

# Health Products and Food Branch Inspectorate

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## APEC Seminar - Post Market Surveillance of Medical Devices

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**Health Products and Food Branch Inspectorate**  
**Health Canada**

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# Study Group 2 - Overview

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- What you will see today
  - Overview of SG2 activities
  - Description of Key documents and concepts



# Medical Device Safety

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- "Post Market" safety
  - adverse event reporting,
  - post market surveillance,
  - and quality systems requirements



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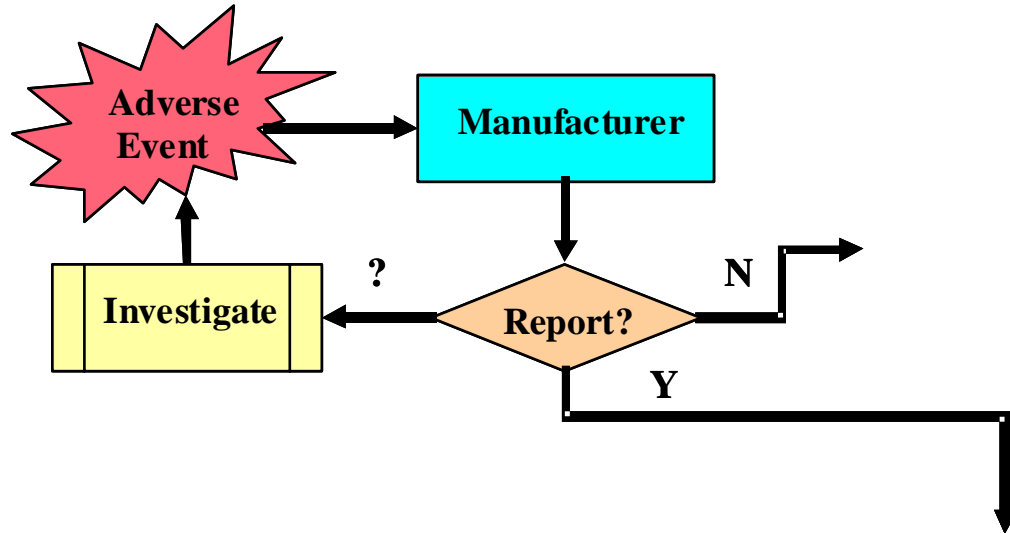
# Study Group 2 - Overview

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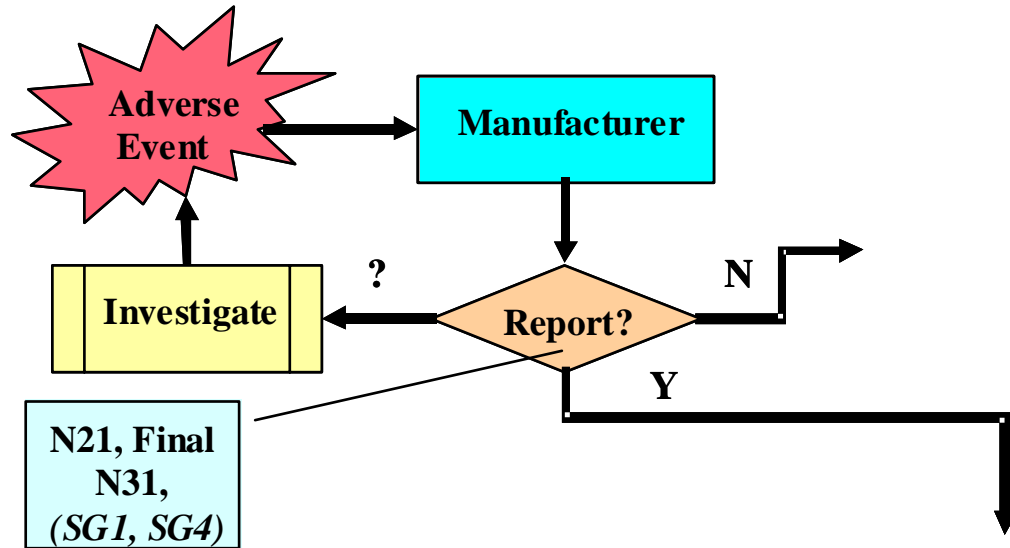
- SG2 Vigilance and Post Market Surveillance
  - Key areas of interest for SG2
  - Medical devices adverse event reporting,
  - Exchange of information between regulatory authorities
  - Post market surveillance



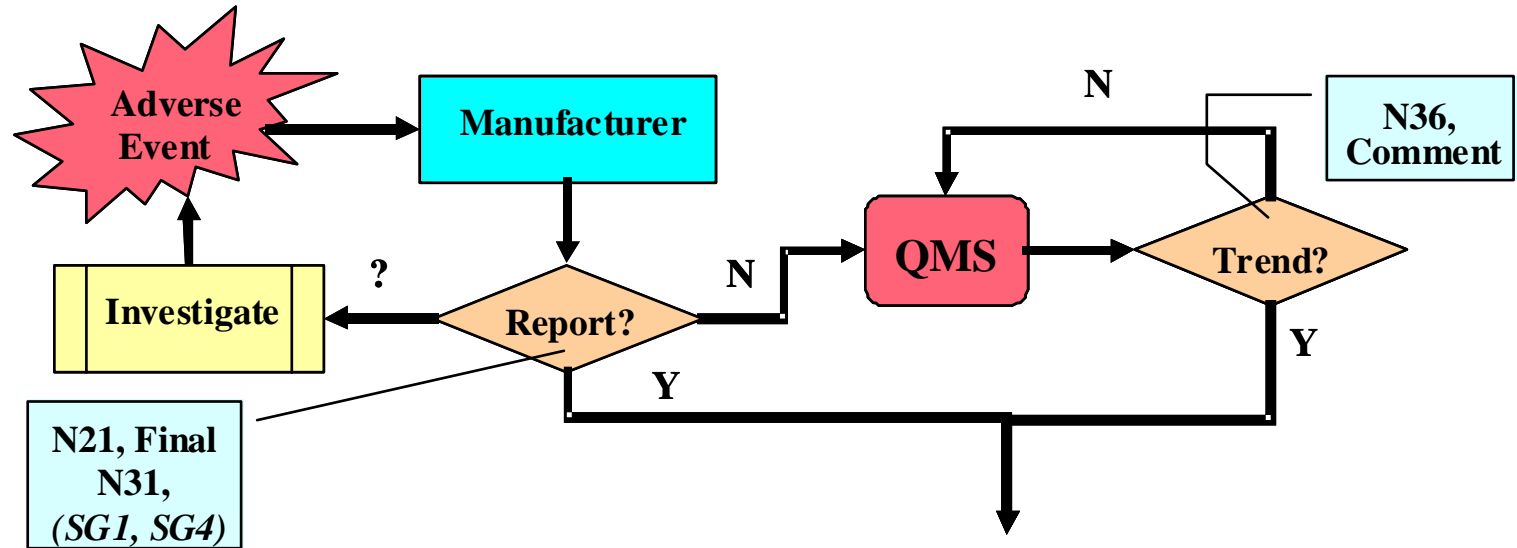
# Overview of SG2 Guidance



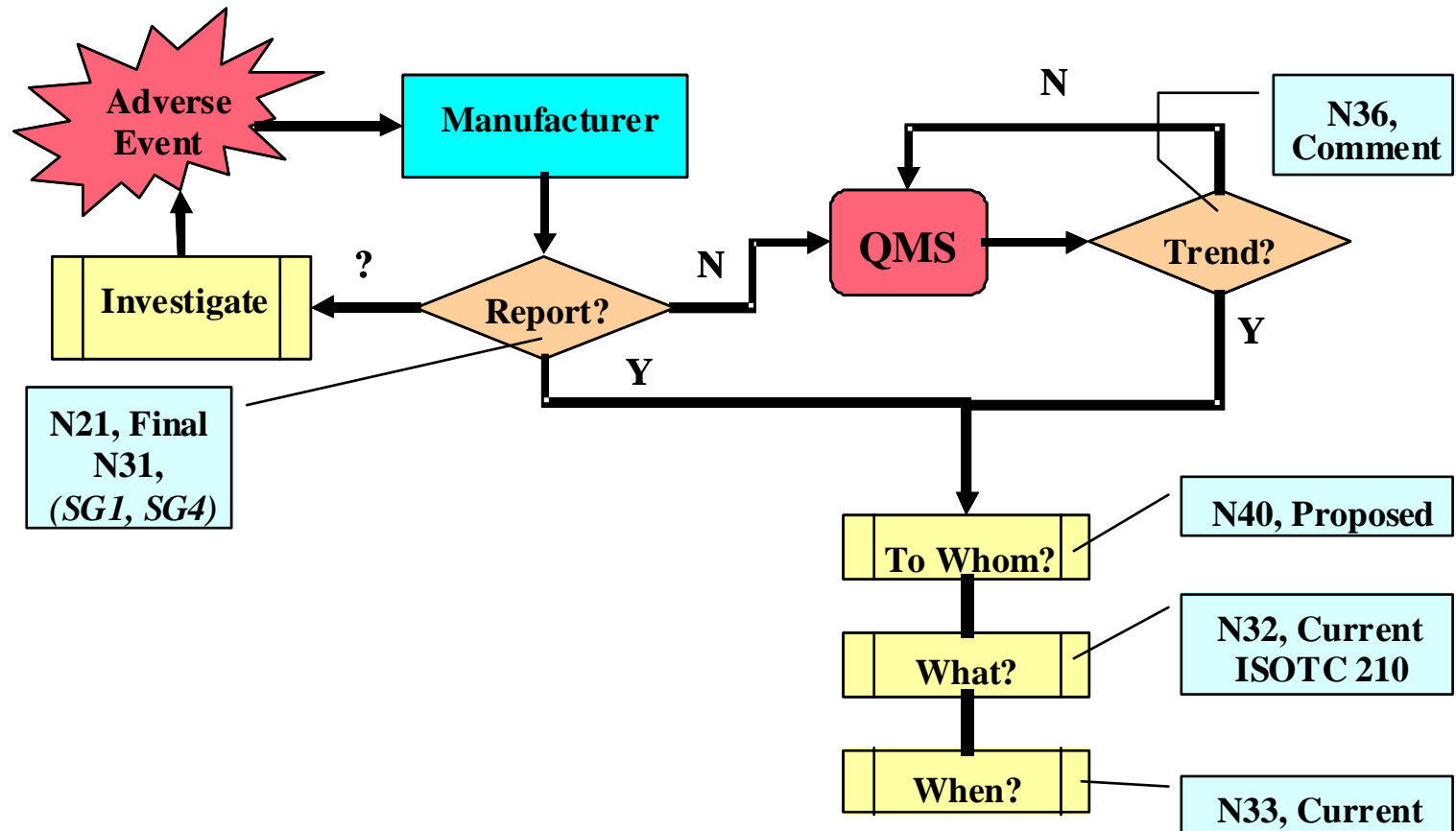
# Overview of SG2 Guidance



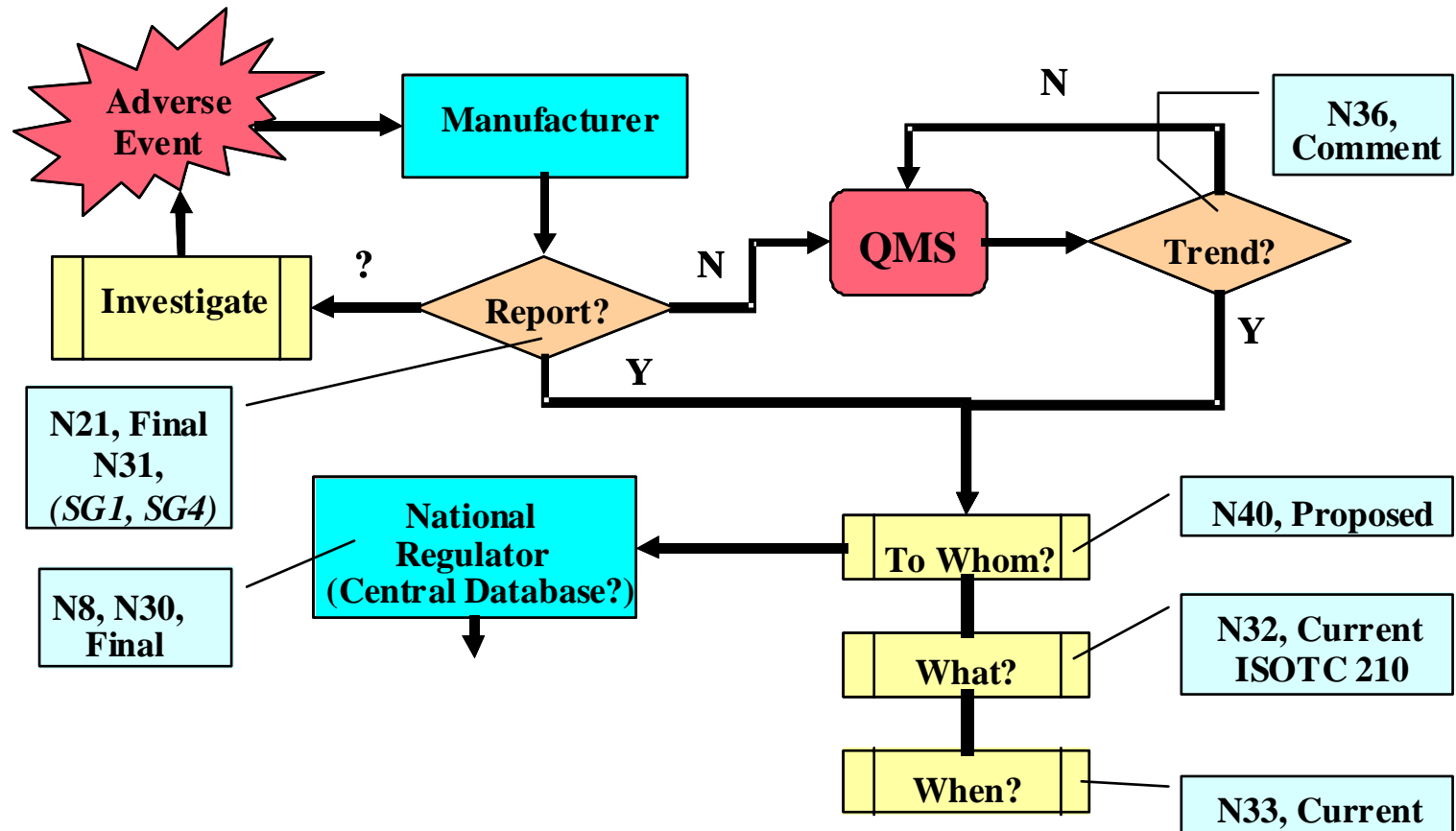
# Overview of SG2 Guidance



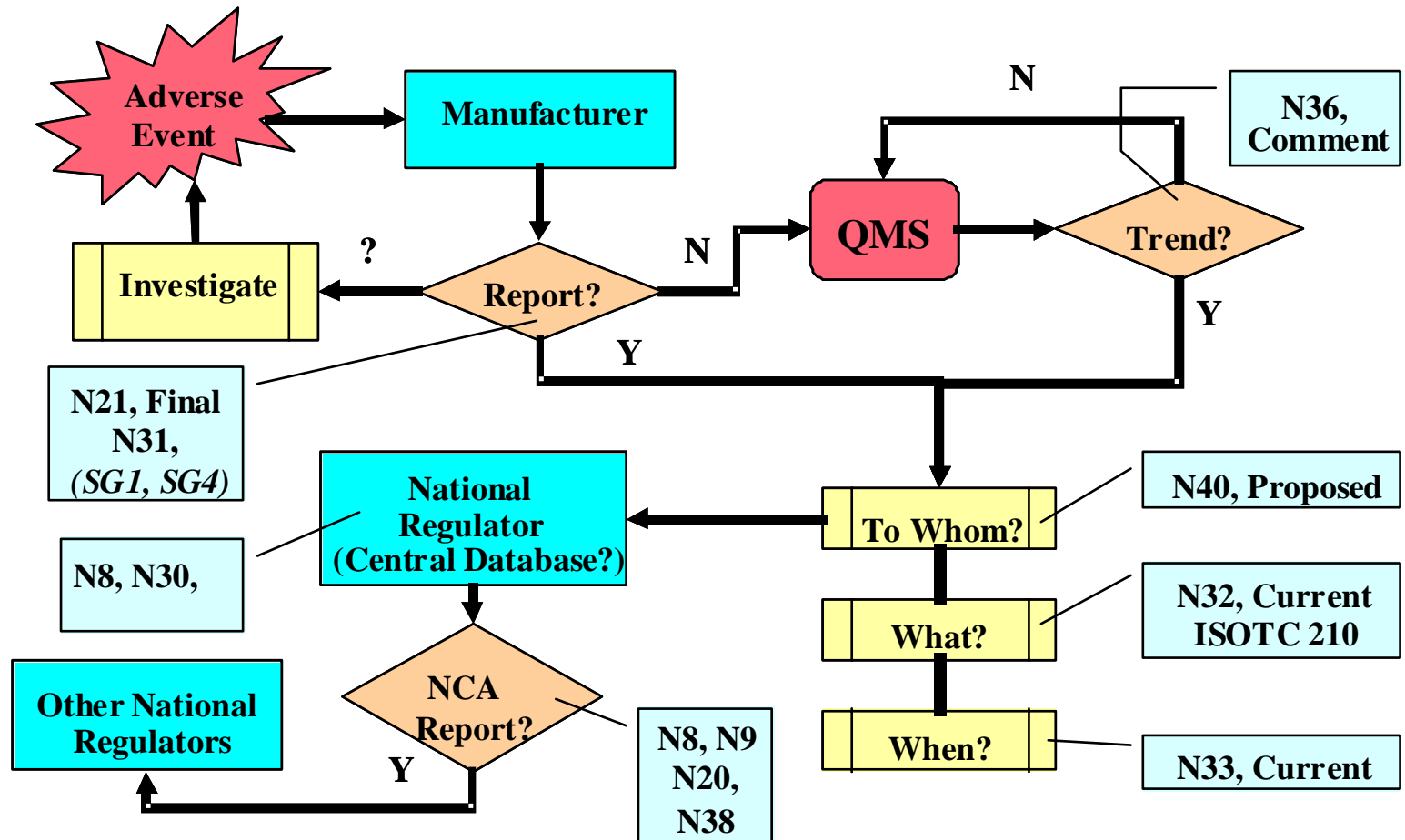
# Overview of SG2 Guidance



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# Overview of SG2

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- Where is the post market surveillance ?
- Proposed project by SG2 to:
  - Identify current surveillance practices
  - Determine areas for harmonization
  - Develop guidance



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# GHTF Study Group 2

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- For more information regarding Medical Device Vigilance/Post-Market Surveillance or SG2 documents please refer to :
- <http://www.gh tf.org/>

