Post-market Clinical Follow-up

Dan O'Leary CBA, CQA, CQE, CRE, SSBB, CIRM
President
Ombu Enterprises, LLC
Dan@OmbuEnterprises.com
www.OmbuEnterprises.com

OMBU
ENTERPRISES, LLC

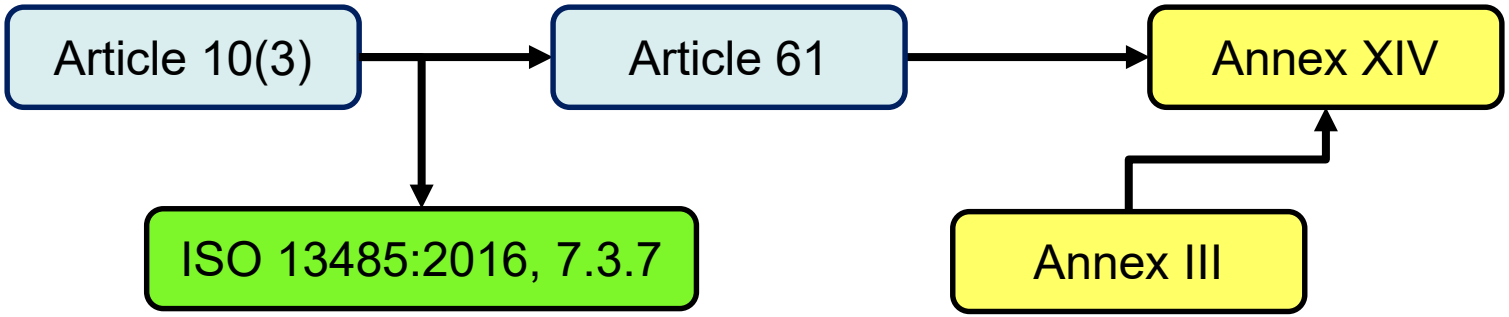
FDANEWS

Topics

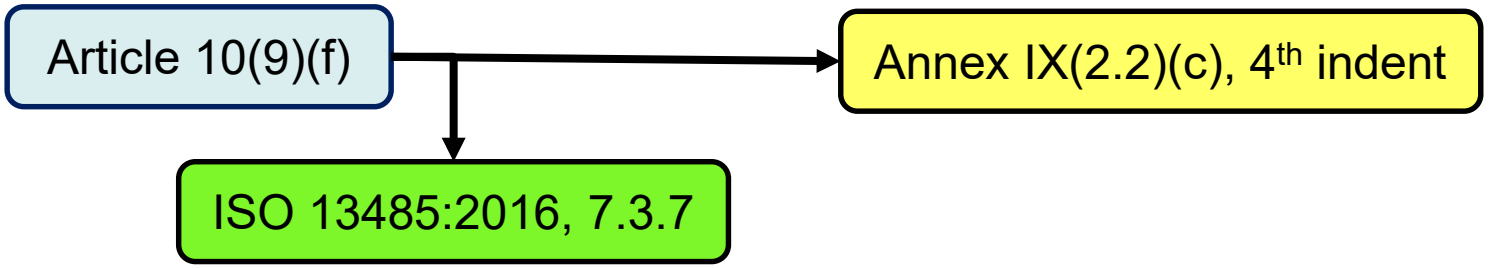
- PMCF Overview
- Determine PMCF Needs
- PMCF Plan
- PMCF Evaluation Report
- Linkage to Other Activities
- Exercise D1 – Developing Elements of the PMCF Plan
- Questions

PMCF Overview

PMCF



PMCF as Part of the QMS



Annex III(1.1)(a)

- The post-market surveillance plan covers:
  - The PMCF plan from Annex XIV, Part B
  - A justification as to why a PMCF is not applicable

Annex XIV(7)

- Analyze the findings of the PMCF
- Document the results in a PMCF Evaluation Report
- The report becomes part of the Clinical Evaluation Report
- The report becomes part of the technical documentation

Report Within a Report

- PMCF Evaluation Report, Annex XIV(7), is part of the Clinical Evaluation Report Annex XIV(4)

Specific Issues

- Article 56 Certificates of Conformity
  - Section 3 says that NBs may:
    - Impose restrictions on the intended purpose of the device
    - Require manufacturers to undertake specific PMCF Studies

- Article 81 Implementing Acts
  - The Commission may create standard electronic forms for PMCF for Clinical Investigation
  - Don’t be surprised if they were to apply in other areas as well

Specific Issues

- Annex II Technical Documentation
- Section 6.1 Pre-clinical and Clinical Data
  - The section, in paragraph (d), requires the PMCF Plan and the PMCF Evaluation Report

Determine PMCF Needs

PMCF Need

- MEDDEV 2.7/1 Revision 4
- 10.2. Specific considerations
- d. Determine PMCF needs
- In order to determine needs, the evaluators should describe residual risks and any uncertainties or unanswered questions. The evaluators should also include aspects such as rare complications, uncertainties regarding medium- and long-term performance, or safety under wide-spread use.

PMCF Need

- MEDDEV 2.12/2 Rev. 2
- 5. Circumstances where a PMCF study is indicated
- Following a proper premarket clinical evaluation, the decision to conduct PMCF studies must be based on the identification of possible residual risks and/or unclarity on long term clinical performance that may impact the benefit/risk ratio.

- PMCF studies may not be required when the medium/long-term safety and clinical performance are already known from previous use of the device or where other appropriate post-market surveillance activities would provide sufficient data to address the risks.

PMCF Plan

PMCF Plan

- The **Post-Market Clinical Follow-up Plan** includes:
  - General methods and procedures
  - Specific methods and procedures
  - A rationale for the methods and procedures
  - A reference to the relevant parts of the Clinical Evaluation Report
  - A reference to the relevant parts of risk management
  - The specific objectives
  - An evaluation of the clinical data relating to equivalent or similar devices
  - Reference to any relevant CS, harmonized standard, and guidance on PMCF
  - A detailed and justified time schedule for PMCF activities

PMCF Evaluation Report

Report

- Annex IX(7)
  - Analyze the findings from following the PMCF Plan
  - Document the results in the PMCF Evaluation Report
  - The PMCF Evaluation Report becomes part of the Clinical Evaluation Report

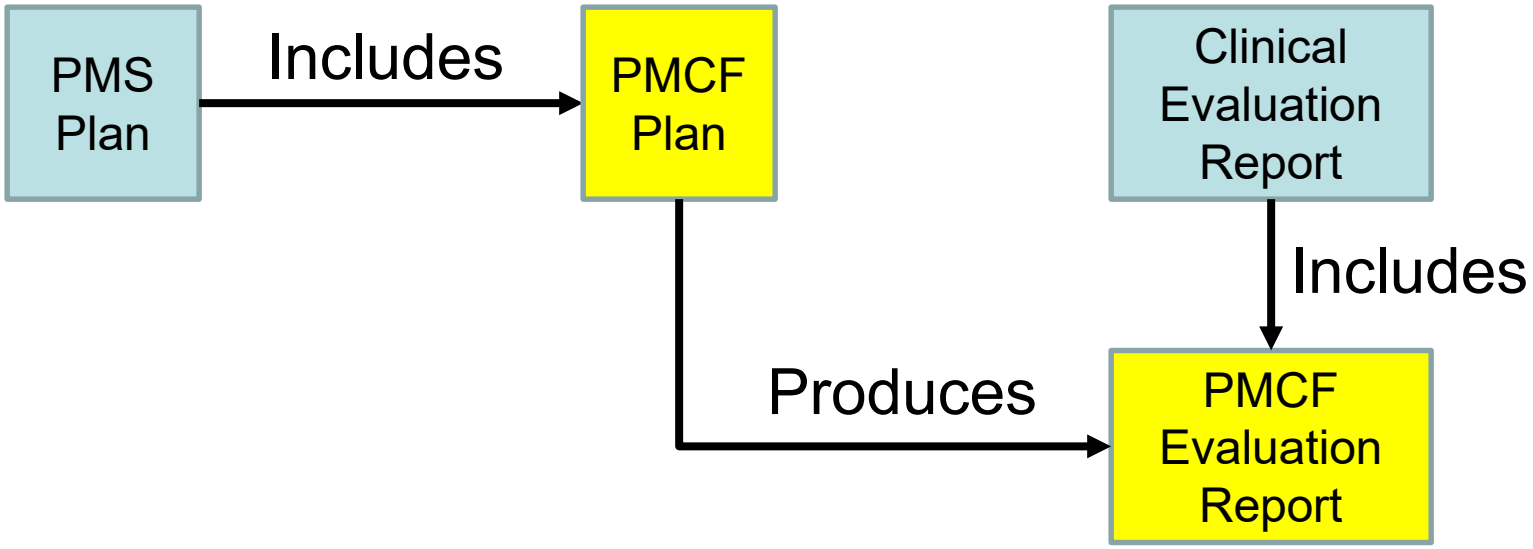
- Annex IX(8)
  - Use the conclusions from the PMCF Evaluation Report for clinical evaluation and for risk management
  - If the PMCF indicates corrective action or preventive action then implement it.

PMCF Updates

- For class III devices and implantable devices, the PMCF evaluation report and, if indicated, the SSCP referred to in Article 32 shall be updated at least annually with clinical data obtained from the implementation of the manufacturer's PMCF plan in accordance with Part B of Annex XIV and the post-market surveillance plan referred to in Article 84. [Art.61(11)]

Linkage to Other Activities

Linkage


PMS Plan
Includes
PMCF Plan
Clinical Evaluation Report
Includes
Produces
PMCF Evaluation Report

Exercises

Exercise D1

- Developing Elements of the PMCF Plan
- Use a hypothetical device to determine and justify general methods and procedures

QUESTIONS