

Key Considerations in Preparing for Commercial Approval and Launch

hosted by Dark Horse Consulting Group

Meet Your Hosts

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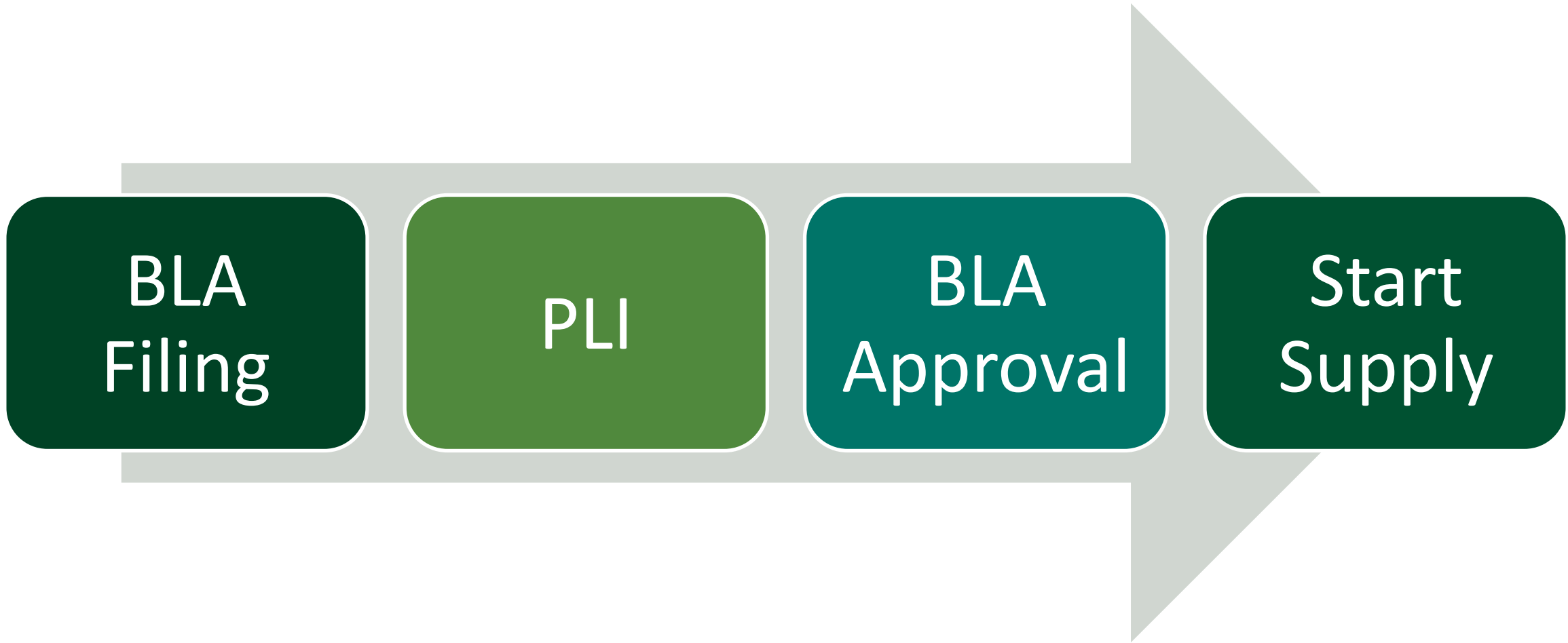
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Converge





BLA
Filing

PLI

BLA
Approval

Start
Supply

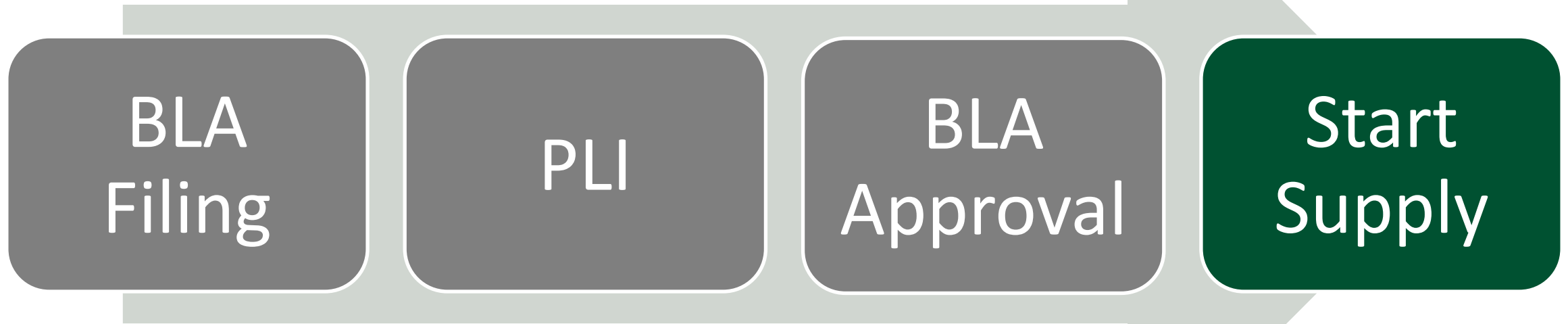
- Comprehensive CMC gap analysis & risk assessment completed for commercial process
- Clear process validation master plan & PPQ strategy defined & aligned
- Robust process control strategy (QTPP, CQAs, CPPs, NORs, PARs) established
- Analytical methods & potency assays are fit-for-purpose & validation-ready



- GMP Quality Systems are mature & inspection-ready
- Formal PLI readiness activities (gap assessments, mock inspections) completed
- Change controls, deviations, & CAPAs are robust & defensible
- SMEs are trained & prepared to support regulatory inspections



- Team & governance in place to rapidly manage FDA IRs/RFIs
- Proactive risk register established for review & inspection outcomes
- Clear strategy to address & remediate any PLI findings
- CMC, Operations, & Supply Chain continue launch prep during review



- Commercial demand planning & supply strategy finalized
- Distribution, cold chain, & logistics are launch-ready
- Clinical/treatment sites are trained & operationally ready
- PMRs, PMCs, & post-approval commitments are clearly planned

THANK YOU!

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