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CMC How? Many Documents (Guidances, PTCs, Etc.) From FDA Guidance For Industry: Guidance For Human Somatic Cell Therapy And Gene Therapy. March 1998. Content And Format Of Investigational New Drug Applications (INDs) For Phase 1 Studies Of Drugs, Including Well-Characterized, Th 25th, 2024

5 - Quality (CMC) Considerations

In The Guidance Documents • Headings That Have A Are Applicable To Clinical Trial Applications • With Subsequent CTA Filings For The Same Drug (e.g. Phase II Or III Studies), Where Much Of The Quality Information May Be Similar, The Sponsor Is Encouraged To Build Upon The Previously Completed QOS (22th, 2024

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