



IX PAN-RUSSIAN
GMP CONFERENCE



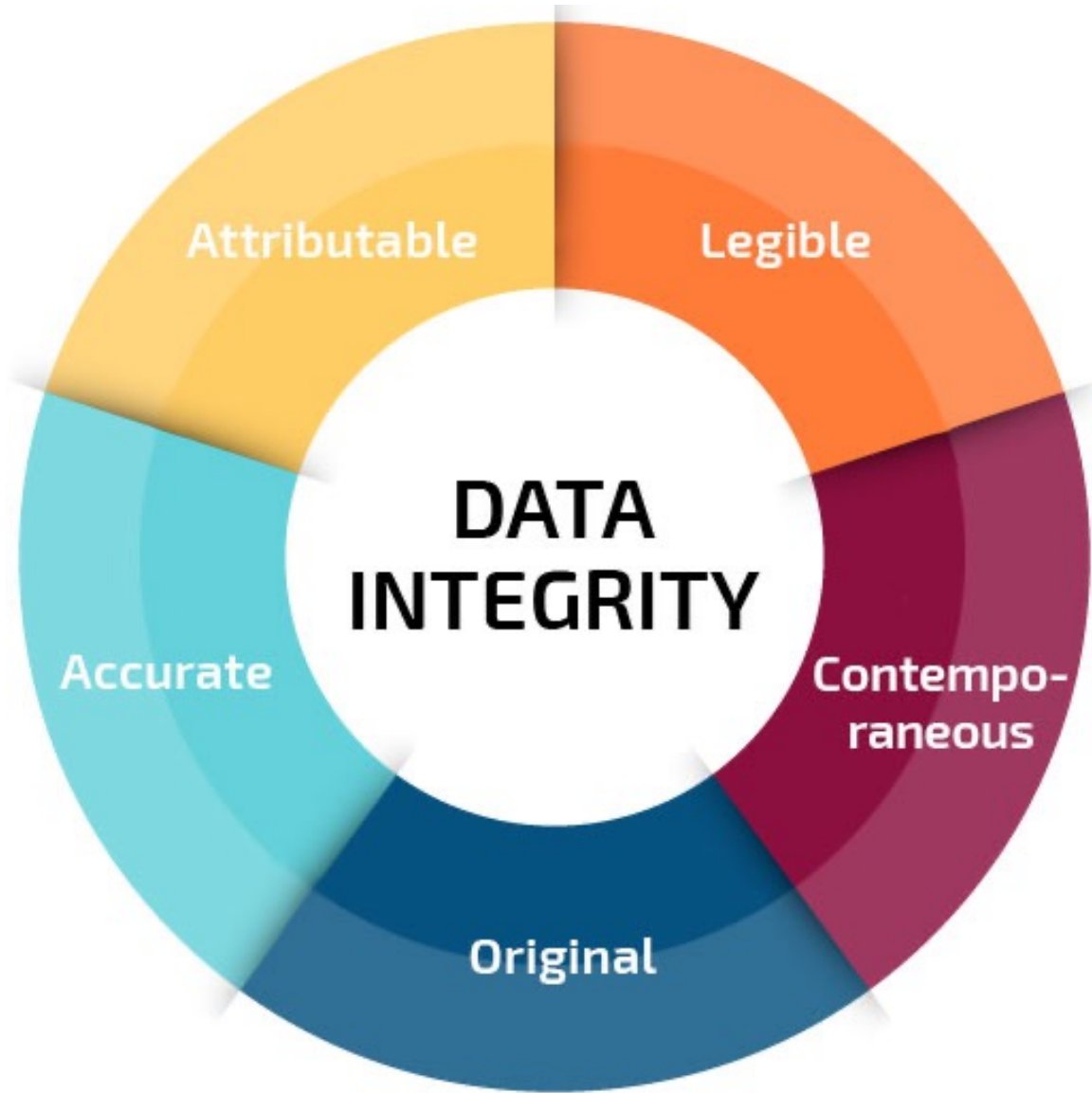
MINISTRY OF INDUSTRY
AND TRADE OF RUSSIA



Data integrity, Implementation in practice, Regulatory expectations

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Both 'In' and 'Out' are out of order



Good Documentation
Practices not followed



A

- **Attributable:** Data should clearly state who performed the action and when?

L

- **Legible:** Data should be easy to understand, recorded permanently and preserved in its original form.

C

- **Contemporaneous:** The data should be recorded at the time work is performed.

O

- **Original:** Data should be preserved in its original form or a certified true copy

A

- **Accurate:** Data should be free from error and as per protocol.



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Thanks



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