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Association for Accessible Medicines

Biosimilars Council
A Division of the Association for Accessible Medicines

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Generic + Biosimilar Medicines Conference

Session: Drug Substance and Drug Product Manufacturers – Partnering to Improve the Process

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Drug Substance and Drug Product Manufacturers – Partnering to Improve the Process

November 4-6, North Bethesda MD

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Main Points:

1. Review & DMF comments vs. Review & ANDA comments

2. “Adequacy status” to DMF does not translate into DMF being adequate with respect to ANDA

3. If DMF is deficient, a notification to ANDA holder would be immensely helpful – to review into deficiencies related, at least, to the open part of the DMF

Main Points:

4. Inspection related to API Intermediate site

5. Qualification Report of an Impurity and the consult report (within Agency), regardless of submitted as part of ANDA or DMF, to be applied to the review of both DMF & ANDA

6. Classification of the facility (DP vs API) that manufactured premix (API + Excipient) - to improve stability of API


Thank You
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