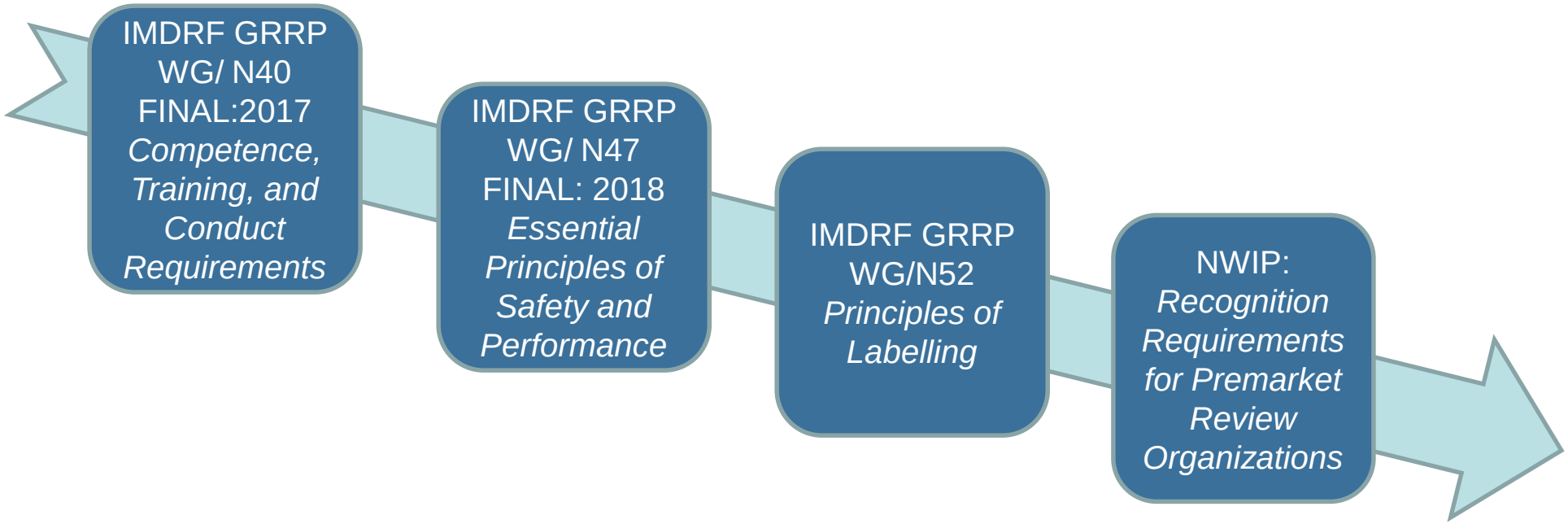
# GOOD REGULATORY REVIEW PRACTICES WORKING GROUP UPDATE

Working Group Chair: Melissa Torres
US Food and Drug Administration

# Good Regulatory Review Practices (GRRP) Goals

The IMDRF Good Regulatory Review Practices (GRRP) working group has focused efforts on harmonizing premarket requirements in alignment with the IMDRF strategic priority to improve the effectiveness and efficiency of premarket review.



# CURRENT WORK ITEMS

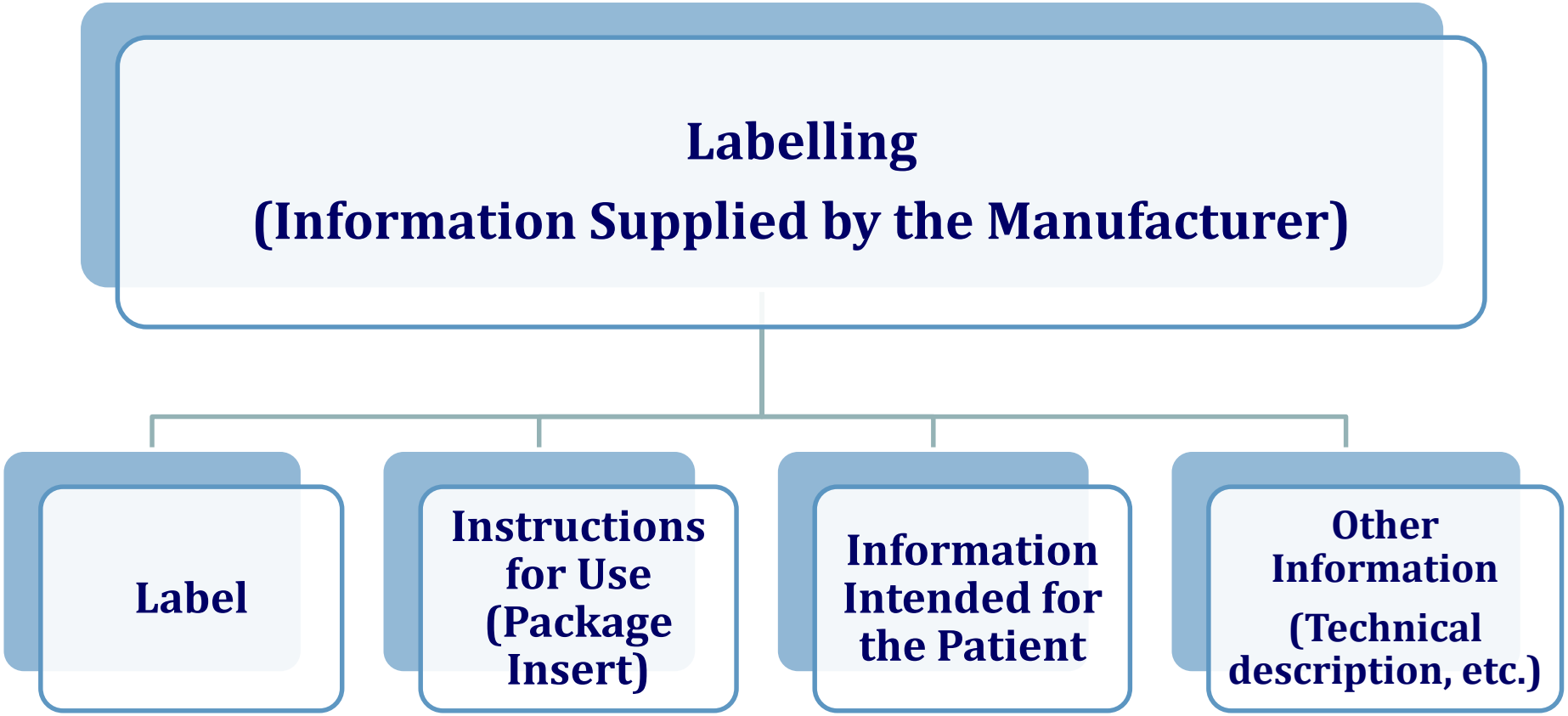
1. Revising GHTF *Label and Instructions for Use for Medical Devices* (GHTF/SG1/N70:2011) to reflect current labeling requirements → IMDRF GRRP WG/N52 *Principles of Labelling for Medical Devices and IVD Medical Devices*

2. NWIP - Drafting *Recognition Requirements for Medical Device Premarket Review Organizations*

# Principles of Labelling: Current Status

- IMDRF GRRP WG (PD1)/N52 *Principles of Labelling for Medical Devices and IVD Medical Devices*
  - Revised GHTF *Label and Instructions for Use for Medical Devices* (GHTF/SG1/N70:2011) based on EU MDR, IMDRF GRRP WG(PD1)/N47, ISO CD 20417, and jurisdictional requirements. For example:
    - Streamlined medical device and IVD medical device requirements
    - Included requirements for SaMD and UDI
    - Included labeling concepts from EP document
    - Included information intended for the patient
- IMDRF GRRP meeting held in December 2018 in Tokyo, Japan at PMDA to review and address the over 500 comments received.
- Document sent to MC for consideration as final.

# Elements of Labelling



# New Work Item Proposal

- NWIP approved in September 2018 MC meeting
- Singapore and US Co-Chairing
  - Lakshmidevi Balakrishnan – HSA
  - Melissa Torres – US FDA
- Develop a conformity assessment/recognition program for medical device premarket review organizations
  - Will model the Medical Device Single Audit Program (MDSAP) by leveraging existing documents where possible and making modifications as necessary to accommodate premarket review requirements.
  - Utilize some requirements outlined in ISO/IEC standards (e.g. ISO/IEC 17065)

# NWIP Benefits

- Promotes consistency, predictability and transparency in the regulatory premarket review programs by developing an agreed upon set of criteria and processes.
- Benefits all regulators, even those just starting to develop a regulatory medical device premarket review system.

# Next Steps

- Finalize *Principles of Labeling* document – March 2019
- Continue working on NWIP through teleconferences
- Face to face meeting May 6-10, 2019 in Singapore to finalize draft of *Recognition Requirements for Medical Device Premarket Review Organizations*
- Submit draft document to IMDRF MC for consideration during the June 2019 teleconference for public consultation

# THANK YOU