



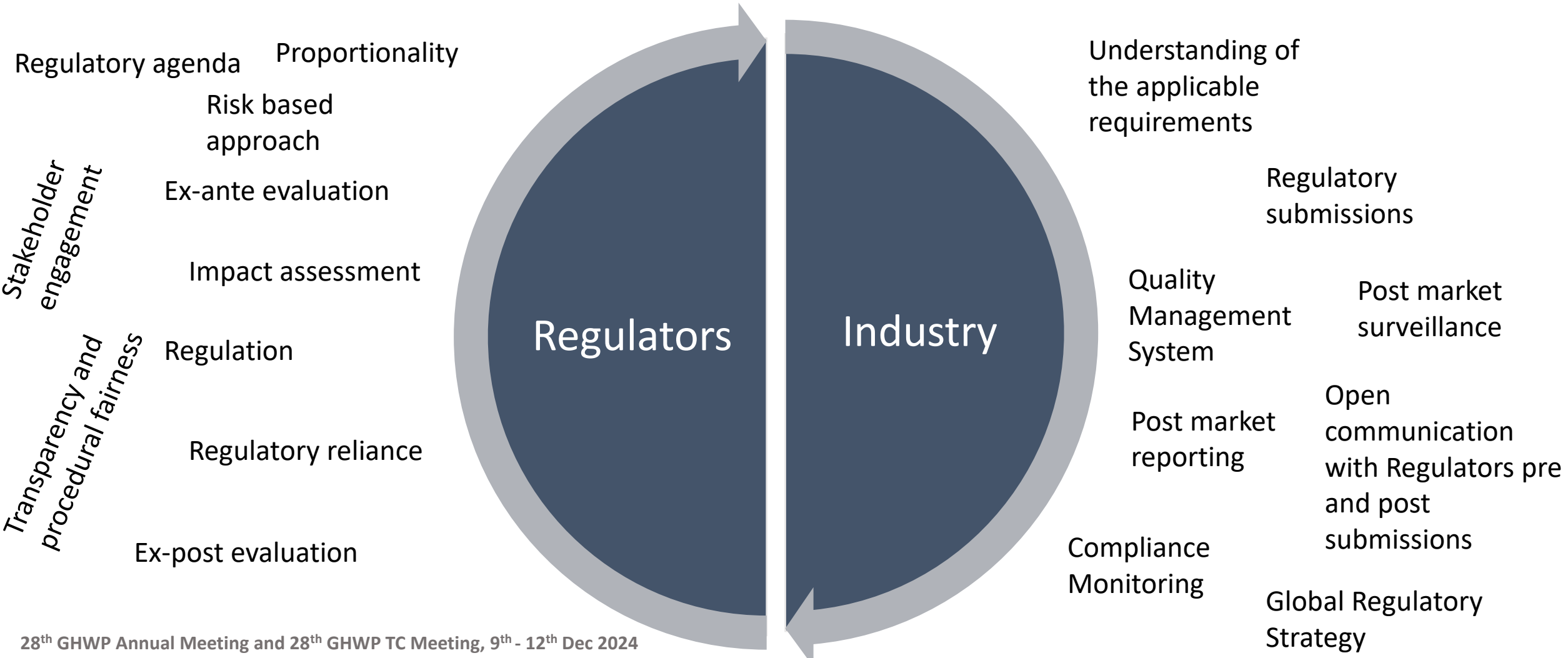
Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

Excel Regulatory Excellence in the MedTech Industry



Regulatory excellence – lifecycle approach



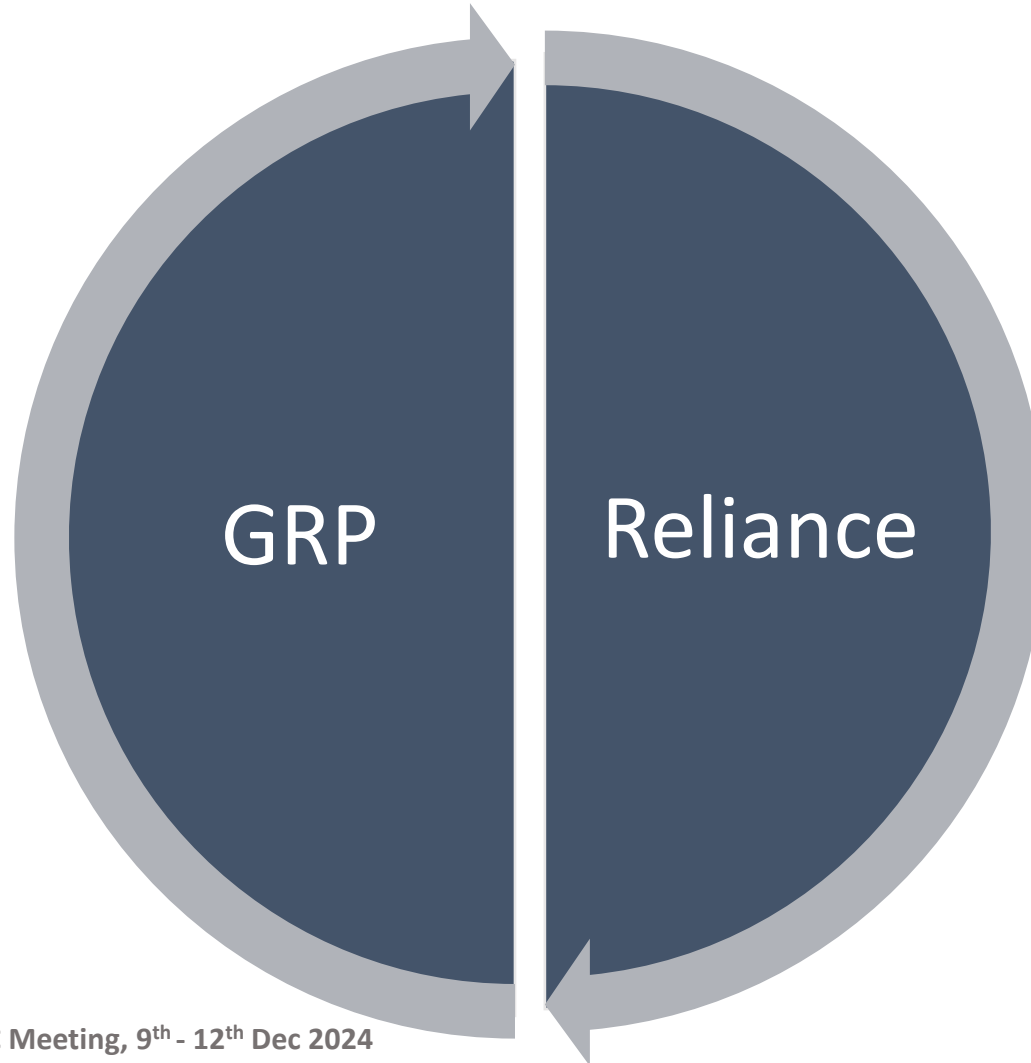
Good regulatory practices (GRP) – foundation of good regulation

1. Issue a Regulatory Forecast
2. Have a National Regulatory Register
3. Provide Opportunity for Public Comment
4. Publish Evidence and Conduct Regulatory Analysis
5. Respond to Stakeholder Input
6. Use Quality Data and Sound Science
7. Employ Risk-Based Approaches
8. Conduct Regulatory Impact Assessments (RIAs)
9. Conduct Pro-Competitive Analysis
10. Asses the International Impact of a Regulation
11. Use International Standards as a basis for National Regulations
12. Conduct Ex-Post Assessments of Regulatory Impacts
13. Establish a Central Regulatory Coordination Body

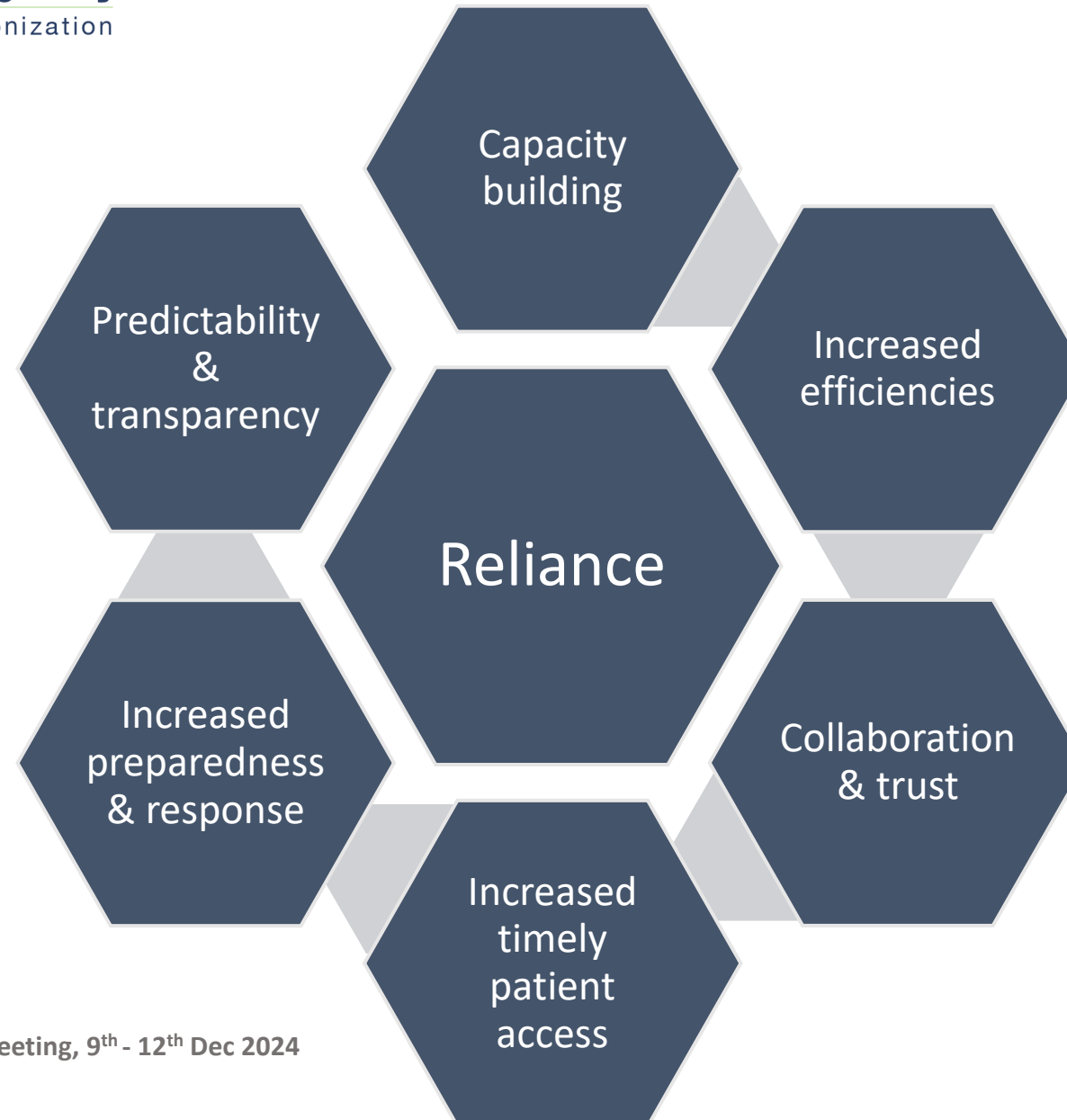




Regulatory excellence – GRP & Reliance



Benefits and opportunities



Thank you!

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