IMDRF International Medical Device Regulators Forum

REGULATORY UPDATES

IMDRF Stakeholders Meeting
Shanghai, China, March 2017

ANVISA

Brazil

Regulatory Updates

- **Public Consultation n° 408/2017-** Mandatory bar code (UDI standard) into pacient cards of cardiovascular stents, hip and knee implants.

Regulatory Updates

- **Resolution RDC n° 211/2017-** Changes the expiration date of medical device registration from 5 to 10 years.

Regulatory Updates

- **Resolution RDC n° 183/2017-** new rules for ANVISA´s GMP certification process.
- Provides for inspecction programs and administrative procedures to grant of Good Manufacturing Practices Certificate to manufacturers of Medical Devices located outside the Brazilian territory and Mercosur.

Resolution RDC n° 183/2017

- Anvisa shall assess the compliance with the Medical Devices Good Manufacturing Practices by the manufacturers located outside the Brazilian territory and Mercosur through specific inspection programs, as a priority.
- The programs shall occur regardless of certification processes.
- The programs shall be defined according to a health risk assessment considering the intrinsic risk of products, the complexity of manufacturing processes, technologies involved, and background data of inspection, monitoring, and authorization of products.
- The audit reports issued within the framework of the Medical Device Single Audit Program (MDSAP) shall be used:

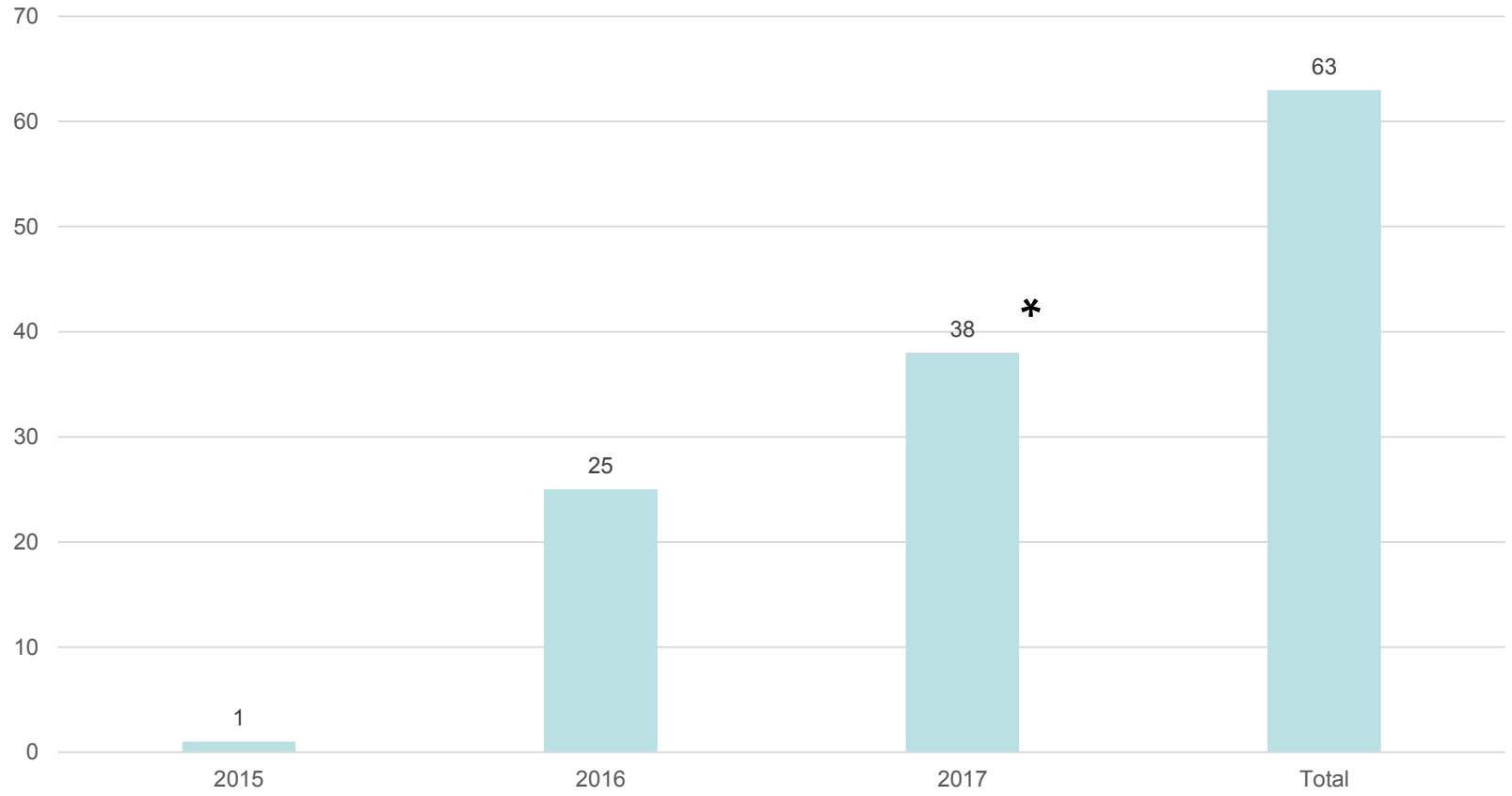
- to grant the Good Manufacturing Practices Certificate
- to assess the compliance with the Good Manufacturing Practices through the inspection programs

Regulatory Updates

- ✓ Auditing Organizations Recognized by ANVISA (Allows ANVISA to use MDSAP regulatory audit outcomes to issue the GMP certificate)

Auditing Organization	Resolution	Date	Published on	Expiry date
Laboratoire National de Métrologie et d'Essais (GMED Certification Division)	31	05/01/2017	09/01/2017	30/06/2018
DQS Medizinprodukte GmbH	194	24/01/2017	25/01/2017	31/12/2018
DEKRA Certification B.V.	193	24/01/2017	25/01/2017	31/12/2018
TUV SUD America Inc.	324	07/02/2017	08/02/2017	31/12/2020
Intertek Testing Services NA Inc.	323	07/02/2017	08/02/2017	31/12/2020
BSI Group America Inc.	651	13/03/2017	14/03/2017	27/02/2021
National Standards Authority of Ireland (NSAI)	1.783	06/07/2017	07/07/2017	15/06/2019
Lloyd's Register Quality Assurance Inc.	2.057	28/07/2017	31/07/2017	16/07/2019
UL Medical and Regulatory Services of UL LLC	2.226	10/08/2017	23/08/2017	03/08/2021
TUV Rheinland of North America, Inc	2.554	08/09/2017	29/09/2017	31/07/2018
QMI-SAI Canada Limited	2.553	29/09/2017	29/09/2017	31/07/2018
SGS United Kingdom Ltd.	3.432	11/12/2017	02/01/2018	11/12/2021
NSF Health Sciences Certification LLC	3.433	11/12/2017	02/01/2018	11/12/2019

ANVISA´s GMP Certification using MDSAP audit reports



* 4,9% of the international GMP Certificates issued by ANVISA in 2017

THANK YOU!