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FDA COMPLIANCE CHECKLIST

for IVD laboratory instruments

Is your device ready for the US market? Go through the checklist to see where you and your product stand:

- ☐ Determine and assign Product Classification, Product Code and Regulation Number
- ☐ Determine and assign Device Classification (Class I, II, III)
- ☐ Determine GMP exemption status (yes/no)
- ☐ Determine required Submission Type (510(k) exempt, 510(k), PMA)
- ☐ Define and establish cGMP compliant processes (if not cGMP exempt)
- ☐ Identify and apply Applicable Standards (UL, FCC, IEC, etc.)
- ☐ Define and implement appropriate Labeling (Product, Packaging, Instruction for Use, Marketing Material)
- ☐ Compile required information for Device Master Record (DMR) and Device History Record (DHR)
- ☐ Plan and complete Process Validation where required
- ☐ Identify and assign your US-Agent if required
- ☐ Complete FDA Establishment Registration
- ☐ Complete FDA Medical Device Listing

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