Leveling the playing field across domestic and foreign inspections . . .

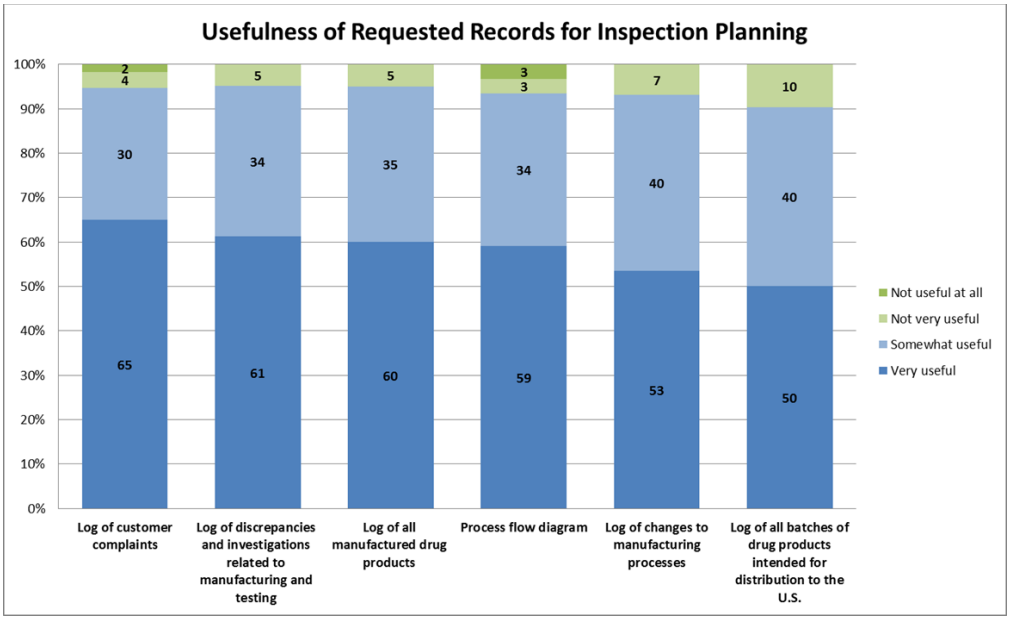
Lessons Learned from a Six-month Test Program

Implementing FDASIA Section 706: A six-month test reveals advantages of investigators requesting inspectional records in advance of drug establishment inspections[1]

Section 706 of the *FDA Safety and Innovation Act* (FDASIA) allows FDA to request records in advance or in lieu of on-site drug establishment inspections. Congress enacted this provision to improve the effectiveness and efficiency of inspections, given the increasing globalization of drug production. Along with other FDASIA provisions, Section 706 could "level the playing field" by allowing FDA to review records ahead of time and take a more risk-based approach to conducting both domestic and foreign inspections. Recognizing this as a useful and potentially broad authority, FDA sought to carefully implement Section 706 to ensure that its procedure for requesting records, including the scope and timing of the information request, was sound. Below are some key findings from a six-month test program led by FDA's Office of Regulatory Affairs (ORA). Record requests were sent in advance of 104 foreign CGMP-surveillance[2] human and animal drug inspections.[3] All of the inspections included were already on FDA's work plan, and no new inspections were created as a result of this six-month program.

Some Key Study Findings Regarding Drug Manufacturers

- The six types of records requested of all establishments in advance of inspection (see chart below) reflect commonly requested documents typically reviewed on the first day of an on-site inspection.
- All records were provided to FDA for most inspections in a timely manner and with high accuracy.
- In general, establishments understood the request and FDA received only a handful of questions asking for clarifications or time extensions. The request gave establishments a better sense ahead of time of the type of information FDA may focus on during the inspection.
- Reviewing records ahead of time allowed investigators to focus site inspections on more high-risk areas. This facilitated the identification of significant issues for the establishment to address in order to protect consumers/patients.
- Investigators used received records and rated them as useful in planning most inspections.
- FDA is using the findings to inform future implementation of Section 706 for drug inspections.



Note: Because of rounding, column totals may not add to exactly 100%.

1 Questions about this document? Email FDASIAImplementationORA@fda.hhs.gov
2 CGMP = Current Good Manufacturing Practice
3 While findings about the request process (e.g., on timeliness and completeness of records received) were based on all 104 inspections, findings from the survey data from FDA investigators were based on 67 of those inspections. For example, in the chart above on the usefulness of requested records for inspection planning, the findings reflect survey feedback from 67 establishments (vs. 43 control establishments during a three-month "control period" in which no records were requested in advance of inspection).