Compliance and Traceability using Regulatory Intelligence

Ramakrishna Pidaparti

Global Head, QARA, Medical Devices

© 2012 WIPRO LTD | WWW.WIPRO.COM | CONFIDENTIAL

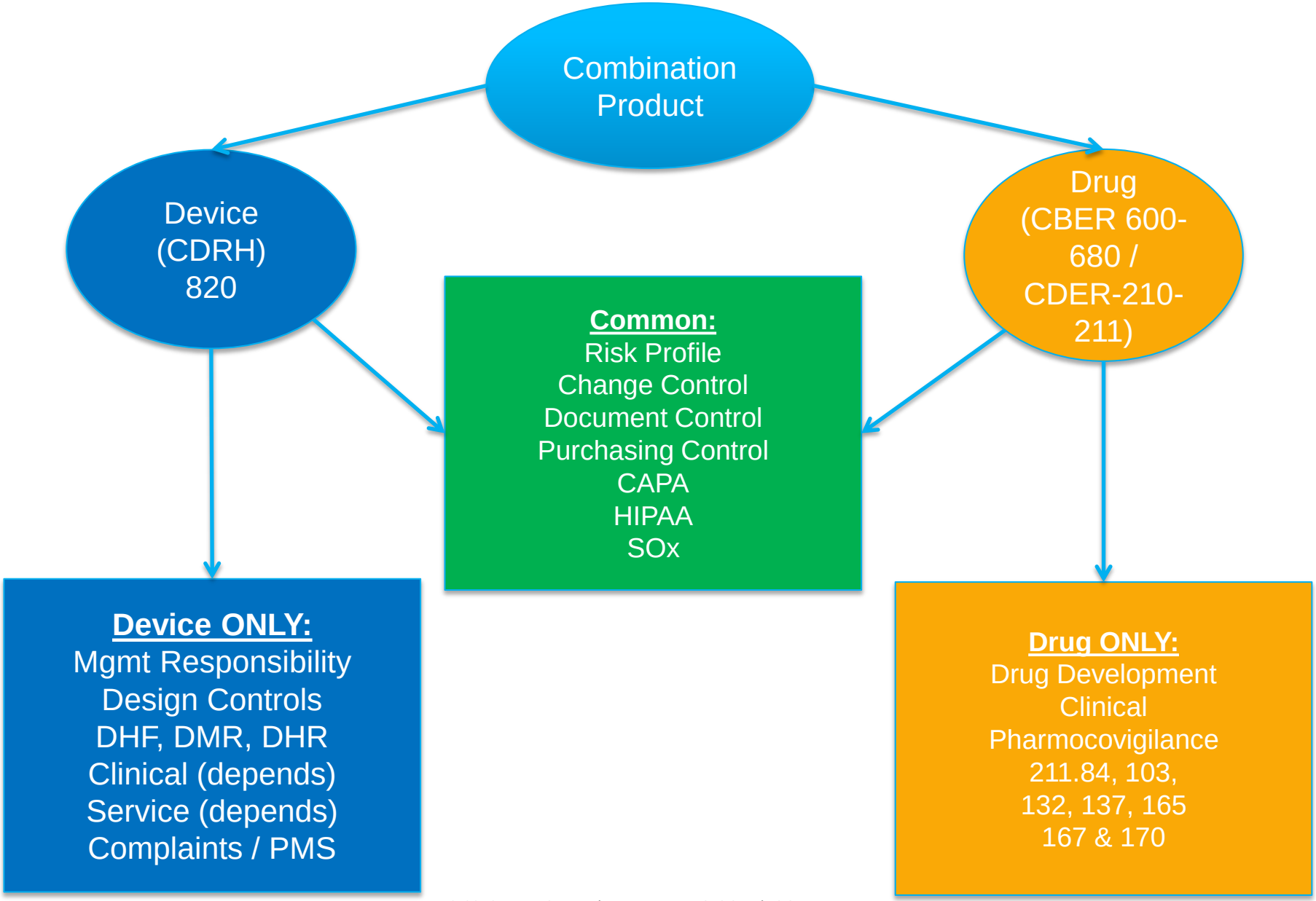
Mission and Vision for IRIS

- IRIS: International Regulatory Information System
- **Vision**:
  - To create IRIS to be used across Medtronic that will provide Traceability to ALL applicable Global Compliance requirements for all Medical Products of Medtronic that will be marketed in all geographies of interest to Medtronic, with the help of cross functional teams - R&D, Product Development, Quality and Regulatory Affairs, and visible to all who need it.

- **Mission:**
  - Create a baseline of Global Regulations (and Standards) impact on Design, Process and Submissions using a Regulatory Intelligence source.
  - Create alerts and tags to better manage New and Changing Regulations (NCR) monitoring.
  - Treat a Product in multiple geos as a Program of multiple Regulatory Project plans one for each geo re-using most by creating content once and publishing it as many times a needed for all geos. This is accomplished by creating a Regulatory Plans for products for multiple geos by identifying common (Core) and unique (Delta) requirements for submissions to reduce rework.
  - Submissions to be handled/managed by submission tools such as RAD (Insight publishing tool).
  - Create an Integrated International (Global) Regulatory Information System

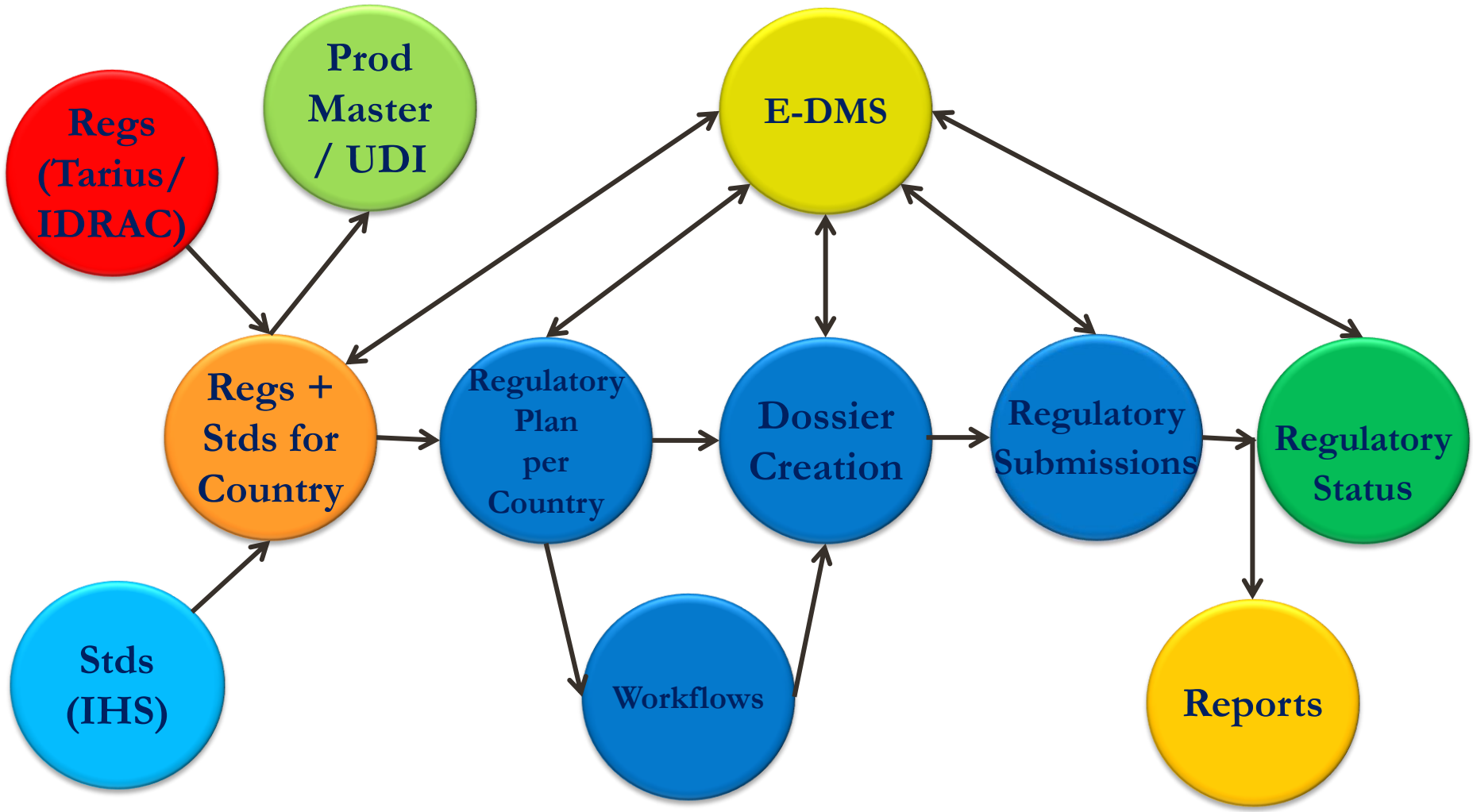
© 2012 WIPRO LTD | WWW.WIPRO.COM | CONFIDENTIAL

QMS for Combination Products (21 CFR Part 4)



© 2012 WIPRO LTD | WWW.WIPRO.COM | CONFIDENTIAL

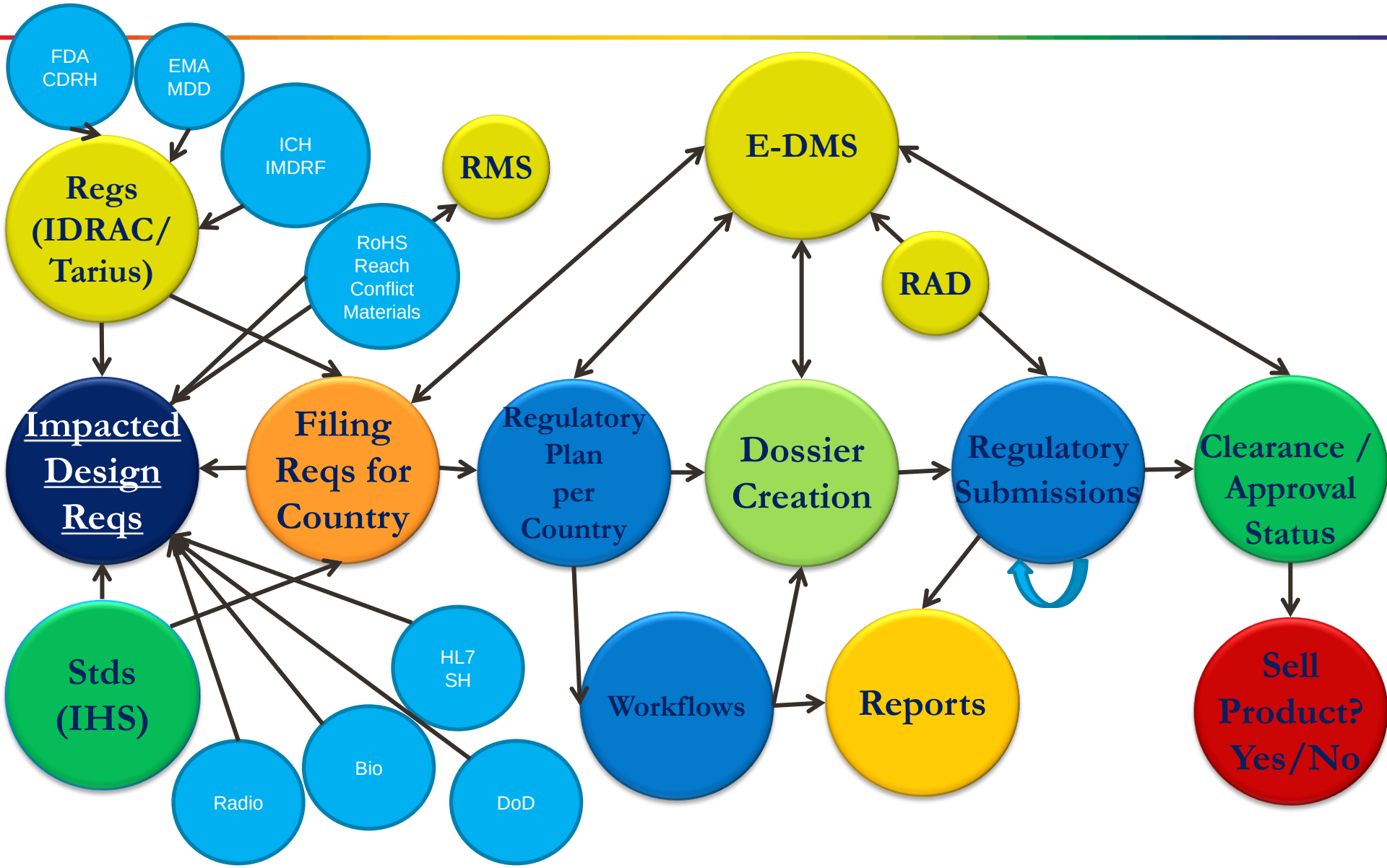
Regulatory Affairs Database



Stakeholders: R & D, Regulatory (local country reps) and Quality

© 2012 WIPRO LTD | WWW.WIPRO.COM | CONFIDENTIAL

Regulatory Affairs Information System Solution



Stakeholders: R & D, Regulatory (local country reps) and Quality

Benefits

- **Benefits:**
  - Financial – Prevents loss of potential revenues in sales due to delays in getting approvals/clearances by knowing upfront exactly what is needed for compliance.
  - Achieve high degree of traceability for compliance
  - Have a baseline of Global Regulations' impact on Design, Process and Submissions using a Regulatory Intelligence source to better manage New and Changing Regulations (NCR) monitoring as well.
  - Productivity gains with more standardized process to managing Regulatory changes but also reuse of applicable regulations and standards based on attributes that are common across the devices by creating for one very complex device that covers many attributes (e.g: SW, HW, Battery, Electrical, Mechanical, Bio-Compatibility, Radio Frequency, Inductive telemetry etc.,)
  - Reduces negative impact due to RA resources changing jobs due to well documented Regulatory impact contents
  - Highly reusable content for reuse across products with common attributes
  - Reduces drastically local footprint to do this work as it is already done in other divisions and will need review / approvals but not discovery/identification phase work.

© 2012 WIPRO LTD | WWW.WIPRO.COM | CONFIDENTIAL



Thank you

Ramakrishna Pidaparti
Global Head, QAAR, Medical Devices
Ramakrishna.pidaparti@wipro.com
781-742-5387

© 2012 WIPRO LTD | WWW.WIPRO.COM | CONFIDENTIAL