Seit Jahren wird von Behörden(!) geschult, dass deutsche Prüfer im Falle von (EU-) Inspektionen ein Finding bekommen (*Major* oder *Critical*, je nach Inspektor Gusto).

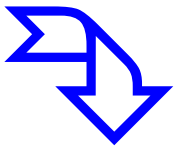
Das Problem wird darin gesehen, dass US-Recht auf deutschen Boden geholt wird. Wie die FDA selber kommentiert, ist das auch NICHT notwendig! Siehe unten, Punkt/Frage 14

14. Must foreign clinical study sites in a multinational study that includes domestic sites be conducted under an IND?

No. A multinational study may include domestic sites under the IND and foreign sites not under the IND. Investigational drug and biologics studies conducted in the U.S. must be conducted in compliance with the IND requirements contained in 21 CFR 312, which includes the requirement that investigators sign the 1572. If a study also involves foreign clinical sites, the sponsor may choose, but is not required, to include the foreign clinical sites under the IND. The investigators from the U.S. sites and any foreign sites included under the IND would be required to sign the 1572. The investigators from the foreign sites that are not included under the IND are not required to sign the 1572.

If the sponsor chooses to conduct a multinational study with U.S. and some foreign sites under the IND, and other foreign sites not under the IND, the sponsor can submit a single protocol to the IND and all sites would follow this protocol. Alternatively, the sponsor can conduct a multinational study with one protocol for sites under the IND (U.S. sites and some foreign sites) and a different protocol(s) for foreign sites not under the IND. If the intent is to pool the data from U.S. and foreign sites, the protocols would ordinarily be very similar or identical. The U.S. sites and any foreign sites included under the IND must follow the protocol that was submitted to the IND. For foreign sites that are not included under the IND, the protocol(s) does not need to be submitted to the IND. In general, if the sponsor intends to submit the data in an application for marketing approval, we recommend that the sponsor identify the foreign sites that will not be conducted under the IND and discuss plans to pool the data from U.S. and foreign sites with the appropriate FDA review division.

Note, however, that 21 CFR 312.32(b) requires sponsors to promptly review information about the safety of the investigational drug obtained or otherwise received by the sponsor from any source, foreign or domestic. Under 21 CFR 312.32(c), sponsors must also notify FDA and all participating investigators in an IND safety report of any adverse experience associated with the use of the drug that is both serious and unexpected. This means that FDA and all participating investigators under the IND would be informed of such an adverse experience, even if it occurred in a foreign study not conducted under the IND.



http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf