Regulatory Updates:

#Brazil

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COLLEGIATE BOARD RESOLUTION – RDC # 183 - October 17th, 2017

- Provides for inspection programs and administrative procedures to grant of Good Manufacturing Practices Certificate to manufacturers of Medical Devices located outside the Brazilian territory and Mercosur.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Definitions

- Finished device: the product, being one, a family, a system, or a set of products, which is ready for use or functionally complete, whether it is packed, labeled, or sterilized, or not;
- Manufacturing site: the establishment where product manufacture or manufacturing stage occurs, and it may be the legal manufacturer, contracted manufacturer, or the Original Equipment Manufacturer – OEM.

Manufacturing Sites subject to GMP Certification

- I – Manufacturing site that makes a finished device in its name or for another company;
- II – Manufacturing site that is responsible for releasing the finished device, related to at least one production stage, except for designing, distribution, sterilization, packing, and labeling stages; and
- III – Manufacturing site of Software as a Medical Device – SaMD.

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Article 8

The grant of Good Manufacturing Practices Certificate of Medical Devices of risk classes III and IV may occur through one of the following, after document assessment:

- I – on presentation of a valid audit report, issued by a third party auditing organization, in accordance with specific programs, both recognized by Anvisa; **(MDSAP)**
- II – using confidential information on inspections, received under Agreements or Covenants with health authorities of other countries;

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Article 8

- III – by assessing inspection or audit report issued by the health authority of an IMDRF member country, or by a third party auditing organization recognized by the health authority;
- IV – by assessing an audit report issued by a third party auditing organization recognized by Anvisa;
- V – by making a risk analysis to assess the need for in loco inspection before granting the Good Manufacturing Practices Certificate, in the case of petitions not referred to or which do not comply with the requirements established for items I to IV above.

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Risk Analysis Matrix

- Risk of the product
- GMP Compliance History
- Information provided in the Reports
- Post Market Surveillance records
- Complexity of the manufacturing process

Brazilian GMP Certificate

- Final Product
- Final Release + 1 Production stage
- SaMD

- Risk Class III and IV

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Brazilian GMP Certificate

- MDSAP
- Confidential Information / RAs Agreement
- Audit Report by IMDRF Country
- Audit Report by AO recognized by Anvisa
- Risk analysis / Anvisa Audit

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Thank you!

Brazilian Health Regulatory Agency

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