

The CTD-Modules



FDA

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EMA

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PMDA

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- 1.9 Documents About Japanese Accepted Names for Pharmaceuticals
- 1.10 Data for Review of Designation as Poisons, Deleterious Substances, etc.
- 1.11 Draft of Basic Protocol for Post-Marketing Surveillance
- 1.12 List of Attached Documentation
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Overview

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Summaries

Quality

- 3.1 Table of Contents of Module 3
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 - Drug Substance/Product, Structure
 - Dosage Form, Components, Excipients
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 - Control of Materials/Critical Steps
 - Process Validation/Evaluation
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