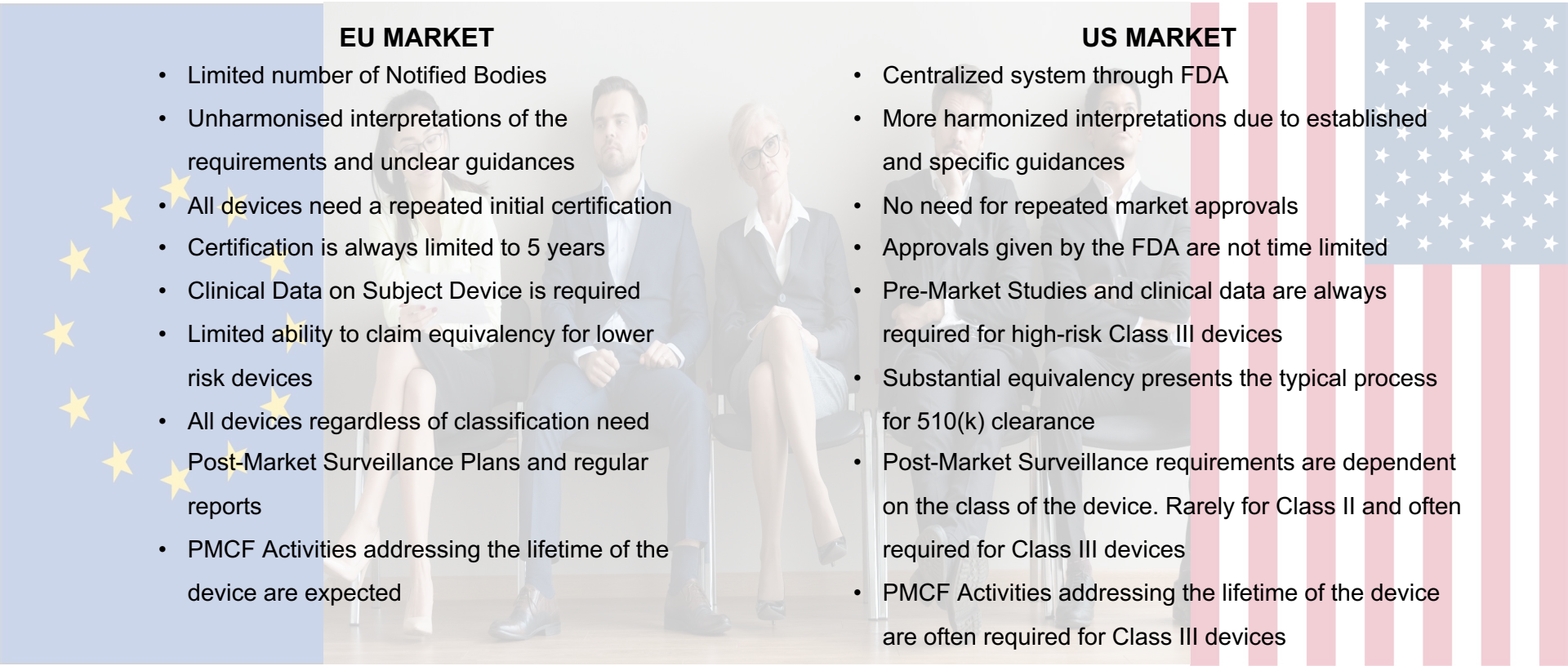
FDA vs. EU Regulatory Pathways

Factors Every Startup Must Consider with Go-to-Market Strategy

Presented by
GURU Regulatory Advisory Board Members

WHERE TO GO FIRST – EU OR US?



EU MARKET

- Limited number of Notified Bodies
- Unharmonised interpretations of the requirements and unclear guidances
- All devices need a repeated initial certification
- Certification is always limited to 5 years
- Clinical Data on Subject Device is required
- Limited ability to claim equivalency for lower risk devices
- All devices regardless of classification need Post-Market Surveillance Plans and regular reports
- PMCF Activities addressing the lifetime of the device are expected

US MARKET

- Centralized system through FDA
- More harmonized interpretations due to established and specific guidances
- No need for repeated market approvals
- Approvals given by the FDA are not time limited
- Pre-Market Studies and clinical data are always required for high-risk Class III devices
- Substantial equivalency presents the typical process for 510(k) clearance
- Post-Market Surveillance requirements are dependent on the class of the device. Rarely for Class II and often required for Class III devices
- PMCF Activities addressing the lifetime of the device are often required for Class III devices

Panel Discussion