

3-Step How to Guide for Regulatory Due Diligence of Pharma and Biotech Products/Companies

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Regulatory Due Diligence

- Regulatory Due Diligence is generally conducted for the following reasons:
 - Mergers
 - Company acquisitions
 - Product acquisition
 - Product in-licensing

Overview of Approach

- Step 1: Plan the Due Diligence
- Step 2: Conduct the assessment
- Step 3: Develop the Due Diligence report

Step 1: Plan the Due Diligence

- Define the scope
- Define the team
- Define roles and responsibilities
- Develop the agenda
- Develop the strategy for Due Diligence

Step 2: Conduct the Due Diligence

- Manufacturing capability assessment
- R&D capability assessment
- Quality and compliance assessment
- Product application assessment
 - Investigational products
 - Marketed products

Step 3: Prepare the Due Diligence report

- Generate the report. Generally includes
 - Risk assessment and benchmarking
 - Recommendations
 - Mitigation plan (if requested)

Project Proposal

- Inputs:
 - Visit manufacturing sites and R&D facilities
 - Requested documents
- Outputs:
 - Due Diligence Report
- Completion time: 3-6 months depending on the scope