Example 1 / Trend Reporting

Description of Situation

Stage 1 audit of the Quality Management System or ISO13485 ‘state of the art’ evaluation of complaint management / customer feedback

Problem Description

(Audit NC) Failure to complete trend reports as required by EU MDR Article 88.

Problem Solving Approach

Problem Statement

- Failure to complete trend reports as required by EU MDR Article 88.

1st Level Root Cause

- Why are the requirements of trend reports per EU MDR Article 88 not being met?

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Nonconformance Example

TREND REPORTING

(NC) Failure to complete trend reports as required by EU MDR Article 88.

EU 2017 745 (MDR) / Article 88 Trend reporting

- 1.**Manufacturers shall report**, by means of the electronic system referred to in Article 92, **any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side- effects that could have a significant impact on the benefit-risk analysis** referred to in Sections 1 and 5 of Annex I and which have led or may lead to risks to the health or safety of patients, users or other persons that are unacceptable when weighed against the intended benefits.
- **The significant increase shall be established in comparison to the foreseeable frequency or severity of such incidents in respect of the device, or category or group of devices,** in question during a specific period as specified in the technical documentation and product information.
- **The manufacturer shall specify how to manage the incidents** referred to in the first subparagraph and the methodology used for determining any statistically significant increase in the frequency or severity of such incidents, as well as the observation period, **in the post-market surveillance plan referred to in Article 84.**

Prove System Works

"The whole is greater than the sum of its parts…"

MDR / IVDR requires a interconnected post market surveillance system.

Changes to a process step require evaluating upstream and downstream processes to ensure

1. **synchronization of information,**
2. **change does not introduce NEW gaps or issues to the Quality Management system.**

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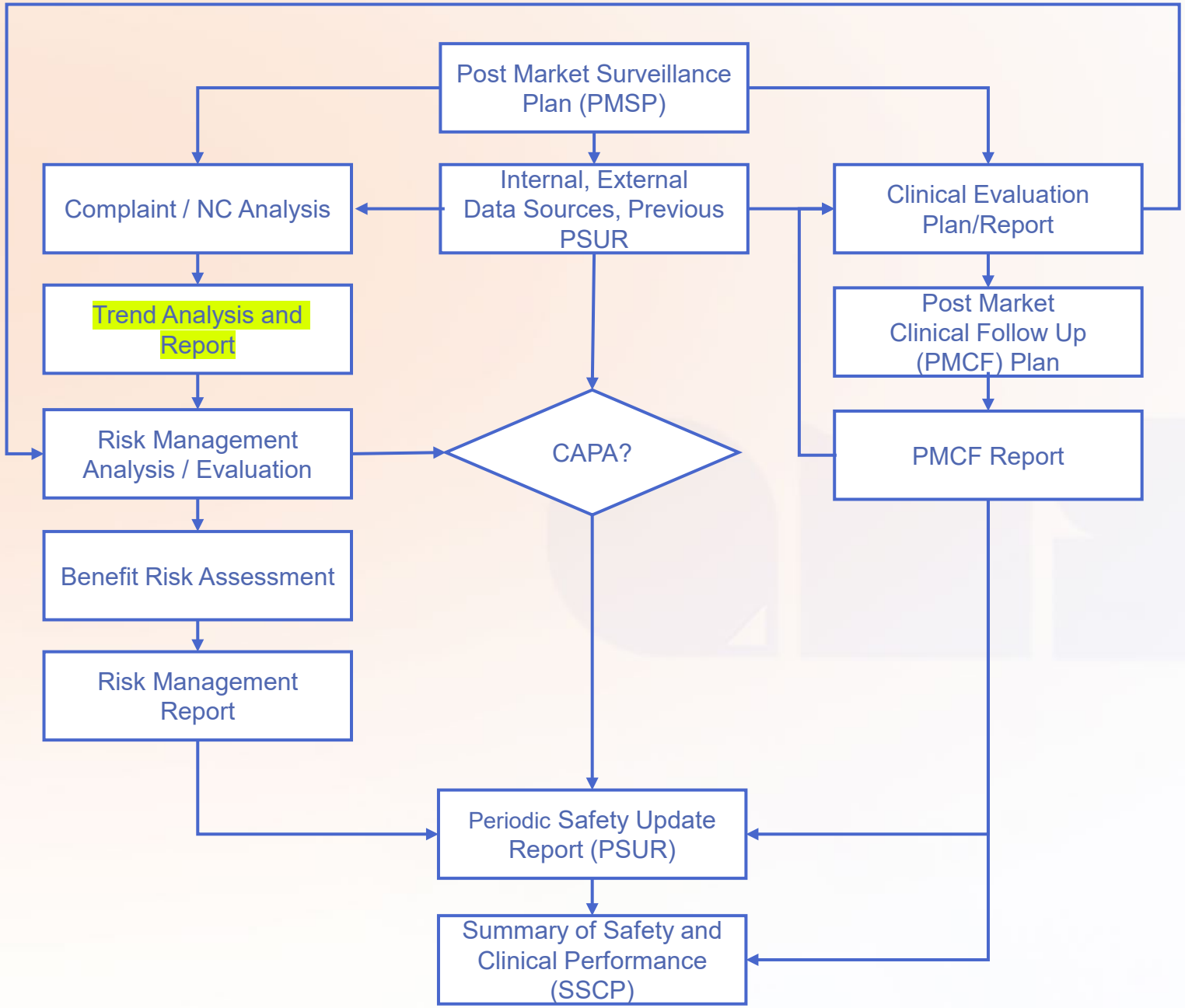
Closed Loop Post Market Surveillance Roadmap (MDR)



6

Gap Assessment vs Process Oriented

Gap Assessment Approach

1. Separate out requirements
2. Determine if existing procedures map to existing requirements
3. Update procedures with new requirements
4. Determine evidence required
5. Create forms and evidence

Process Oriented approach

(1) Identify Processes affected

(2) Review QMS Velocity procedures for enhancements to existing procedures

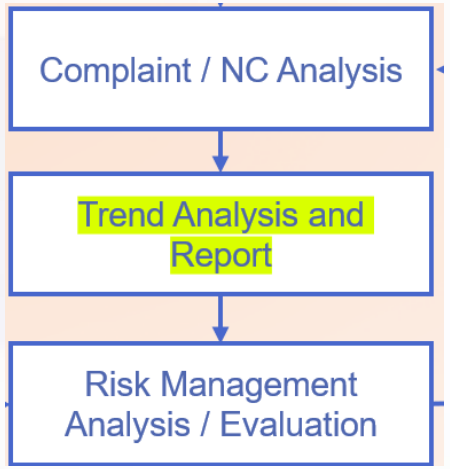
(3) Update input and output quality subsystem procedures at the same time (systemic remediation of the issue)

QMS Velocity

(1) Identify Processes Affected

Gap Assessment Approach

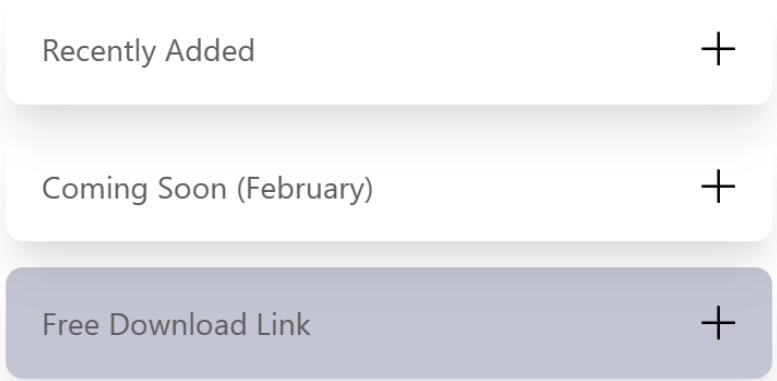
Process Oriented approach



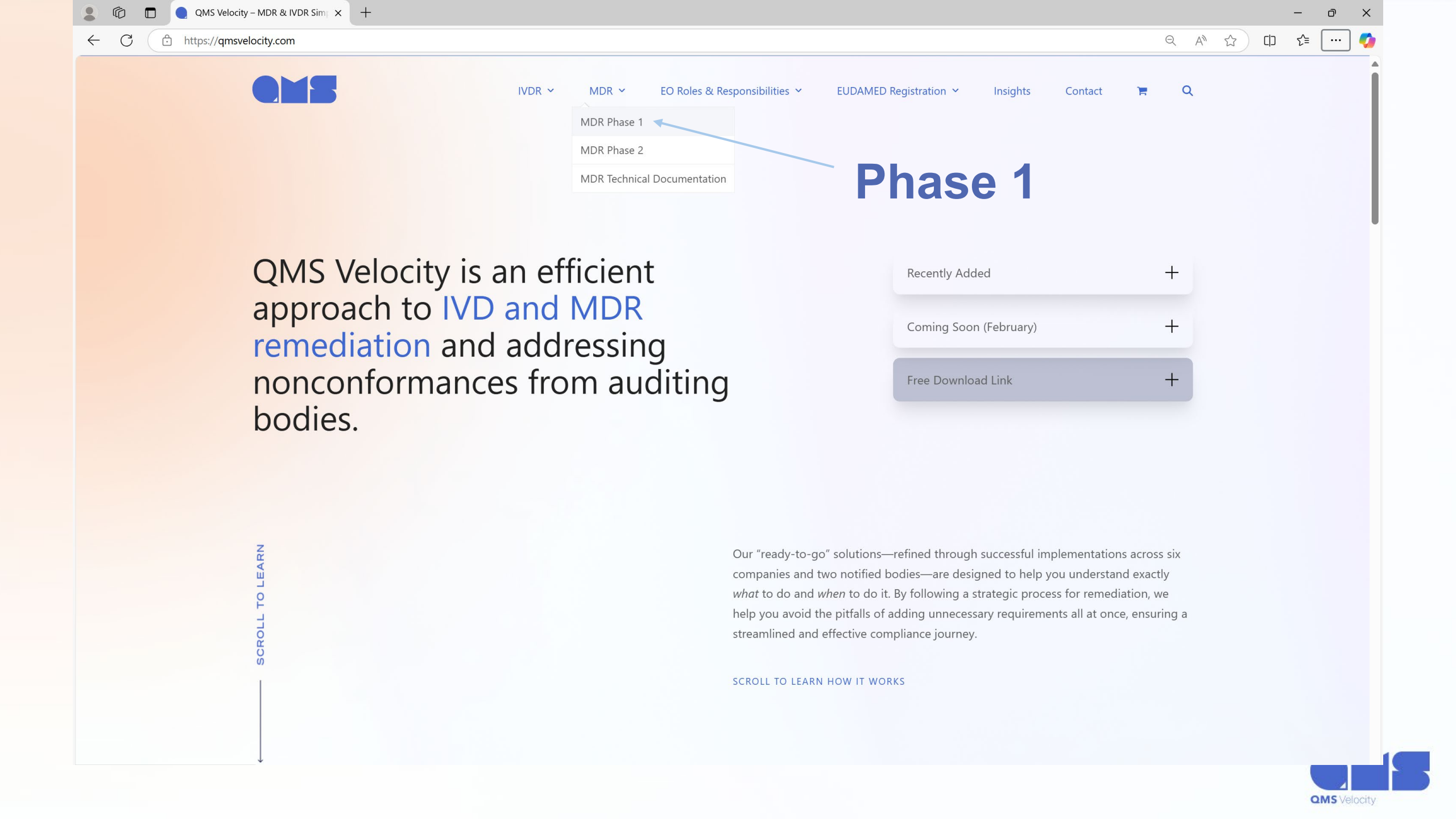
QMS Velocity

(2) Review QMS Velocity procedures for enhancements to existing procedures

QMS Velocity is an efficient approach to IVD and MDR remediation and addressing nonconformances from auditing bodies.



QMS Velocity


QMS Velocity – MDR & IVDR Sim
https://qmsvelocity.com
IVDR
MDR
EO Roles & Responsibilities
EUDAMED Registration
Insights
Contact
MDR Phase 1
MDR Phase 2
MDR Technical Documentation
Phase 1
QMS Velocity is an efficient approach to IVD and MDR remediation and addressing nonconformances from auditing bodies.
Recently Added
Coming Soon (February)
Free Download Link
SCROLL TO LEARN
Our “ready-to-go” solutions—refined through successful implementations across six companies and two notified bodies—are designed to help you understand exactly *what* to do and *when* to do it. By following a strategic process for remediation, we help you avoid the pitfalls of adding unnecessary requirements all at once, ensuring a streamlined and effective compliance journey.
SCROLL TO LEARN HOW IT WORKS
QMS Velocity

MDR Phase 1

Vigilance and Risk Management

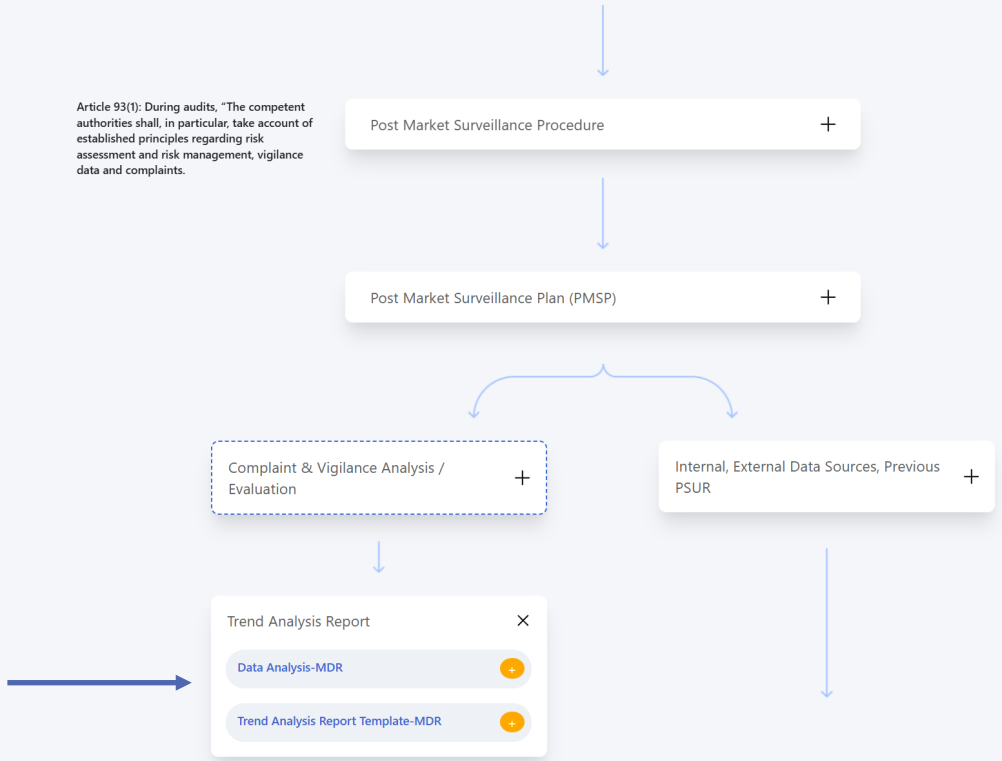
MDR Phase 1

Phase 1 | Phase 2 | MDR Technical Documentation

Quality Planning | **Vigilance and Risk Management** | Clinical Deliverables | Process Outputs

Vigilance and Risk Management

Article 93(1): During audits, "The competent authorities shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.



QMS Velocity

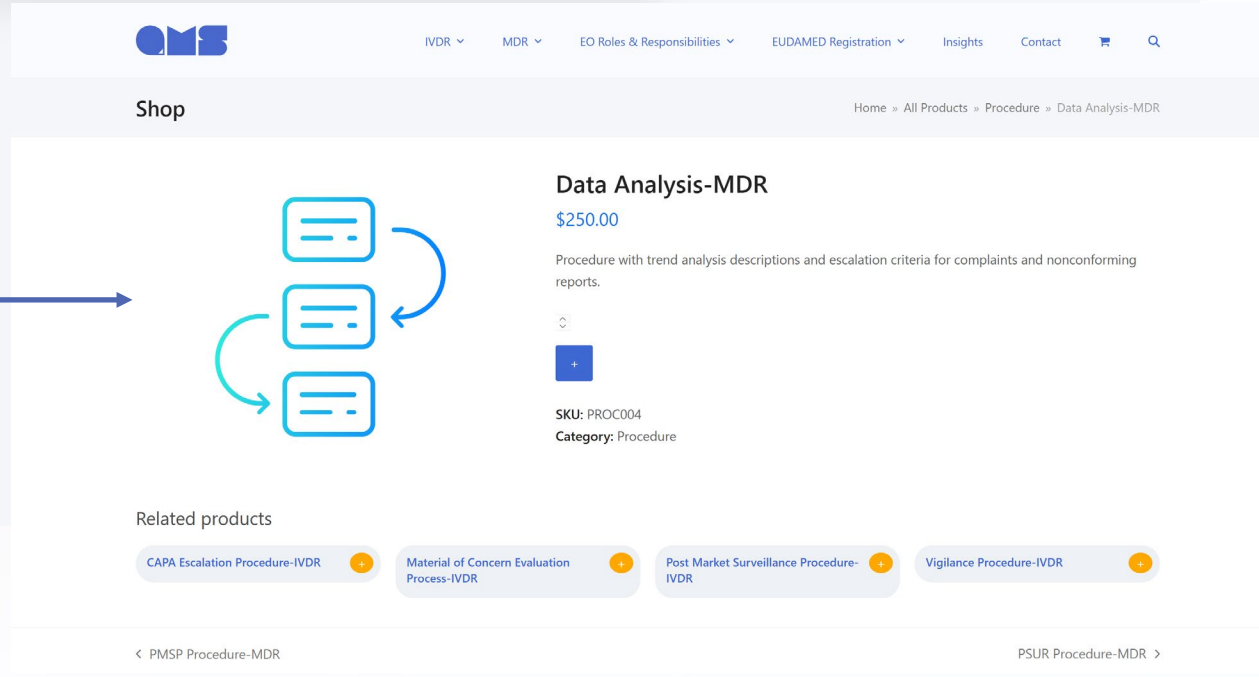
Complaint & Vigilance Analysis / Evaluation +

Internal, External Data Sources, Previous PSUR +

Trend Analysis Report ×

Data Analysis-MDR +

Trend Analysis Report Template-MDR +



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Don’t Start with a Blank Page

Turn Key Solutions

- Not blank templates that require a lot of work to customize
- A lot of information can be used to plug and play into existing quality documents

Clear guidance for executing trend analysis using relevant data sources

6. PROCEDURE

6.1. Feedback / Marketing Purposes

6.1.1. Customer survey or customer feedback related to product improvement recommendations are reviewed in a summarized manner during management review.

6.2. Feedback / Customer Complaints

6.2.1. Customer complaints are managed annually through the post-market surveillance system and complaint management processes. The complaint analysis process is detailed and integrated in the complaint management procedure of consistency and ease of use.

6.2.2. The following provides the process and requirements to identify any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side- effects that could have a significant impact on the benefit-risk analysis intended benefits.

6.2.3. At least once a semester (6 months), <Department> shall consolidate complaints and trending based on harm, hazards, or failure modes.

6.2.4. All customer complaints used for trending analysis shall be aligned to the product Risk Management File based on the manifested harm reported and assigned the harm severity score relying on the product Harms list.

Section 6 continues to describe process And requirements

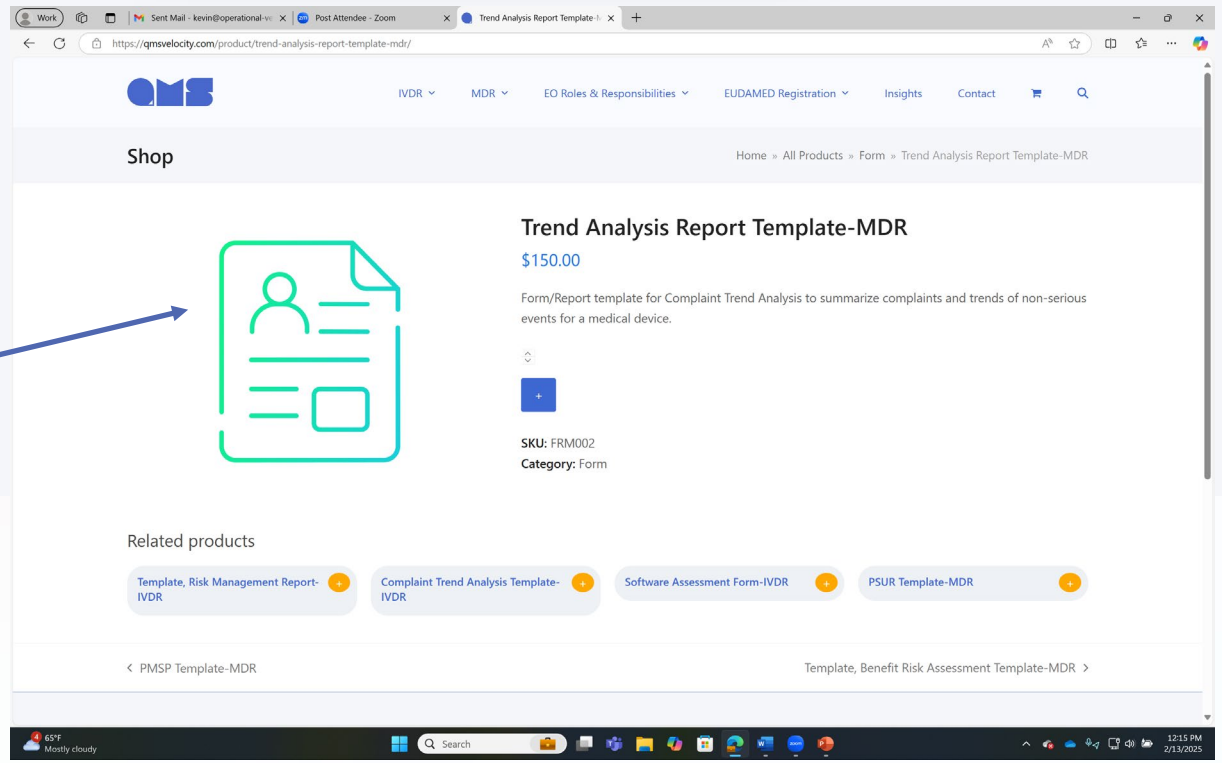
Complaint & Vigilance Analysis / Evaluation +

Internal, External Data Sources, Previous PSUR +

Trend Analysis Report ×

Data Analysis-MDR +

Trend Analysis Report Template-MDR +



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Turn Key Forms/ Templates

- Documents are editable and ready to use. Minimize/Eliminate time formatting.
- Tables and texts are organized to communicate understanding and clarity of information provided
- Guidance and examples are provided to help facilitate completion of forms

Comprehensive
Assessment
With information
Highlighted to minimize
Missing data required
To demonstrate compliance

Conclusion:<A statement should be made here. For example, 'There was no significant increase in the number of incidents.' Or, 'There was a significant increase in the number of incidents. The cause of the incidents is known. The issue is being addressed through <CAPA reference.>

7.4. The following table identifies any significant increase in the frequency of nonserious events

Table 5. Evaluation Significant increase in the frequency of nonserious events

Complaint Category	12 Month Count	Projected Occurrence (%)	Existing Risk Score	Actual Occurrence (%)	New Risk Score	Action Required (Yes/No)
TBD	TBD	TBD	TBD	TBD	TBD	TBD

7.5. The following table summarizes any complaints that were found to have unrecognized hazards are present.

Table 6. Complaints with New Hazards (MM/DD/YYY through MM/DD/YYYY)

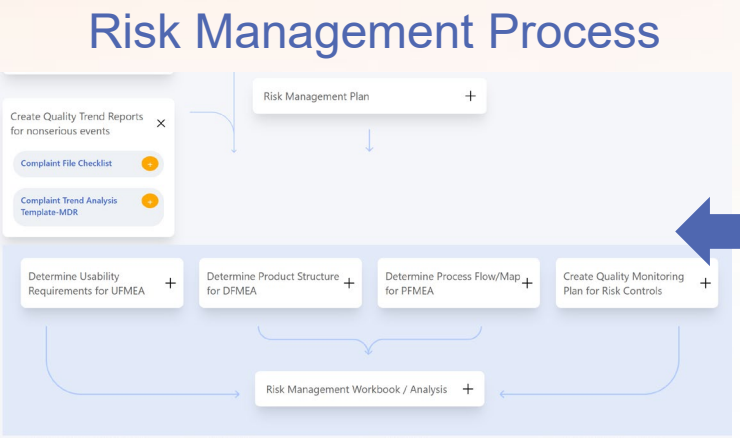
Complaint Identification	Product	Incident Date (dd/mm/yyyy)	Hazard
TBD	TBD	TBD	TBD

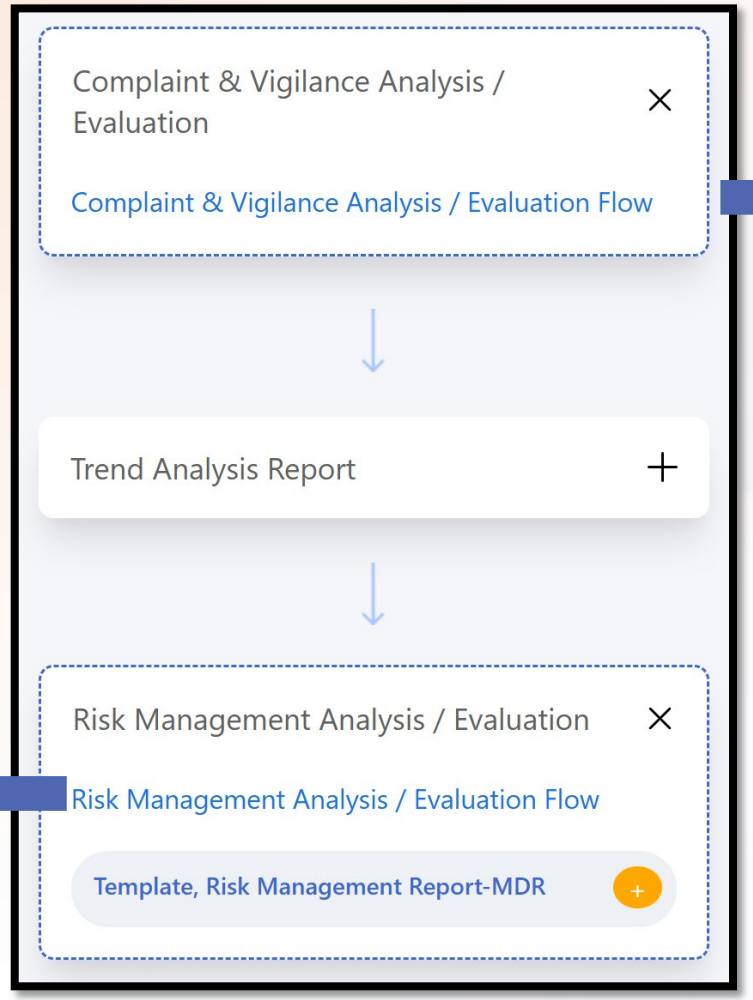
7.6. The following table summarizes any complaints in which estimated risks, arising from hazardous situations or harms are no longer acceptable.

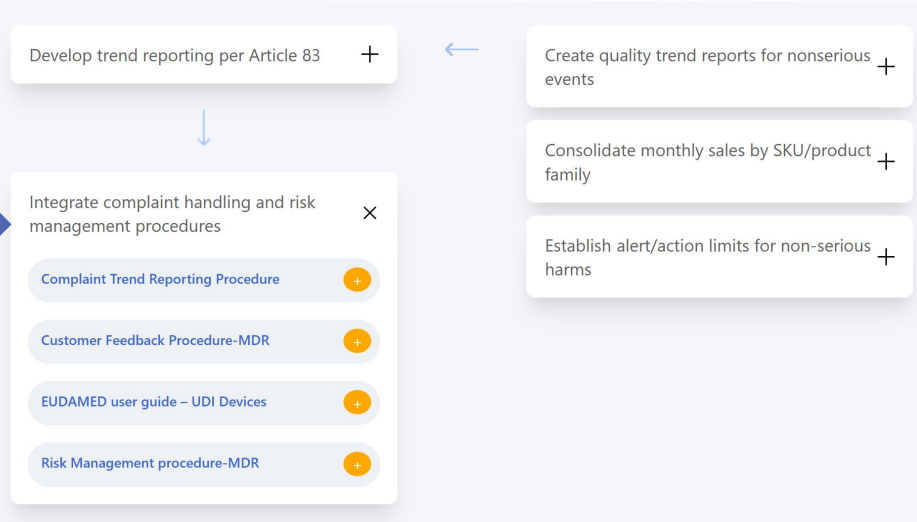
Table 7. Complaints with Risk Scenarios that are no longeracceptable (MM/DD/YYY through MM/DD/YYYY)

Complaint Identification	Product Name	Incident Date (dd/mm/yyyy)	Harm	Hazardous Situation
TBD	TBD	TBD	TBD	

(3) Update input and output quality subsystem procedures at the same time







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