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QUOTED. 15 October 2019. Sandi Schaible.

by

All devices on the European market will require pre-clinical testing if their design history files do not meet certain requirements under the EU Medical Device Regulation. See what Sandi Schaible, senior director of analytical chemistry and regulatory toxicology at WuXi Medical Device Testing, said about it here.

“Given that the designation process takes about 18 months, it is unlikely that all applicants will be designated by 26 May 2020.” – Sandi Schaible, senior director, WuXi Medical Device Testing

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