REGULATORY UPDATE

IMDRF Stakeholders Meeting
Florianópolis, Brazil
September 2016

ANVISA
Brazil
Regulatory Updates Resolution

- RDC ANVISA nº 94 (27/07/2016)

  - Update of technical standards for surgical and no surgical gloves.
Regulatory Updates Resolution

- Extending for three years the deadline to develop the technical dossier for IVD products; and for two years to equipments and materials, according to IMDRF WG N9 e N13 documents (ToC).
Resolution RE n. 859 published on April 7th 2016.

- Allows ANVISA to use MDSAP regulatory audit outcomes from Intertek Testing Services NA Inc. to issue the GMP certificate.
Resolution RE n. 2.058 published on August 1st 2016

- Allows ANVISA to use MDSAP regulatory audit outcomes from Laboratoire National de Métrologie et d’Essais (G-MED Certification Division) to issue the GMP certificate.
THANK YOU!