

Clin Pharm Earns an A-

I tallied up all the reasons for non-approval in each of the 88 Complete Response Letters. The stacked barplot below shows whether a particular factor was mentioned as a consideration in the approvability decision. These counts are not mutually exclusive, as multiple factors could be listed in each letter.

CMC/Quality and Facility issues are the most common reason cited in the CRLs. Among 88 letters, 44 noted Facility issues and 43 noted Quality issues.

I counted 8 letters in which a Clinical Pharmacology-related issue was cause for non-approval. My tally of Clinical Pharmacology included instances in which PK data and/or dose selection were critical to the approval decision, regardless of whether it was labeled a “Clinical Pharmacology” comment. I did not include instances in which Clinical Pharmacology comments were listed as additional comments. These additional comments will be highlighted separately. Overall, Clin Pharm with a tally of 8/88 earns an A-. I'm an optimist. I think it's a sign that model-based drug development and other Clin Pharm tools are effective.

<https://lnkd.in/enNxA-g6>

