

Review Initiation Strategy in TFDA/CDE

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TFDA/CDE Review Initiation Strategies

- 1. Applicaation Screening and Validation
- 2. Early Identification of Major Deficiencies (Filing meeting)



1. Screen and Validate

- Project manager is responsible
- Use checklists/templates
- Adminstrative review (check content/format of application)



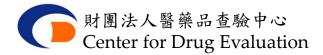
2. Early Identification of Major Deficiencies

- The Goal of "Filing meeting": Communicate filing deficiencies
- Reviewers from specific discipline responsible
- Held by 20 days following application



2. Early Identification of Major Deficiencies

- General technical review at this step
- Internal commucation always begins before the filing meeting
- No pre-meeting prior to the meeting
- "Teamleader" should help to recognize the critical issues in the submission and increase interaction between disciplines



Others:

No consulation mechanisum in the review initiation stage in TFDA/CDE