PUBLIC SUBMISSION

As of: 6/15/22 8:59 PM
Received: June 06, 2022
Status: Posted
Posted: June 09, 2022
Tracking No. l43-6t8z-4nr1
Comments Due: June 06, 2022
Submission Type: Web

Docket: FDA-2013-N-0242
Current Good Manufacturing Practice for Positron Emission Tomography Drugs

Comment On: FDA-2013-N-0242-0016
Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs

Document: FDA-2013-N-0242-0017
Comment from Michael Nickels

Submitter Information

Name: Michael Nickels
Address:
Saint Louis, MO, 63104
Email: mnickels@wustl.edu
Phone: 3142738246

General Comment

- The estimates of time required for all activities described in this document are inaccurate. The amount of time required to perform any regulatory paperwork should be increased by a minimum of a factor of 2.5 to 4, depending on the task. For example, the estimate that a Master Batch Record (MBR) only requires 8 working hours to complete is completely inaccurate. This number should be closer to a total of 40 working hours and may be more. This is due to the regulatory burden that has been placed on facilities producing under cGMP. This burden includes creation of Change Control Documents, pre-approval of the change control, QA review of the change control, creation of draft MBR, review of MBR, approval of MBR, QA review of MBR, completion of Change Control documents associated with the creation of the MBR and finally QA review of the change control. In total, a minimum of three different personnel are required for the creation, modification, review and approval of any given document. With each person devoting one hour to each process, this 9 step process requires a minimum of 27 hours of working time to complete. With MBRs being a complex document, this process requires more time at each step. This should be accounted for in each of the estimates of time required for all documents.
- A crucial aspect of record keeping appears to have been ignored in this review. This aspect is the filing, scanning and relocation to secondary storage of paperwork. This requires a large amount of working hours and should be accounted for.
- The final conclusion that the increase in working hours (which is off by a factor of 3 to 4) and records is due to external control testing laboratories is not the major contributing factor to the increase. The major contributing factor to the increase in a PET facilities' record keeping burden is the increased regulatory requirements placed on facilities by the FDA. The creation of change control procedures, multiple levels of review for any document creation or modification, and QA oversight throughout the entire recordkeeping process is the major contributing factor to any increase.