

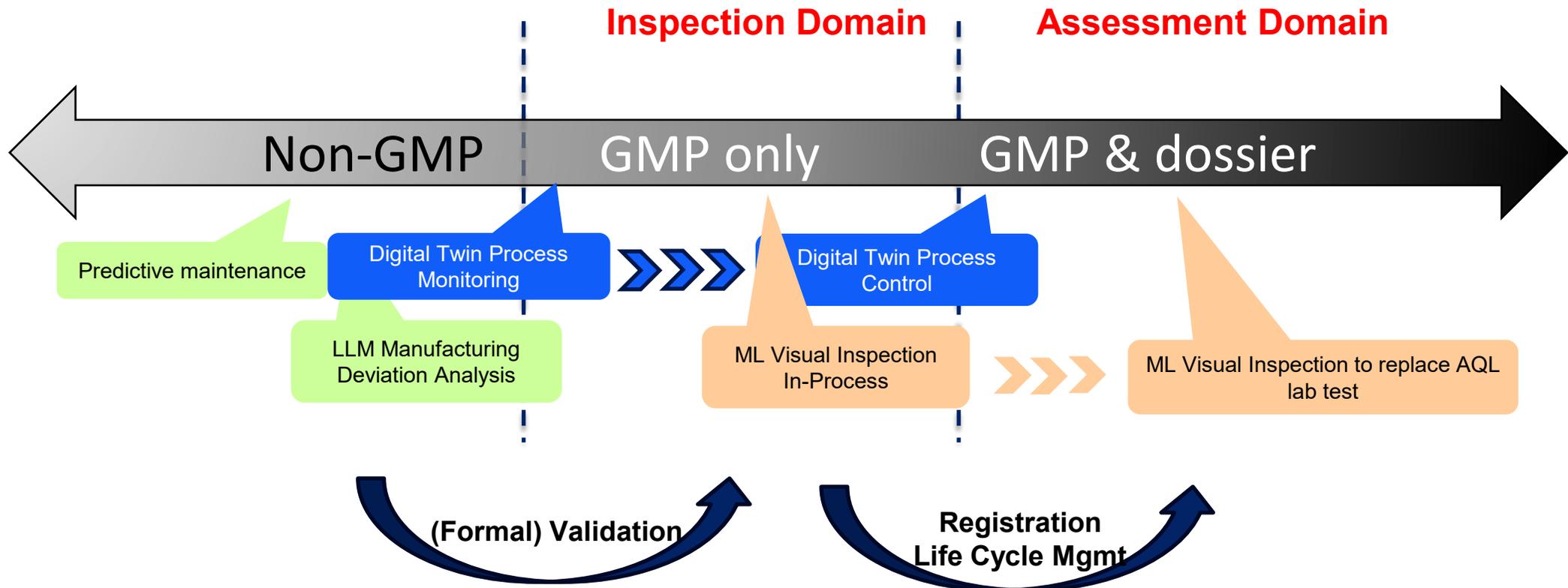
# AI in Development and Manufacturing – A New Era in Well Characterized Biologics

Session introduction

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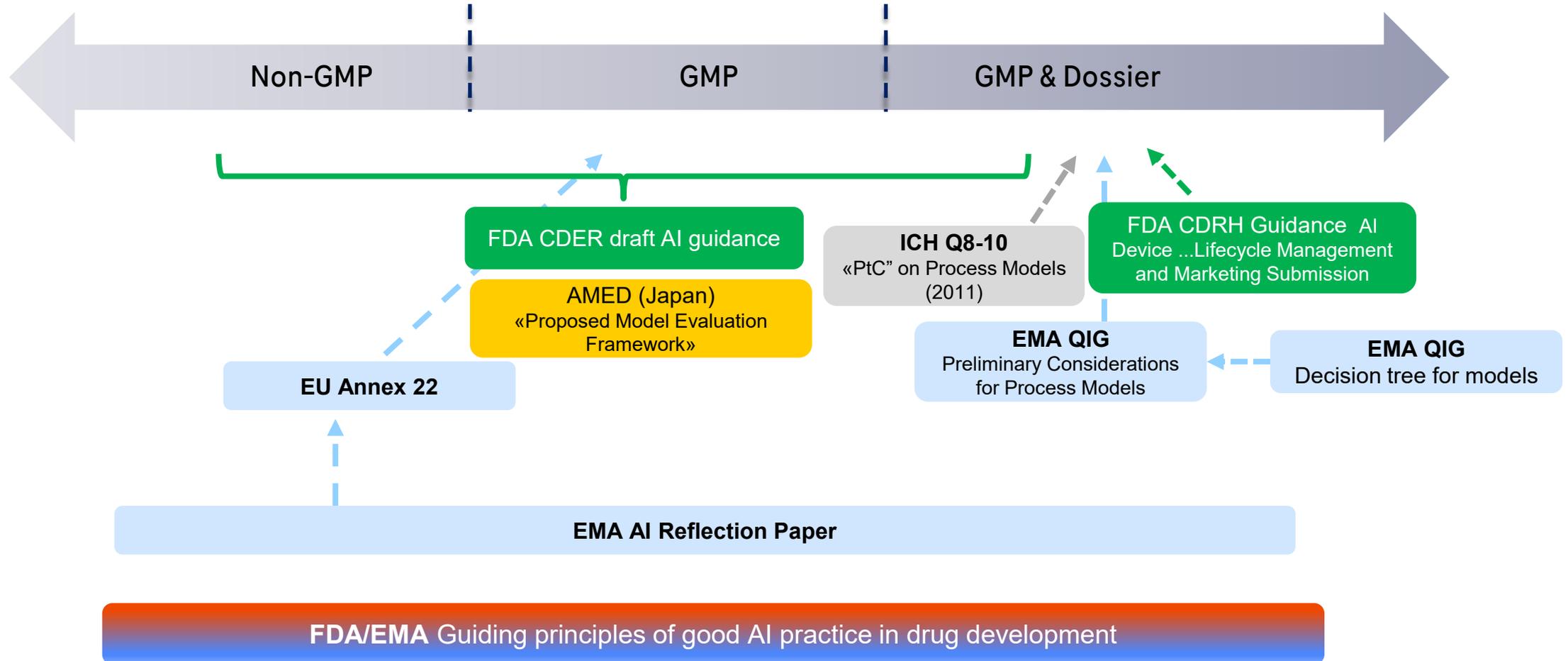
# Current state of discussion: The Compliance & Regulatory Spectrum of AI and ML

From a practitioners perspective, the question of mapping different AI applications on the spectrum of regulatory decision making, i.e. are they GxP relevant and if they are GxP, are they registration relevant?



# “The Spectrum” of AI and ML – Current Emerging Guidance Mapping

Different guidances address different parts of the spectrum – not yet aligned



**Doing now what patients need next**

# The Frame of «AI and ML» Compliance Topics



*Many are not entirely new...*



*Where do these fit in existing frameworks already...?*

*How to address these?*