

# Health Products and Food Branch Inspectorate

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## GHTF SG 2 Chairman's Report to Plenary

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**Health Canada**

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# Presentation Summary

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- SG2 Aim
- SG2 Achievements
- SG2 Documents under development
- NCAR Exchange Statistics
- Future
- Concluding Remarks



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# Aim of GHTF SG2

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- Improve protection of public health and safety of patients, users and others
- Evaluate reports and disseminate information which may reduce the likelihood of or prevent repetition of adverse events
- Define post market medical device reporting and surveillance requirements and guidelines on an international basis



# SG2 Achievements

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- Compared participating countries regulatory systems to determine a baseline for harmonization
- Developed guidance for manufacturer reporting of adverse events
- Developed an international system for exchange of high risk reports between competent authorities
- Six Final Documents on Website



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# Documents Under Development

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| Reference Number | Title  |
|------------------|--|
| N32R3.2          | Universal Manufacturer Report Format   |
| N20R10           | National Competent Authority Report Exchange Criteria                                      |
| N36R4            | Manufacturer's trend reporting of adverse events   |
| N38R7            | Application Requirements for Participation in National Competent Authority Report Exchange |



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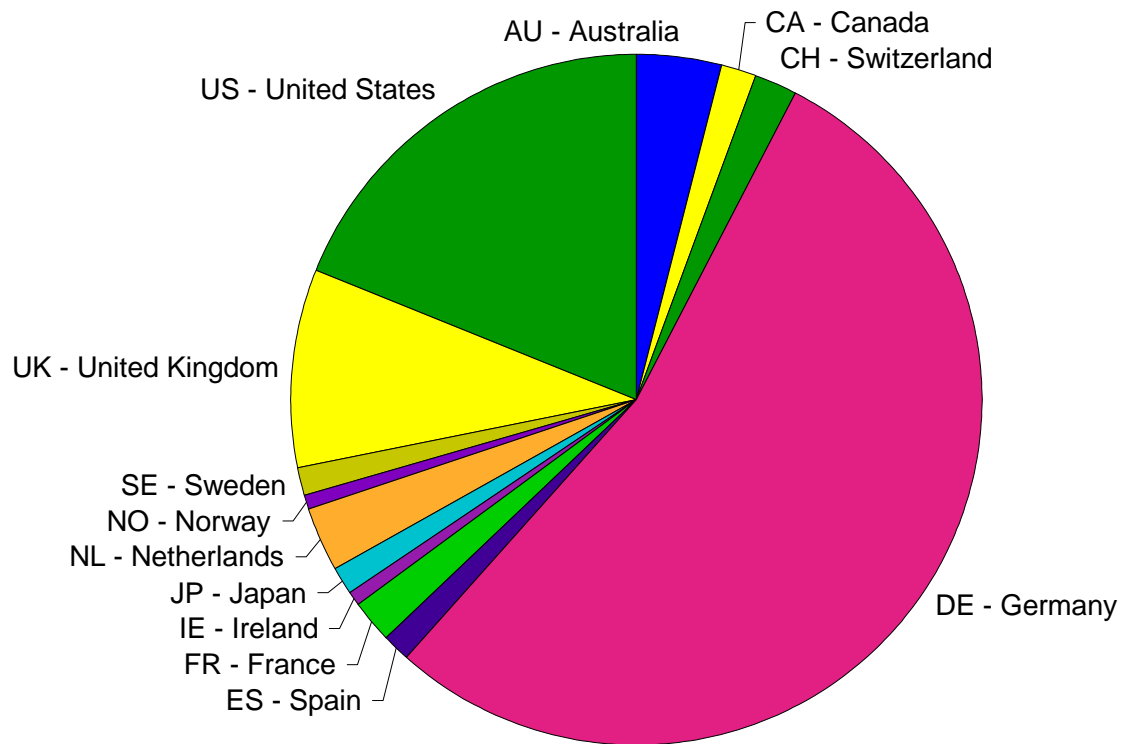
# Documents Under Development

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| Reference Number | Title  |
|------------------|--|
| N31R7.1          | Proposal for Reporting of Use Errors with Medical Devices by a Manufacturer or its Authorized Representative |
| N33R10           | Medical Device Post-market Vigilance and Surveillance; Timing of Adverse Event Reports                       |
| N40R1            | Who Should Adverse Event Reports be Sent To?   |



# Summary Statistics for NCAR Exchange



Total to date = 303 reports



# Future Directions

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- Proposal to Steering Committee on Post Market Surveillance Project
  - Determine current post market surveillance practices
  - Identify areas for harmonization
  - Develop guidance for harmonized surveillance and sharing of information



# Future Vision

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- Part of SG2's vision is to have an international adverse event report management system
  - manufacturers enter their reports and have access to their own data
  - competent authorities have access to all data and would coordinate database management etc.



# Thanks

- Special thanks to Dr. Larry Kessler, Chair Study Group 2, 1995 to 2001.

