

# Review Initiation Strategy in TFDA/CDE

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# TFDA/CDE Review Initiation Strategies

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

## 1. Screen and Validate

- Project manager is responsible
- Use checklists/templates
- Administrative 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 communication 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 consultation mechanism in the review initiation stage in TFDA/CDE