From: Toth-Allen, Jean
Sent: Thursday, November 30, 2006 2:40 PM
To: [purged]
Subject: RE: tech base

Dear [purged]:

Thank your for your inquiry.

Unfortunately, I am not sure exactly what you are referring to with regard to "tech base" medical product development. While I can take some guesses based just on the terms themselves, nothing that I would come up with is presently addressed in regulation or guidance. If you could provide some context in which this terminology is used, I might be able to point you in the right direction.

Sorry I cannot be more helpful. If you can provide further context with regard to this issue, need further information, and/or have additional questions, please submit them once again to the official GCP mailbox, gcp.questions@.fda.hhs.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practice Program
OSHC, Office of the Commissioner, US FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [purged]
Sent: Thursday, November 23, 2006 11:02 PM
To: OC GCP Questions
Subject: tech base

What is advanced and early "tech base" medical product development? Thanks.

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[purged]