



IMDRF International Medical
Device Regulators Forum

IMDRF VII National Competent Authority Report Exchange Programme

Jean-François ROCHE

**DG GROWTH - Health Technology and Cosmetics Unit,
European Commission.**



WG composition

- Australia:
Pamela Carter (Director, Device Vigilance and Monitoring Section, Office of Product Review, TGA)
- Brazil:
 - Stela Candioto Melchior (Gerência de Análise e Avaliação de Risco, ANVISA)
 - Maria Gloria Vicente & Guilherme Buss (Health Surveillance Specialists, ANVISA)
- Canada:
Barbara Harrison (Senior Corporate Regulatory Compliance Advisor , Health Canada)
- European Union:
 - Jean-François Roche [Chair] (Policy Officer, GROW I4, EU Commission)
 - Andrea Hanson (Product Manager, Health Products Regulatory Authority, Ireland)
 - Carmen Ruiz-Villar (Head of Service , Vigilance Unit , Medical Devices Department, AEMPS)
 - Ekkehard Stoesslein (Deputy Head of Division, BfArM)
- Japan:
 - **Koichi Fujiwara & Miho Sato** (Office of Safety, PMDA)
 - Masahiro Takahata (MHLW)
- USA:
 - Nancy Pressly (Associate Division Director, FDA)
 - Millin Courtney (MDR Analyst, FDA)
- Invited expert: AHWP/ Saudi Arabia:
Essam M. Al Mohandis (Executive Director of Surveillance and Biometrics, SFDA)



State of play

- IMDRF N14 REV 4 DOCUMENT WAS ENDORSED FOR PUBLIC CONSULTATION BY IMDRF MC IN WASHINGTON.
- PUBLIC CONSULTATION TOOK PLACE UNTIL END DECEMBER.
- COMMENTS RECEIVED FROM 1 JURIDICTION, 4 PROFESSIONAL ORGANISATIONS AND 1 COMPANY
- 2 TELECONFERENCES HOLD WITH THE NCAR WORKING GROUP ON 14 AND 21 JANUARY
- SOME LIMITED CHANGES INTRODUCED IN FINAL DOCUMENT



Main changes in N14 Final

- More accurate definition of the role of NCAR Secretariat
- Clarification of wording of chapter 6.1 on report exchange for confidential and non confidential NCARs
- No changes on substance
- Editorial changes throughout the document



Work Plan

1. March–mid April 2015

- Drafting of implementation materials on reporting criteria, participation, confidentiality and reporting forms

2. Mid April – October 2015 (Pilot phase)

- Participation limited to IMDRF MC members who already participated to the GHTF exchange program
- Use of implementation materials for new members
- Twinning between a new and a former participant

3. November 2015- April 2016 (full implementation)

- Progress report to the MC (IMDRF IX)
- Possible proposal for an extension (2nd phase)



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Thank you
for your attention!