ANVISA
Agência Nacional de Vigilância Sanitária

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Brazilian GMP for Medical Devices and the experience with the new MDSAP procedure

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3rd Brazil-Japan Seminar on Regulations on Pharmaceutical and Medical Devices

Certification and inspection of medical devices

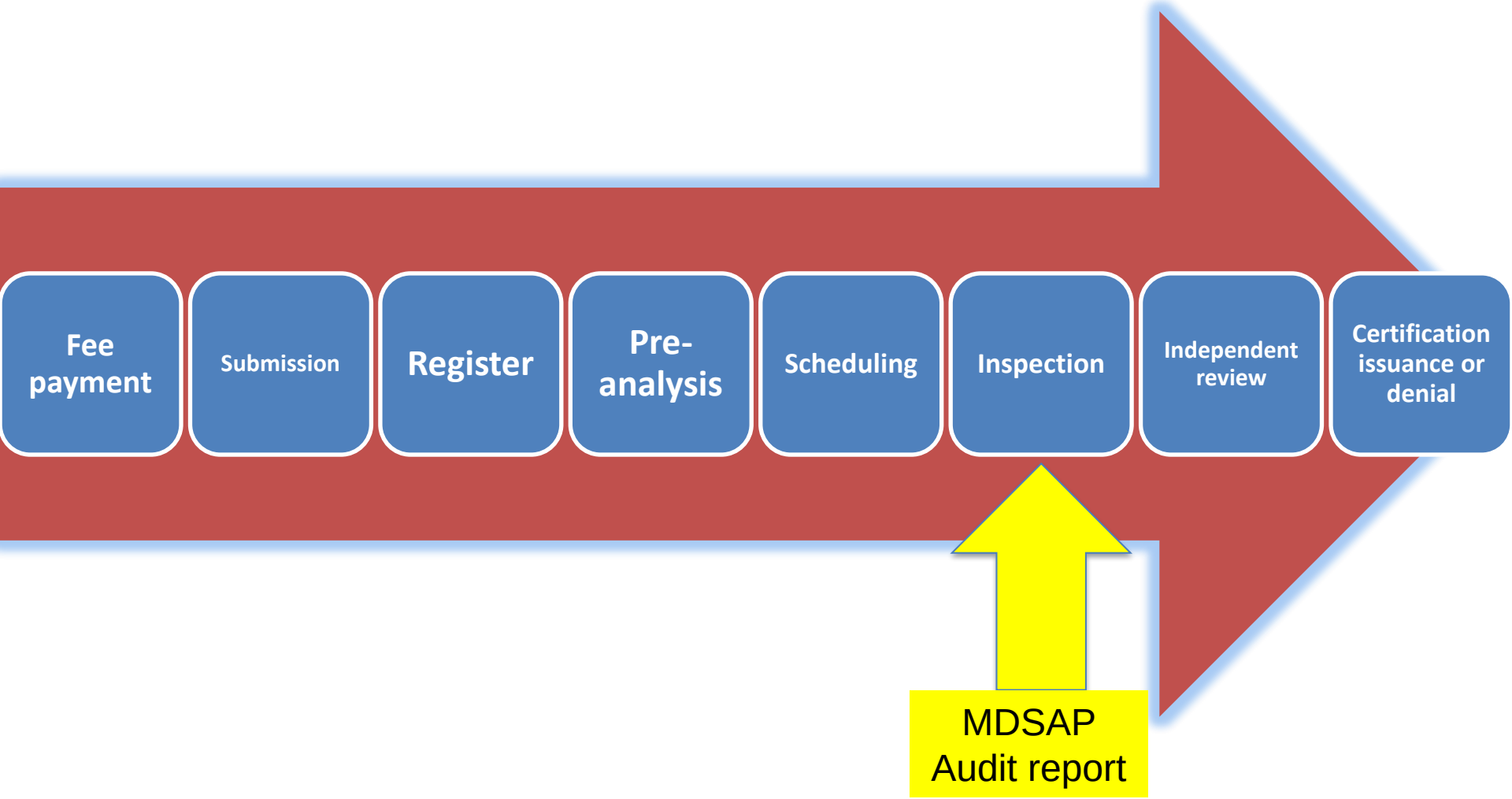
- Resolution RDC nº 39/2013
- Resolution RDC nº 15/2014

✓ **Establish the GMP certificate as a requirement for pre-market approval of medical devices and IVDs under Class III and IV.**

ANVISA INTERNATIONAL INSPECTION

- **Inspection team:** At least two inspectors
- **Inspection duration:** Normally four days, depending on complexity and number of lines to be inspected
- **Criteria:** Requirements on Resolution RDC nº 16/2014

GMP CERTIFICATION FLOW



Application of MDSAP results in Anvisa´s regulatory decisions

LEGAL BACKGROUND

Federal Law 9.782/1999 - Art. 7º, Inciso X, § 7º : To comply with the provisions of section X of this article, the Agency may use confidential information about inspections received under agreements with foreign health authorities, **as well as authorize national or international organisms accredited by the Agency to carry out inspections at manufacturing plants** (Included by Law No. 13,097, of January 19, 2015).

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LEGAL BACKGROUND

ANVISA Resolution RDC Nº 39/2013 - Art. 4°, Sole Paragraph: The grant of certification *(GMP certificate)* that is mentioned on heading of this article may occur **upon presentation of valid audit report issued by a third party auditing organization, under specific programs, both recognized by ANVISA.**

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LEGAL BACKGROUND

Resolution - RE Nº 2.347/2015

Art. 1. **Recognize the Medical Device Single Audit Program - MDSAP for the purposes mentioned in the Sole Paragraph of Article 4 of Resolution - RDC No. 39 of 14 August 2013**, as amended by Resolution of the Board of Directors - RDC No. 15 of March 28, 2014.

- Single paragraph. **Auditing organizations** which meet the requirements established under the program **will be recognized by ANVISA by the publication of an individual al act.**

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It is necessary to publish “Specific resolutions – REs” in the Brazilian Official Gazette for each recognized AO in order to legaly allow ANVISA to have their reports used for regulatory purposes

Application of MDSAP results in Anvisa´s regulatory decisions

ANVISA REs Granted to MDSAP AOs to Date	
BSI Group America Inc.	RE 3454/2015
TUV SUD America Inc.	RE 80/2016
Intertek Testing Services NA Inc.	RE 859/2016
Laboratoire National de Métrologie et d'Essais (G-MED Certification Division)	RE 2058/2016

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MDSAP results at Anvisa	Nº
Total number of MDSAP manufacturers in the program (20/09/2016)	**130**
Manufacturers certified by ANVISA using MDSAP outcomes to date	**22**

Application of MDSAP results in Anvisa´s regulatory decisions

Undergoing an MDSAP Pilot audit may accelerate Anvisa´s GMP certification process, which is a pre-requisite to the marketing authorization

Perspectives

As more AOs become authorized to conduct MDSAP audits, a increase of the number of manufacturers in the program is anticipated, as well the number of ANVISA certificates issued based on the program

Thank you for your attention!

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