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The steps are: Set design basis (1 week) Confirm performance/scale-up of pilot plant operations (2-20 weeks, depending on how smoothly pilot plant runs) Optimize and select design (10-20 weeks) Detailed design and equipment selection (about six months) In parallel to these process design activities there will be activities related to getting approval for the new drug: Conduct clinical trials (6 months to 2 years) Review clinical trial results (typically 3 to 6 months) Obtain FDA approval ...

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Chapter 2 Solution 2.1 This process can be drawn in more detail, but a simple block-flow diagram is adequate. There may be a need for some heaters and coolers in the plant (e.g. after ...

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