



PSUR Flow Chart

04MAR2022



The Frestedt Difference

- Clinical Experience (expert-level)
- Caring Attitude (high-quality)
- Creative Solutions (problem-solving)
- Constant Attention to Detail (coaching)

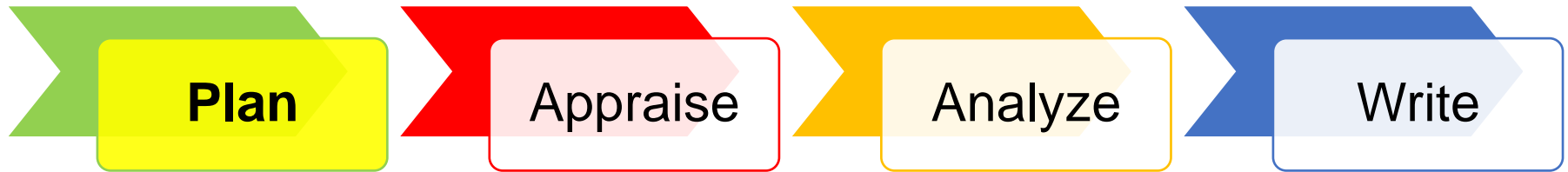
Frestedt Capabilities

10-15 PSURS/year

3-5 simultaneously

6-12 week TAT

PSUR Process - PLAN



KNOW THE GOAL: To update safety and understand post-market performance

TACTIC: Look across all departments for the BIG PICTURE about safety
FOLLOW QMS PROCESS: TRACK data (complaints, usage, other data)

LINK PROCESSES TOGETHER! → CE/RM/PMS are interrelated

Notified Bodies are looking for SAFETY KNOWLEDGE
Knowledge requires DATA ANALYSIS

PSUR Process- APPRAISE



ANSWER THE QUESTION: Should the data be included in the PSUR?

TACTIC: Gather data across all device use to be COMPREHENSIVE
QMS PROCESS: REVIEW reports (globally), SEARCH databases

COMBINE DATA TOGETHER! → **ONE COMPILED data collection**

PSURs are about SAFETY UPDATES
Updating requires NEW data!

PSUR Process - ANALYZE



DO THE WORK: Analyze the collected and appraised data

TACTIC: Separate human data from non-human data

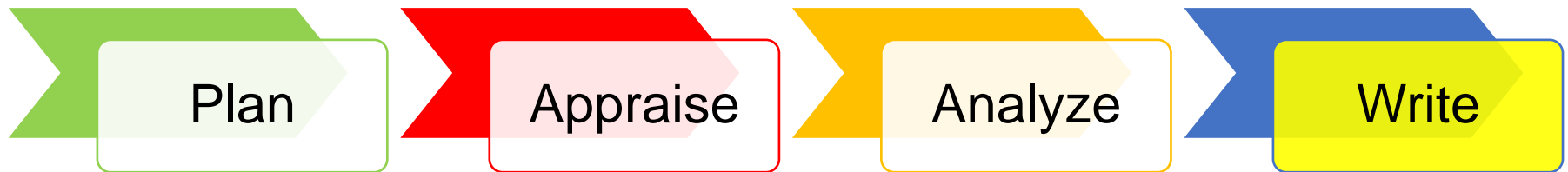
QMS PROCESS: GROUP data (Adverse Event, Device Dysfunction)

CREATE CODES ALTOGETHER! → Trends analyses are required

Quality Control is IMPORTANT

1st person enters, 2nd checks, 3rd (more experienced) adjudicates

PSUR Process- WRITE



WRITE CLEARLY AND COMPLETELY: Tell the story in “report” format

TACTIC: Have an independent reviewer offer advice about clarity

QMS PROCESS: CHECK the regulations (were all requirements met?)

USE MDR ARTICLE 86 CHECKLIST! → Safety must be clearly demonstrated

CONCLUSIONS do not write themselves

**CONNECT complaints/usage, device lifetime, risk/benefit, PMCFER, CER
DOCUMENT IMPROVEMENTS!**

Key PSUR Pointers/Advice

Use RISK-based approach

Align data (part numbers/naming/formats/outputs/limits)

Explore CAPA Quality Databases

Review PMS/Vigilance/Complaint review board notes

Watch for new guidance

Use consistent method to IDENTIFY TRENDS

Consult with EXPERTS



HOW TO REACH US

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