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Proposal

Assessment

Development

Validation

- Product Information
- Space Requirements
- ProcessInformation
- Regulatory& ClinicalInformation
- •Funding Information
- Contractual
 Considerations
- Intellectual Property

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- Opportunity & Strategy
- Clinical Requirements
- Regulatory & Compliance Requirements
- Technology Requirements
- EquipmentRequirements
- Business Plans
- Quality, Productivity
- Enhancement of Academic Synergies

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- Process
- Timelines
- Materials
- Equipment
- Clinical Development
- Documentation
- Budgets
- Product Testing
- Contracts & Billing
- Quality Agreement

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- •Timeline of Events
- Validation
 Plans
- Risk Based Assessments
- Equipment Qualification
- MaterialsQualification
- Documentation
- Validation Assessment
- Budget Review

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- Product Review
- Product Conformance
- •Clinical
 Outcomes
 (therapeutic, AE)
- Regulatory Compliance
- Quality Monitors
- Financial Review
- Customer
 Satisfaction