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Common Issues in the Submission of Technical Documentation for In Vitro Diagnostic Devices (IVDs)

The following points summarize frequently observed deficiencies in technical documentation submissions for IVDs. These examples are intended to highlight potential pitfalls and do not constitute formal guidance or recommendations.

Data Completeness and File Submission Errors

- Files are submitted in incorrect formats, such as *.docx files or ZIP files containing unnecessary subfolders (refer to the "*Requirements for Submissions in Digital Format*" available on the mdc website).
- File name length restrictions are not observed.
- Mandatory content required by Annexes II and III is incomplete or missing.
- Points marked as „not applicable" are not or insufficiently justified.
- Evidence of compliance is not clearly assigned or explicitly referenced (e.g., Unique Device Identifiers (UDI), supplier details, Certificates of Analysis (CoA)).
- Product samples for self-testing or near-patient testing devices are not provided.

General Content Deficiencies

- Instructions for Use (IFU) are incorrectly submitted as evidence for the product description, sampling procedures, or sample processing methods.
- The product description lacks critical information, including:
  - Visual representations of the product (e.g., photos or drawings),
  - Components and accessories (as required by the IVDR),
  - Details on combination use (e.g., sample preparation, methods, devices, software),
  - Market release format (e.g., kit, retail packaging, shipping packaging),
  - The countries where the product will be marketed, including language requirements for labelin,
  - Consistent descriptions of product variants across documents.
- UDI information is insufficiently defined or unclear for individual products.
- The intended use does not comply with IVDR Annex I, Section 20.4.1(c), or is presented inconsistently across documents (e.g., Declaration of Conformity, product description, risk analysis, or performance evaluation). Missing indications and contraindications are common.
- The classification of the product as an IVD, as well as the corresponding risk class rule, is not sufficiently justified.
- Raw materials are misclassified, and specifications or packaging materials are incomplete or missing.
- Automated processes (e.g., instruments, software) are not adequately specified, including missing version numbers or revision details.
- Previous product generations or performance data from already marketed products are not clearly described or traceable.
- Labeling and IFUs are incomplete or missing in required languages, and residual risks are not adequately disclosed (e.g., warnings or contraindications).
- The development and manufacturing processes are not clearly documented, particularly outsourced processes and quality controls.
- General Safety and Performance Requirements (GSPR) (Annex I, IVDR) are not fully or transparently justified, and supporting evidence is often inadequately labeled.

- Gaps in risk management are evident, including unclear responsibilities, lack of clinical expertise, and insufficient risk assessments, especially for legacy product.
- Stability testing is poorly documented, with missing test plans or methodologies.
- The use of human, animal, or microbial materials is not sufficiently documented, and related safety evidence is incomplete.
- Post-Market Surveillance (PMS) findings are not integrated into the documentation, and the selection of comparable products or databases for PMS activities is not justified.

Performance Evaluation Deficiencies

A common issue in technical documentation submissions is the absence of a comprehensive and structured performance evaluation plan, particularly for „legacy products“ already on the market. Manufacturers often fail to demonstrate how product conformity will be established. Key details regarding the use of historical data, literature sources, interlaboratory study results, or unpublished internal data are missing. When equivalent product data is used, the equivalence is not adequately justified.

Performance Evaluation Plan

- Justifications for non-applicable analytical and clinical performance characteristics are insufficient or unclear.
- Acceptance criteria for analytical and clinical studies are undefined, or references to relevant standards are missing.
- Statistical rationales for the number of samples or replicates and the selection of users or study groups are inadequately documented. References to applicable standards (e.g., Annexes, tables) are absent.
- Criteria for the acceptability of the risk-benefit ratio are not defined.

Analytical Performance

- Evidence is often based on legacy devices without clearly addressing differences between the legacy product and the product under evaluation. The transferability of legacy data to the IVDR-compliant product is insufficiently justified
- Study design descriptions are incomplete, lacking details on sample materials, acceptance criteria, sample size rationale, and methodology. References to internal SOPs or external guidelines (e.g., CLSI) are insufficient.
- Definitions for outliers and exclusion criteria are missing, and repeat measurements are not addressed.
- Justifications for comparator products and the selection of interfering substances and cross-reactants are absent.
- Combination use, such as integrating multiple devices or methods, is inadequately documented.

Clinical Performance Evaluation

- Qualifications of principal investigators for clinical performance studies are not adequately presented.
- Comparability between the legacy product and the device under evaluation is not sufficiently established.
- Definitions of outliers and exclusion criteria, along with measures for repeat testing, are missing.
- Rationale for not collecting clinical data in user environments or clinical settings is absent.
- Study reports are not signed by an authorized individual or physician. Information on study location, duration, and materials used is often incomplete.
- Results are frequently summarized superficially, without clearly linking individual study outcomes to the test reports.
- Deviations or excluded data are insufficiently discussed or explained.

Data from Literature and Other Source

- Literature search protocols are incomplete, missing search terms, inclusion/exclusion criteria, or key words.
- The state of the art is insufficiently supported or documented.
- When clinical performance is based solely on literature, a detailed summary of both positive and negative findings is absent.
- Risks identified through literature review are not assessed or discussed.

Performance Evaluation Report (PER)

- Data in the PER is not explicitly linked to specific requirements.
- A clear summary explaining how the product meets the state of the art, particularly compared to other products, is missing.