МИНПРОМТОРГ РОССИИ

Государственный институт лекарственных средств и надлежащих практик

II Всероссийская GMP-конференция

18-20 сентября 2017 года

Геленджик

II ВСЕРОССИЙСКАЯ GMP КОНФЕРЕНЦИЯ

US-EU Mutual Reliance Agreement on cGMP Inspections

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Vice President, Quality and Regulatory Compliance
Novo Nordisk A/S

Agenda

- Major achievements with the MRA
- The foundation and rationale for the MRA
- Major milestones
- Benefits of MRA

Major Achievements with the MRA

Based on the original agreement from 1998 the following has been agreed:

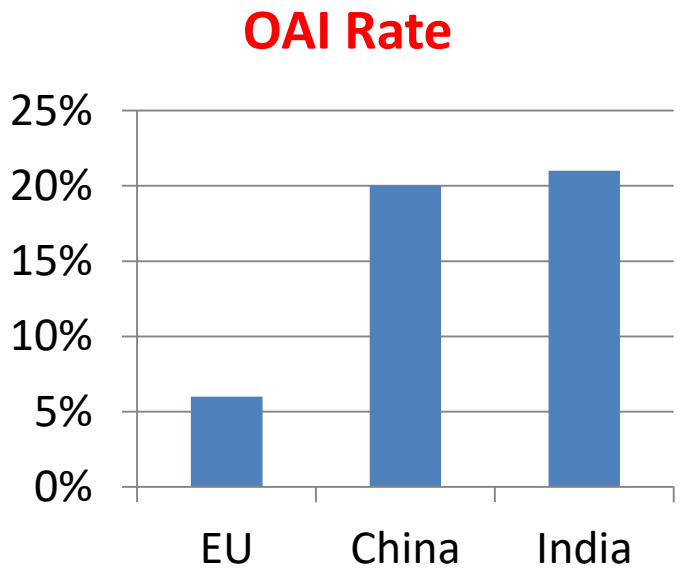
- Recognition
  - Inspections US/EU
- Reliance
  - Inspections in 3rd countries (i.e. outside US/EU)
- Waiver
  - Import testing US to EU

Scope:

- Includes a vast majority of drugs
- Certain products will be reevaluated in the future, such as vaccines and veterinary products
- Surveillance and, under certain conditions, pre-approval inspections of marketed human drug facilities located within the US and EU

The Basis and Rationales for the MRA

- Resource management based on risk
- Same/similar standard setting
  - ICH and PIC/s
  - QbD joint pilot program
  - Parallel scientific advice interaction
- Confidence built up in the past
  - API inspection program
  - Good clinical practices/bioequivalence inspection collaboration
- Capability assessment



Note: 2015 inspection data - from FDA public presentations

MRA: Capability Assessment

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Conflict of Interest (COI) Evaluation

FDA evaluates the inspectorate's COI policies against EMA and FDA ethics regulations

Joint Assessment Program (JAP) Audit Observation

FDA experts observe EU audit of member states

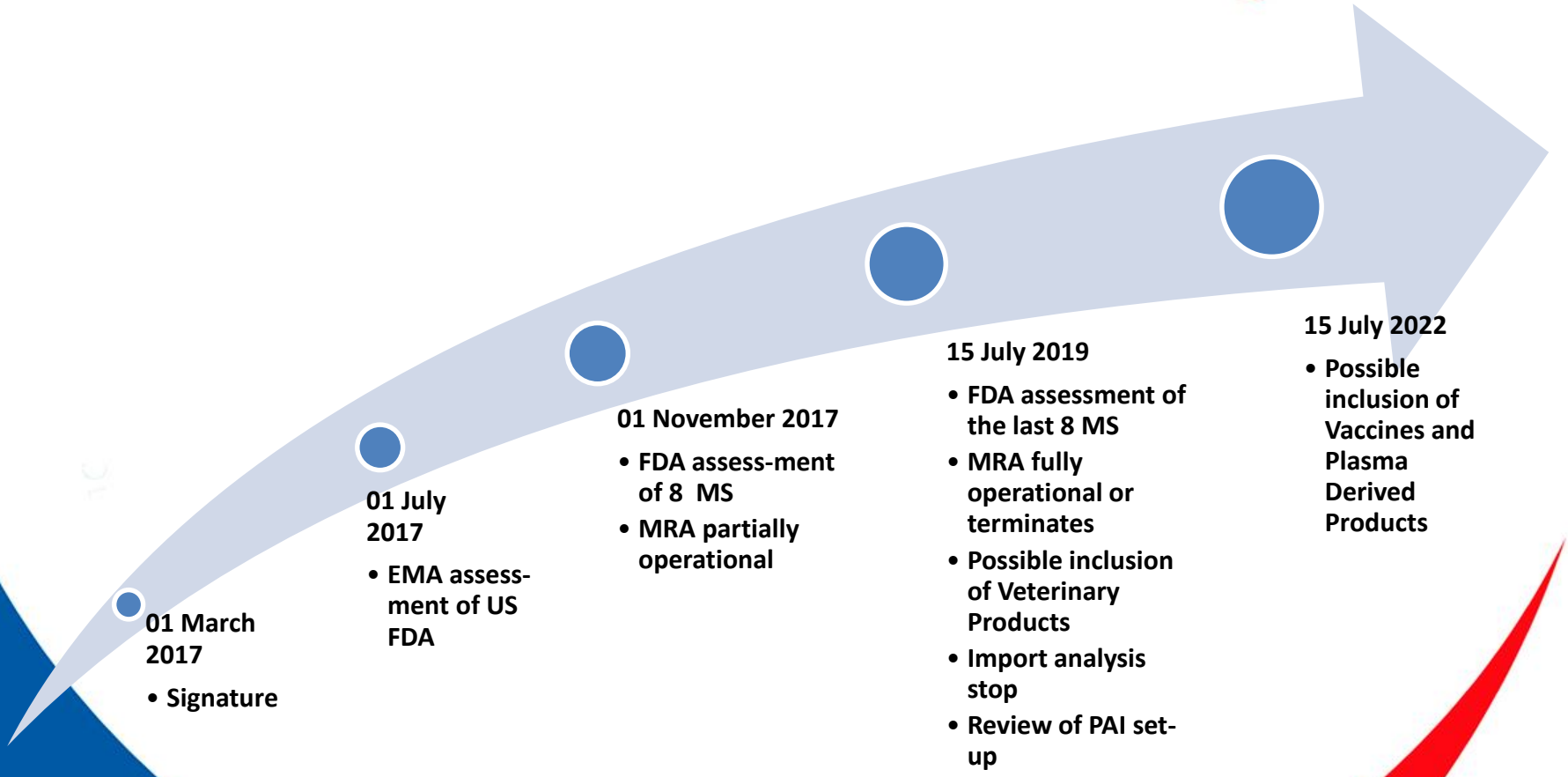
Primary Assessment

FDA experts review the final EU audit report, the observers' reports, the inspections reports, and supporting information

Secondary Assessment

Representatives of FDA's senior leadership assess the primary team's conclusions and make the final capability determination.

Milestones


01 March 2017
• Signature
01 July 2017
• EMA assess-ment of US FDA
01 November 2017
• FDA assess-ment of 8 MS
• MRA partially operational
15 July 2019
• FDA assessment of the last 8 MS
• MRA fully operational or terminates
• Possible inclusion of Veterinary Products
• Import analysis stop
• Review of PAI set-up
15 July 2022
• Possible inclusion of Vaccines and Plasma Derived Products

MRA: Benefits

- Stronger drug inspection expertise
- Greater efficiency
- Decreased duplication inspections
- Reallocation of resources to areas with a higher public health risk

Acknowledgement

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- **Henrik Friese**

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- **Natalia Morgunova**

  Head of Regulatory BACIS
- **Irina Krasnokutskaya**

  RA Manager

Thank You!

Спасибо!

Questions

Организаторы

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