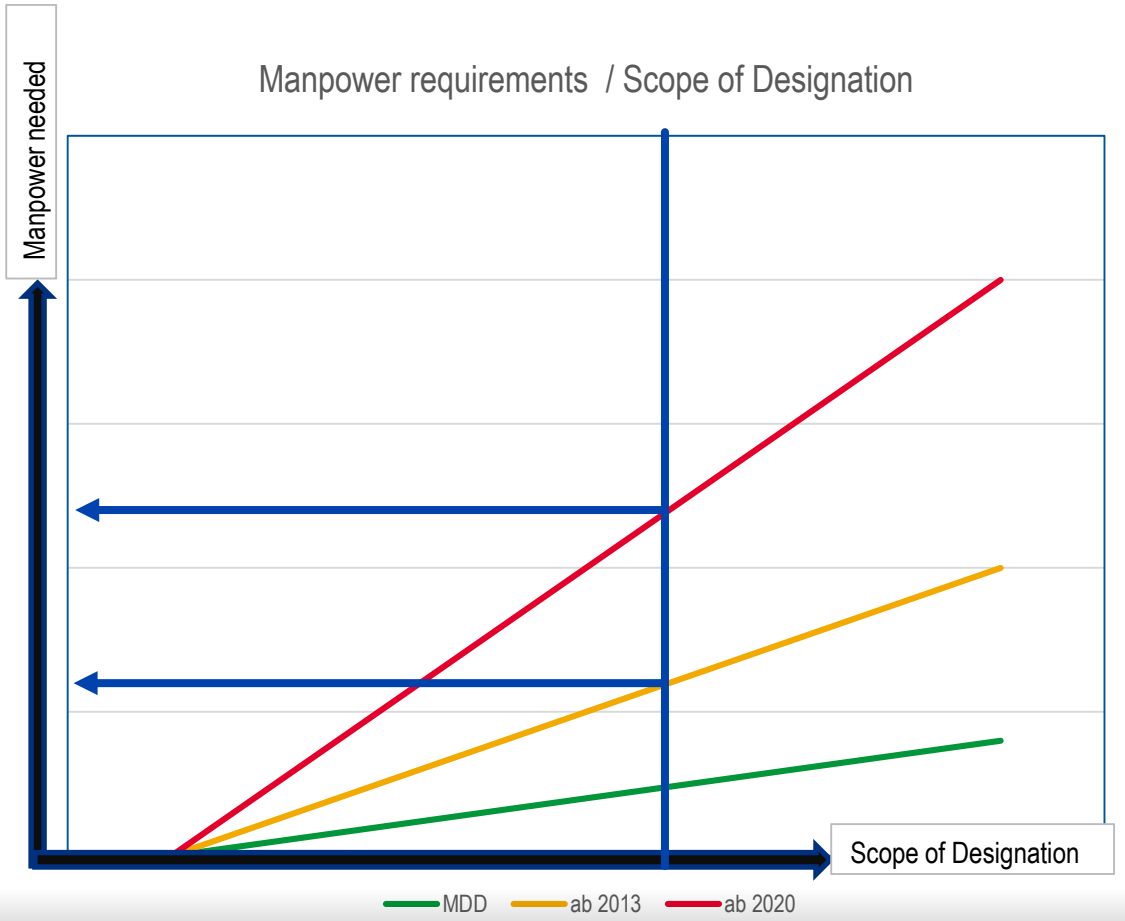
Scope of Designation

- Increase on product experience
- More experts needed for same scope

Effect on:

- Notified Bodies
- Manufacturers

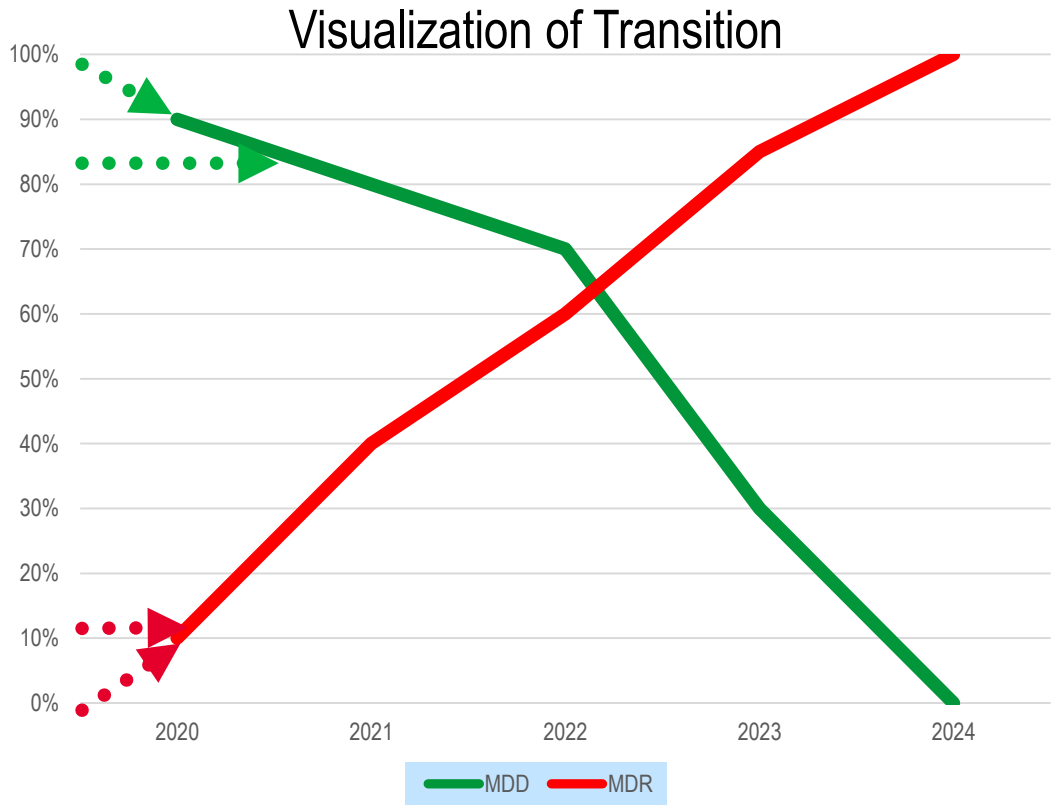
Relationship Personnel – Scope of Designation



Transition from MDD to MDR

Challenges to combine

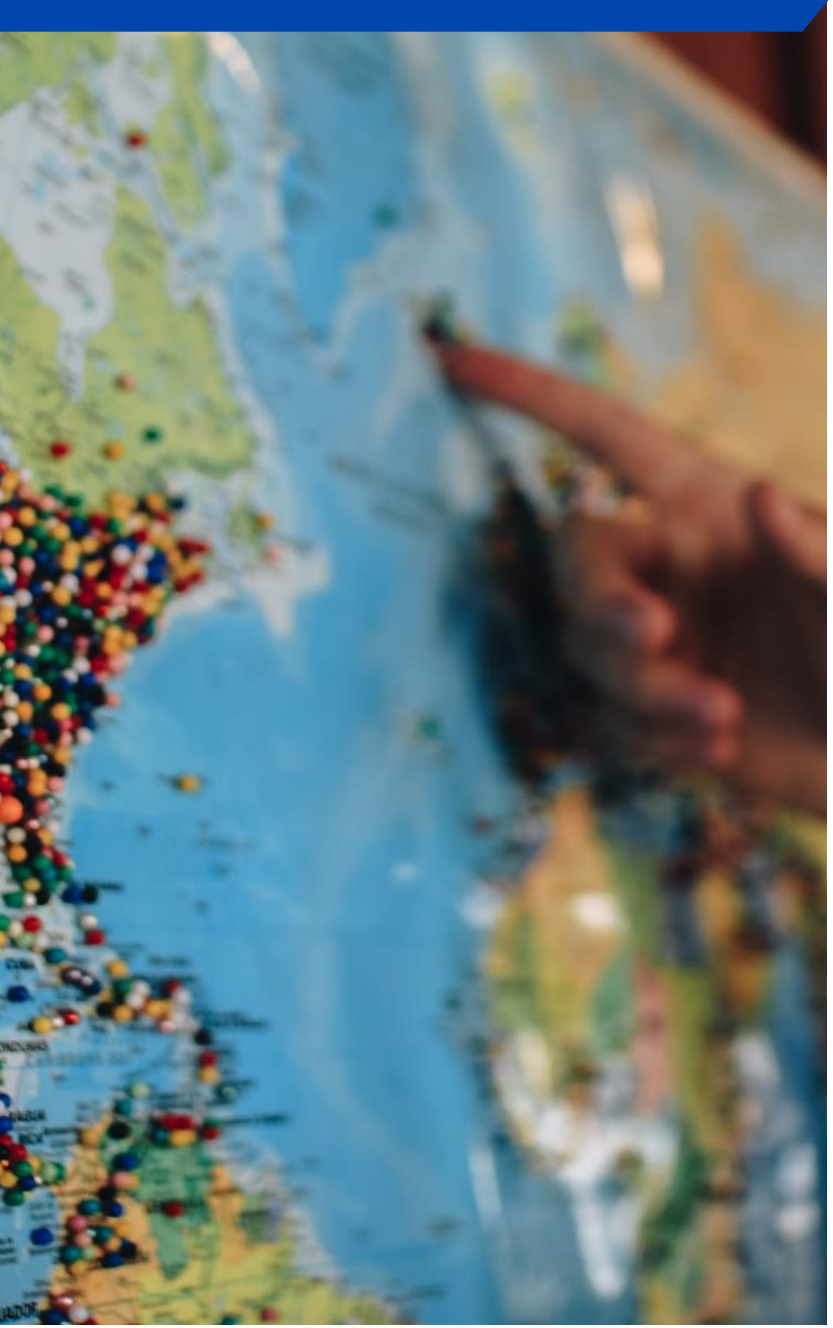
- Different QMS Systems (manufacturer)
- Several jurisdictions
  - MDD, MDR, ISO, MDSAP, ...
- Big time on TD assessment
  - New MDR Sampling plans
  - More time for assessment of one TD
- MDD TD Assessment
  - PSUR Requirements
  - PMS, PMCF
  - Significant Changes
- One File for MDD in 2022 – the very next year for MDR?
- Some Notified Bodies increased their staff dramatically (2- or 3 fold) in the past years



What we are working on

- Providing input on: Harmonization on global level
- Providing input on: Harmonization on European level
- Input means:
  - What means: significant changes according to MDR Article120?
  - What means: appropriate surveillance of MDD/AIMD/IVDR?
  - Harmonization of auditors and experts by providing training
  - Understanding the effect of the new nomenclature on sampling plans
  - Many questions regarding classification. What is a screw?
  - Content of Technical Documentation: data from production phase, language, details
  - …….
- Input means also: additional resources for NBCG/NB-Med

Very
First
Experience



Planning & Preparation

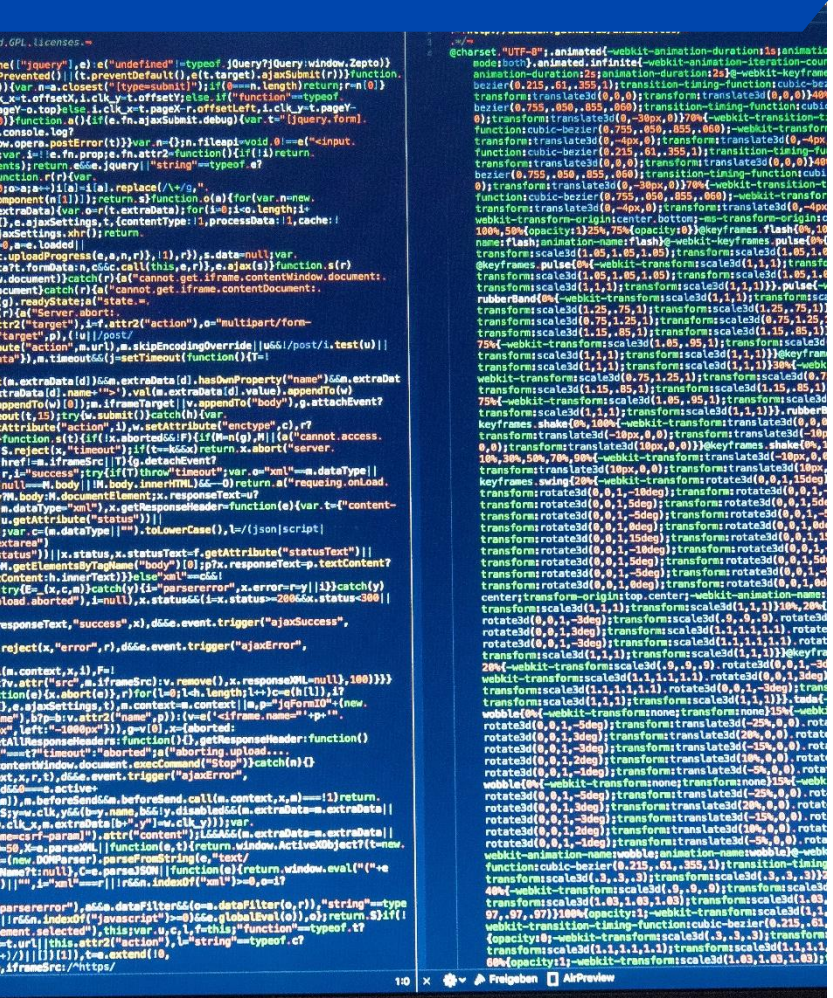
- Huge focus on the contract review and application
- Authorization requirements (especially for legacy devices) broader; more scope necessary >> Audit team
- Demonstrating competency for notified body personnel more complex

- Full auditing readiness of manufactures not given
  ➢Delay of audit schedule

- Stage 1 / 2 setup is no challenge so far

Auditing

- SOPs for requirements from the MDR sometimes not in place due to focus on ISO 13485
  - Technical Documentation requirements
    - create
    - update
    - control
  - Language requirements
    - Manuals / Labels / Information provided with the device
    - Information provided through Software User Interfaces
    - Information provided on devices
  - CE Marking of devices (Hardware / Software)
  - Selection of applicable Risk Class and Conformity Assessment Procedure



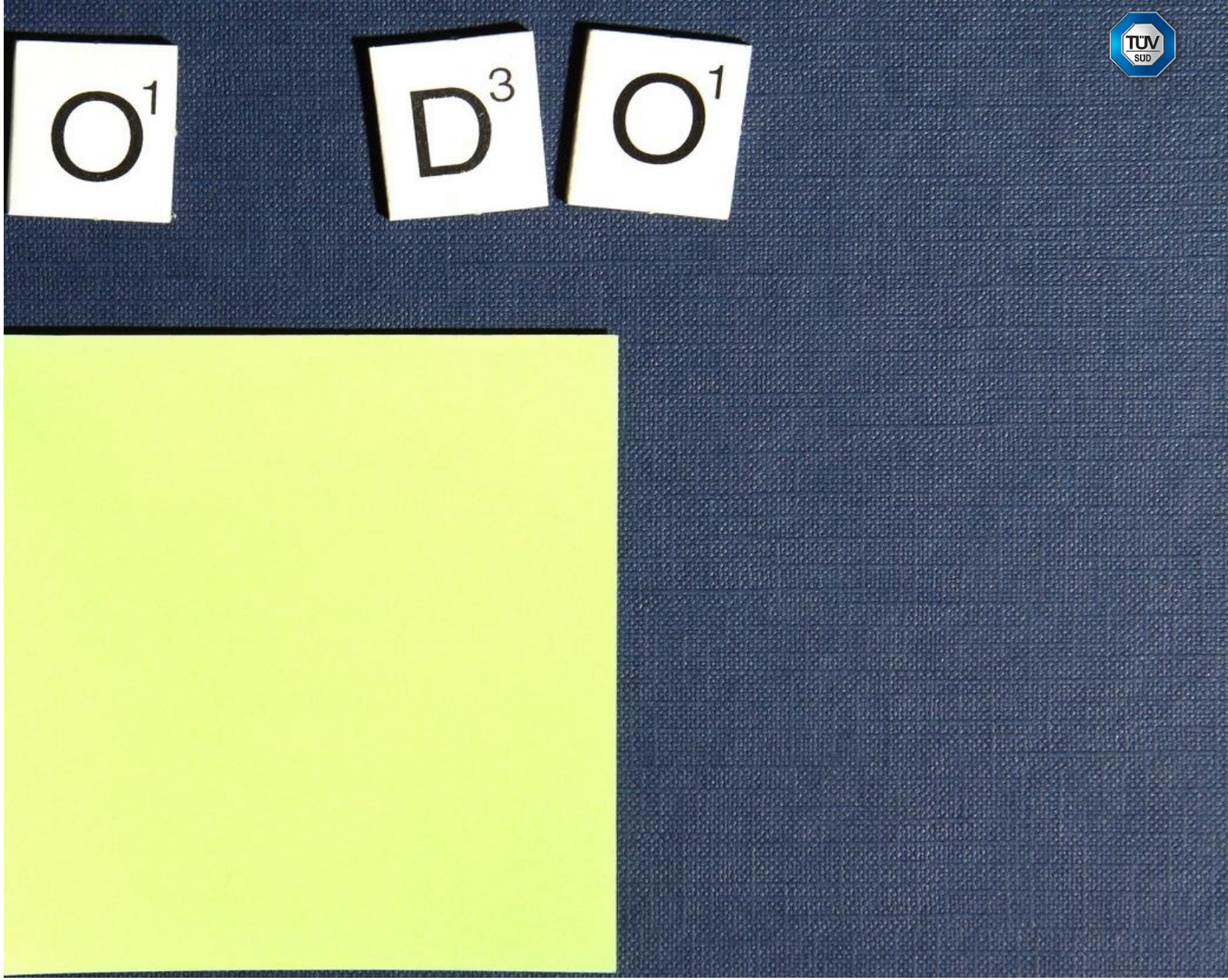
Technical Documentation Assessment

- Consistency was expected to be a huge issue, and it truly is.
  - Wording and consistency throughout the TD of
    i. Intended purpose
    ii. Indications
    iii. Contraindications
    iv. Risks, remaining risks, risk benefit ratio
    v. Claims

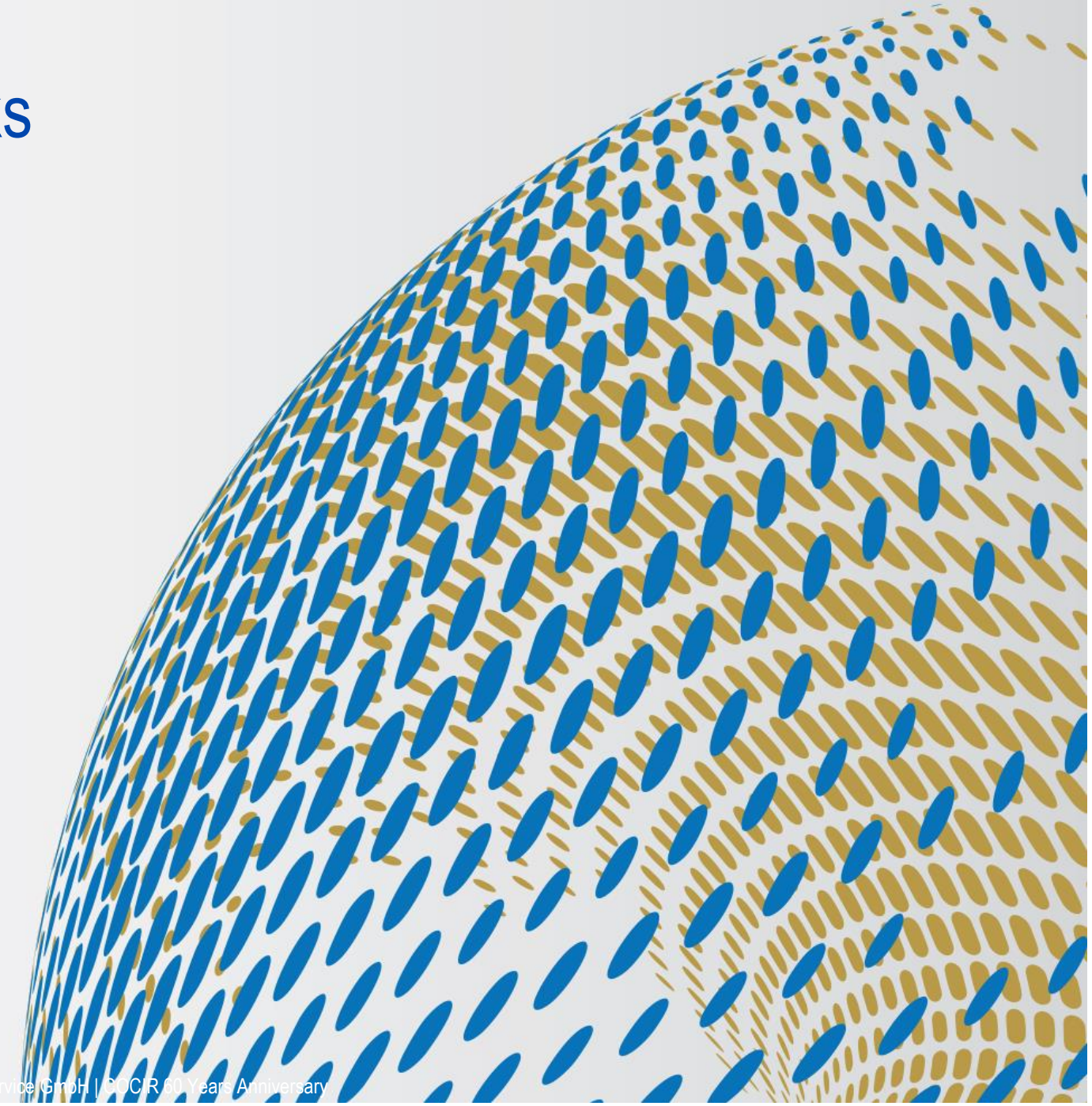
- Completeness of TD
  - Promotional materials >> CER
  - Language requirements and translations
  - Process data ?
  - Verification / Validation methods (GSPR and general)
  - Standards applied and documented evidence showing compliance
  - Information on design stages applied
  - Information on pre-clinical testing
  - Post market activities unclear

Conclusions

- So far no major issues discovered
  - expected challenges did occur
- Documentation effort has increased
  - within expected range
- Consistency & completeness remains the biggest issue
  - More requirements increase this issue directly



Thanks



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